**IN THE MATTER OF THE INQUIRIES ACT 2005**

**IN THE MATTER OF THE INQUIRY INTO THE EVENTS AT THE COUNTESS OF CHESTER HOSPITAL – THE THIRLWALL INQUIRY**

# WRITTEN OPENING SUBMISSIONS ON BEHALF OF THE ROYAL COLLEGE OF PAEDIATRICS AND CHILD HEALTH ("RCPCH")

## Introduction

1. The Royal College of Paediatrics and Child Health (RCPCH) starts its submission by expressing its deepest sympathies to the parents and wider family members whose children were injured, killed or harmed during 2015 and 2016. As a body dedicated to the health and wellbeing of children, and with a membership of professionals whose aim is to care for them, it is a source of profound shock and sadness to the College that someone whose role was to protect and preserve life chose to take it. We acknowledge the enduring pain and sorrow of the families and greatly respect their courage.

2. The RCPCH accepts that its actions in undertaking the review commissioned by the Countess of Chester Hospital (COCH) did not directly assist in uncovering the causes of death and recognise that this contributed to the uncertainty and lack of clarity that bedevilled the response. It also apologises that it was not sufficiently supportive to paediatricians and other clinicians then working at the hospital and acknowledges the stress, anxiety and damage that has been caused to them by the actions of Letby.

3. The RCPCH splits its submission into two parts:
   (a) Reflections upon its review of the Countess of Chester Neonatal Service and what should or could have been done differently. It highlights the steps subsequently taken to remedy the weaknesses in the review process, and to prevent similar mistakes in future. There are a set of detailed witness statements produced by the RCPCH (INQ0017463-0021) and by the reviewers who undertook a review at Countess of Chester Hospital in 2016, which set out in some detail what happened before, during and after the review. These opening submissions will not seek to repeat earlier material, but will identify areas of concern raised by the Inquiry team or by the reviewers in accordance with the directions set out at paragraph 10 of the note on core participant openings dated June 2024 ("Note on opening").

(b) Submissions in response to the general topics upon which the Inquiry seeks the views of the Core Participants at paragraph 17 of the Note on Opening, where it seeks to answer those questions as far as it is able.

**Role of the RCPCH**

4. The corporate witness statement of the RCPCH [INQ0017463 at 8-17] sets out the activities and work of the Royal College. It is a membership organisation whose aims are to advance the teaching and practice of paediatric medicine, to improve the health of children and improve standards of care, alongside educating and examining those who train in this speciality. It has over 23,000 members, the vast majority of whom are paediatricians. To fulfil these aims, it provides research, policy work and advocacy alongside providing the mandatory qualification for those wishing to specialise in paediatric medicine in the UK. It also undertakes work internationally on child health and paediatric medicine.

5. One of the RCPCH's roles is to provide advice and a framework for safe staffing, which at the material time were set out in "Facing the Future" Standards [INQ00010244]. These identified relevant standards for acute paediatric care. Since 2006, the RCPCH has been commissioned to run the National Neonatal Audit Programme [INQ0010254]. This seeks to create a national measure to improve patient outcomes by using clinical audits and national benchmarking.

**The RCPCH review of COCH in 2016**

**Factual background**

6. The "Invited Review" service was set up by the RCPCH in 2012. At the time of the COCH review in 2016, the RCPCH had undertaken around 60 reviews. The RCPCH was and is one of many Royal Colleges who provide such work, (as described in the corporate witness statements of the RCPCH and that of the individual reviewers). The aims of a review process are in general to provide an expert examination of the workings and functioning of hospitals or other forms of paediatric service (such as community paediatric service) – to either advise on steps for improvement or to recommend changes to the design of a neonatal or paediatric service within a hospital or region. A review is triggered by an invitation or request, usually from the hospital or service in question. There is now a set of standards for invited reviews [INQ0010195] set out by the Academy of Medical Royal Colleges, but there was no such set of standards in place in 2015.

7. An invited review is not designed as a regulatory process. It is a peer review process to examine the safety and efficiency of paediatric services or their configuration [INQ0017463-00010 and INQ0010214]. Where unsafe or concerning issues are revealed by a review, the RCPCH and the Head of Invited Reviews service at the time of the 2016 review both accept

that the escalation processes (and guidance given to reviewers at the time in question) were less robust than they are in 2024 ([Sue Eardley paragraph 27 [INQ0101348 at 007]). The review process involved clinicians with relevant expertise, along with lay people who were aware of relevant standards of care and governance in hospitals to interview staff, patients, managers and others over a short period of time (1-2 days) and then make recommendations. This is what happened in this case. The review programme was supported by a Programme Board of clinicians which was ultimately accountable to the Trustees.

**Approach to undertake the review and finalising the terms of reference.**

8. The RCPCH was approached by email on 28 June 2016 by the Medical Director of the COCH, Ian Harvey, to undertake a service review [INQ0009559-004]. Discussions were held by telephone with the Head of the Invited Review Service, Sue Eardley (of which Ms. Eardley's notes no longer exist) and a proposal was sent on 30 June 2016 by the RCPCH to the hospital [INQ0009559-002], with the terms of review amended by Ian Harvey. The email from Ian Harvey identifies that the Neonatal Unit was being downgraded from that date from Level 2 to Level 1 (i.e. it was not going to be able to take babies who do not require intensive care and often would only take babies born after 32 weeks gestation ) , but not any other information [INQ0009599-002]. The information sent at that time [INQ0009599-001] by Ms. Eardley asked whether the parents of the infants who died would be interviewed by the review team but wanted to confirm the "duty of candour" arrangements.

9. A note from Ian Harvey [INQ0003362] recalls that he advised Ms. Eardley of the fact that a nurse had been suspended and she had been told that there was a spate of unexpected deaths with no conclusion. Ms. Eardley cannot recollect this note [paragraph 38 of Ms. Eardley's witness statement at INQ0101348-010] but does identify that she was told there had been an increase in mortality and that doctors had raised concern about a nurse. These doctors had seen a pattern of attendance on shift at the Unit by Lucy Letby when studying the deaths (paragraph 47 of Ms. Eardley [INQ0101348-012] ). Dr Shortland, the Invited Programme Review director, remembers a discussion a couple of days before the review was to take place at which Ms. Eardley mentioned to him that a nurse had been suspended but that the primary purpose of the review was to look at other factors on the neonatal unit that could have led to an increase in mortality and he did not consider that the fact a nurse had been suspended should "ring alarm bells" (paragraph 49 of the witness statement of Dr Shortland [INQ0099070-0015] ). Dr David Milligan (the lead clinical reviewer) remembers that some form of terms of reference may have been sent to him and that he did write to Ms. Eardley in advance of the review having seen the staffing schedule to identify that Letby was the focus of concerns of some paediatricians (David Milligan witness statement paragraph 3, INQ0102061 -001).

10. The RCPCH's view in 2024 (paragraph 53 of INQ0017463-0018) is that the proposals and terms of reference were compiled very quickly. The Crisp review – an external review commissioned by RCPCH into its invited review process which examined in some detail the COCH review as part of its remit - [INQ0010238] and also found that at that time the RCPCH seldom turned down approaches for reviews, and there was not any risk-based approach to the reviews undertaken by the RCPCH before accepting the work. The RCPCH now also considers that there should have been some clinical involvement from either someone on the review team or the Invited Review Programme Board in drafting the terms of reference given the issues raised. It further considers this to be the case because the Unit had been changed by the hospital from a Level 2 Unit (which could provide special care to babies born from 27 weeks) to a Level 1 Unit (which took babies who did not require intensive care and were often born after 32 weeks). The view of the RCPCH in 2024 is that the reviewer and/or a clinician on the Programme board should have met the Medical Director to talk through the review. Ms Eardley disagrees with this but accepts that the review was initiated swiftly (paragraph 51 of witness statement of Ms. Eardley [INQ0101348-0013]). The view of Dr Shortland (then the Programme Lead for the Invited Reviews service) was that reviews should not take place if there was a significant likelihood that a criminal offence had been committed (paragraph 34 of his witness statement- INQ0099070-011) but that there was a brief discussion with Ms. Eardley before the review visit took place and his opinion on the basis of the information was that the review could proceed (paragraph 49 of Dr Shortland evidence [INQ0099070-0015] ), albeit that he did not see the terms of reference, briefing or data sheet.

11. The proposed terms of reference did include as its fourth term [INQ0012748] to identify "*any identifiable common factors or failings that might, in part or in whole, explain the apparent increase in mortality in 2015 and 2016*". Ms. Eardley believed (paragraph 56 of her witness statement [INQ0101348-0014] ) that this term of reference was to "*assure [Mr. Harvey] and the board that there was no other factor causing the raised mortality before he addressed the concerns of the doctor about the nurse."*

12. The review team comprised two experienced consultant paediatricians, one of whom was a neonatologist (neonatology is a subspecialty of paediatrics concerned with the treatment and care of newborn babies), and a paediatric nurse with extensive neonatal expertise, alongside two other individuals who had a thorough grounding in NHS standards and procedures – including Ms Eardley. All of the individuals had attended a RCPCH induction and development day bar David Milligan – the lead clinical reviewer - who had undertaken other training for National Clinical Assessment Service (NCAS) (described at INQ0017463_0013 and paragraph 5 of the witness statement of David Milligan [INQ0102061-001] ). That induction did not include training on how to deal with allegations concerning criminal offending

by staff members. None of the other reviewers (i.e. Ms. Mancini, Dr. Stewart, Ms. McLaughlan) were aware of the issue concerning Letby until the first morning of the review (see paragraph 21).

13. "Standard" information was collated by the COCH to give to the review team including relevant Care Quality Commission (CQC) reviews, and other relevant external reports (such as the Perinatal Mortality Surveillance report (INQ0017463-0025)). Gathering data and information such as this is a normal part of invited reviews to enable the review team to understand the performance and standard of care provided at the hospital or unit who have requested a review.

**Reflections on the organisation of the review**

14. First, COCH either did not provide adequate information to the reviewers in advance of the review about the concerns which had been raised about Lucy Letby by the paediatricians or sought to minimise it. The evidence of the reviewers other than David Milligan and Ms. Eardley is that they did not know about any concerns or allegations regarding an individual nurse until they arrived at COCH. The RCPCH's guidance in place at the time (paragraph 7.5 of INQ0010214) did identify that the RCPCH would not undertake a review where the police were currently involved. Whilst the police were not involved at the time of the review, had the full information been provided to the whole review team and the IR Programme Board, it is likely that the review would not have been allowed to take place by RCPCH.

15. Second, an invited review is not an adjudication. This review was not, in the eyes of the reviewers, about Letby but about whether there was practice, cultural or other issues (such as competence) which the reviewers could discern which could have contributed to the rise in mortality or which showed a lack of standards at the Unit . The guide to invited reviews [INQ 00102147] provides the scope of expectations .

16. Third, the information compiled, primarily by Sue Eardley, between the commissioning of the review (early July) and the arrival of the reviewers for their visit (beginning of September), was gathered over a brief period of time – shorter than the RCPCH considers would be "usual for a review". There was not the time to digest or to have group discussions in advance of the review taking place between the reviewers which may have led to others understanding that the paediatricians had concerns about malfeasance on the ward.

17. Fourth, at that time, there was no risk-based approach operated by the RCPCH as to whether invited reviews should be accepted in the circumstances given, or whether an invited review was indeed the right way forward.

18. Fifth, whilst the COCH supplied the "staffing rota" [INQ0010072] to the reviewers as part of the pack sent to them in advance of the review (which formed the basis of concerns raised by the paediatricians in respect of Letby). This included an analysis by the doctors of Letby's presence on the rota at each case . and they had an analysis by Ms. Eardley [INQ0012846] , in the absence of further information or evidence, all the reviewers (bar Dr. Milligan, the lead reviewer [INQ0102061, paragraph 4, and [INQ0012748 – Dr. Milligan's comment about Letby being on shift for all but one of the unexpected and/or unexplained deaths] ) consider that would not have put them on notice of wrongdoing by a member of staff (see for example, Ms. Mancini at 50 [INQ0102614] .

19. Sixth, Ms. Eardley asserts that she was under pressure at that time [INQ0101348-0047] ,.There had not been thought given by her to the sorts of issues raised by malfeasance or criminal activity by a staff member related to babies. The relevant guide for reviewers issued by the RCPCH did not tell the reviewers what to do in this situation.

**The review**

20. Several of the reviewers (i.e. Ms. Mancini, Dr. Stewart, Ms McLaughlan) found out collectively on the morning of 1 September 2016 that there were allegations made by paediatricians that the deaths were suspicious and that Letby may have committed crimes, but it is described by one reviewer as being played down by the COCH Medical Director and Director of Nursing (Ms. Eardley at paragraph 49, 50 and 129 [INQ0101348-0013 and 0032: her contemporaneous note of the meeting at [INQ0010124]. As set out above, Ms. Eardley and Dr. Milligan did know about the allegations in advance, but the other reviewers were not informed of this and should have been (as recognised by Ms. Eardley in her witness evidence) .

21. The reviewers went on to interview the consultant paediatricians and nursing staff, along with Neonatal network staff and relevant executives from the hospital. Dr Brearey and Dr Jayaram were interviewed between 0930 and 1000 on 1 September 2016 [INQ0010123 and INQ0010124] and both identified that at the time of the deaths of the babies, they did not consider that Letby being on shift for all the deaths was significant. The notes then state that Dr Jayaram wondered if there was "*something they were missing in the review of all the cases*" [Sue Eardley paragraph 89 [INQ0101348 -022 and INQ0010124 at 009 – 0014] but the only consistent factor was that Letby had been on shift, and that after having spoken to the Medical Director and the Director of Nursing, Letby had been put on day shifts, but there had then been collapses in the day. The notes make it clear that after this change in Letby's shifts both paediatricians considered that there had been "*foul play*" (INQ0010123). None of the reviewers considered that this was more than an "assertion", and it was not reflected in the interviews with nursing staff who considered that Letby was a good nurse. The reviewers considered that this information alone was not sufficient to consider that there was foul play,

or to consider that it could investigate if this were the case to any further degree. The RCPCH agrees that it was not the role of the reviewers to act in a forensic context, but that given the issues raised, the RCPCH invited review board should have been contacted for advice. Further, any RCPCH review which examines allegations of criminality would have been entirely inappropriate– and might could have prejudiced any subsequent disciplinary or criminal investigation by the appropriate bodies.

22. The reviewers agree (see for example paragraph 84 of Ms. Mancini [INQ0102614-0019]) that they did consider aborting the review following the interviews with Drs Brearey and Jayaram. The RCPCH guidance for reviewers (INQ0010214 at paragraph 7.7) stated that if issues of criminality become known, the review should be completed in respect of its original remit, but the reviewers should not investigate other issues or those relating to the potential criminality. The rationale given at the time in notes by the senior clinical reviewer – Dr Milligan – which is repeated in his witness evidence [INQ0102061-003] - was that the terms of reference indicated that it was important to get the background and so the review was not abandoned. Some of the reviewers consider that they were right to continue with the review – as it allowed COCH to "discount" explanations related to for example, competence, understaffing or unhygienic practices as reasons for the unexplained and unexpected deaths (see further paragraph 50 of the witness statement of Ms. Mancini [INQ0102614-0010] and paragraph 86 [INQ0102614-0020] ). The Crisp review interviewed some of the reviewers who said (INQ00101783-0024) that they had a duty to complete the work and they would let the College down if they had "walked out".

23. Others consider that with hindsight it should have been abandoned. The view of the RCPCH from 2024 is that the review should have been abandoned when it was known that the deaths were suspicious as the review provision was not designed to assess such allegations, and it was plain that there were serious concerns expressed.

24. Ms. Alex Mancini (the nurse reviewer) and Ms. Claire McLaughlan (the independent reviewer) interviewed Letby on the afternoon of 1 September 2016 [INQ0010121, handwritten notes , and INQ0014602 transcript]. There was no standard protocol to guide the Invited Review service on how to approach this situation; there had been no previous situation where this had arisen (paragraph 70 of INQ0017463-0023 – 0024). The Crisp review [INQ00101783] concluded that the review team were not given sufficient guidance by the RCPCH about the risks of conducting such a review. The RCPCH from the vantage point of 2024 agrees with the Crisp review that it did not give the reviewers sufficient guidance and that the risks of interviewing Letby should have outweighed any advantages.

25. These two reviewers disagree with the College that they should not have interviewed Letby. Both reviewers considered that Letby had not had the proper HR procedures followed by being left "in limbo" without any proper investigation. Both Alex Mancini (the specialist neonatal nurse: see INQ0102614 ) and Claire McLaughlan (INQ010895 – 0012, paragraphs 36 and 37 ), (the independent reviewer with an extensive background in NHS processes and standards) considered that the hospital had not followed their own HR procedures. Taking someone off duties was not a usual course of action and they did not consider that Letby had been suspended . She was a nurse on the unit and Ms. Mancini considered that she should have been allowed to express her views about the culture and workings of the unit (Mancini paragraph 65 [INQ0102614-0015]. The reviewers considered at the time that if there were allegations, there should have been a formal human resources investigation. The Inquiry may wish to determine if this was a correct perspective. The reviewers consider that the hospital had failed in its duties both to the babies, the unit and Letby by not acting. As is said by Alex Mancini about the fact that Letby was rostered on to shift at all the times of the death contemporaneously [INQ0010147 which is a comment made in one of the draft reports regarding the COCH]:

> *"…the significance of this one nurse being rostered on shift at the time of each of the deaths had not been investigated through a thorough process and is only [sic] individual senior consultants' subjective view. There is no evidence or reports to suggest this nurse's clinical judgement or skills were in question. We were not shown any reports to suggest that this nurse had not cared for these babies appropriately. Not sure I am making sense, but I think it is important that we recognise that these allegations were only hearsay and have no substance*".

26. The RCPCH submits that it does appear that the staunch support for Letby expressed by the nursing staff during their interviews [INQ0014603] and the COCH executive team was an influence on the decision to continue with the review (para 126 of Eardley: INQ0101348-0032]). As described by Ms. Eardley, whilst the expression that the consultants view was "subjective" was inapposite, the review team was presented with evidence that Letby's presenceon shift correlated strongly with incidents of babies showing sharp deterioration or dying (para 143 of INQ0101348-0036).

27. Dr Milligan (paragraph 7 of his witness statement [INQ0102061-002]) and Ms. Eardley (paragraph 127 of her witness statement: INQ0101348-0032] ) both remember Ian Harvey (the medical director) mentioning to them that he had determined that there should not be any police contact before the review had finished and that he had taken internal advice from a board member who was also a retired senior police officer.

28. The issues that the Inquiry may want to consider arising from this are:

(a) What should the hospital have done when these allegations were first raised?
(b) Was in fact the review a substitute for having an individual examination of each death which should (or ought) to have taken place immediately after the deaths occurred?
(c) Was the reviewers' response to the allegations made by the doctors appropriate?
(d) Should the RCPCH have undertaken any service review only after a case note review was undertaken?
(e) Should there have been more discussion with the medical director and the review team to identify that in fact a case note review was a more appropriate form of external review?
(f) Should the review have been aborted on the first morning?
(g) Should the reviewers have interviewed Letby?
(h) Should the RCPCH have insisted that the board contact the police?
(i) Should the board have decided not to contact the police until after the end of the RCPCH review?
(j) What due diligence should have been undertaken by the RCPCH to understand the request for an invited review by the COCH?

29. The RCPCH accepts that it did not have an escalation policy in place or any guidance on what to do faced with the situation that the reviewers faced on 1 September 2016 (INQ0017463-0032). The relevant guidance seemed to suggest that a general review of service provision could continue even in cases where the police may be involved (paragraph 7.7 of INQ0010214). The guidance states that "*clear scope boundaries should be agreed before further work takes place in order to avoid prejudicing other investigations*." The RCPCH considers that such work should have been undertaken with the COCH when the concern regarding Letby was revealed. The reviewer's statements indicate that they considered that it was proper to speak to Letby and that the information as presented did not suggest in a definitive or realistic way at that time that a criminal offence had been committed.

30. The RCPCH considers that a member of its Invited Review Programme Review board should have been alerted at this time and asked to contribute to decision making [INQ0017463-0032].

31. The RCPCH also accepts that there appears to be a mismatch between what the Medical Director claimed to have expected (a case notes review) when this was not expressly set out in the terms of reference (INQ0010172) and what the RCPCH considered that they were going to do. This is reflected in Ian Harvey's witness statement (INQ0107653), in which he suggests that there was misunderstanding about the scope of the review but accepts that there was no mention of a case-note review as part of the agreed terms of reference (paras 343 and 828).

**Findings of the review**

32. The findings of the review would never have been able to make decisions about the allegations (as they then were) in respect of Letby, and the review was not designed for that purpose. The feedback given by the reviewers on 2 September 2016 told the COCH this (INQ0010197).

33. The review findings identified that the RCPCH review team were not equipped to carry out a detailed case note review, nor was it included in the terms of reference of the review, as that was a specific task which only very few experts had the time and expertise to do and so had to take place after the RCPCH report (INQ0010172).

34. The RCPCH did provide interim advice and recommended actions both at the end of the review itself (on 2 September 2016) and then in a letter three days later (INQ0009611). In that letter (which as a relatively contemporaneous document is likely to reflect the views of the team at the time) it was made clear that it was only on 1 September that members of the review team (Mancini, Stewart, McLaughlan) knew that a nurse had been moved from the neonatal unit and that this had been done without a formal process nor clear notification of why this had happened.

35. The report was subject to a quality assurance process from two senior clinicians, Dr Nic Wilson, and Dr David Shortland. Dr Shortland saw the report and in November 2016 [INQ0012748 and paragraph 75-77 of his witness statement [INQ0099070-026]) said that the review was both interesting and complex but "*almost felt a bit like the Grantham situation 30 years ago and my only question was why they didn't involve the police if they had those suspicions*". Dr Shortland was a senior registrar in Nottingham in 1989 /1990 and was involved in caring for some of the infants who had been cared for in Grantham by Beverley Allitt.

**The RCPCH's final report**

36. The RCPCH final report made 22 recommendations: six related to strengthening processes about managing or investigating deaths: four related to staffing: five related to management and governance of the neonatal unit and six were directed at the neonatal network involving transport to and from other NHS units.

37. The RCPCH made a number of findings which, the RCPCH submits, were, unfortunately, similar to what would be found in comparable units at the time in question. This included significant gaps in medical and nursing rotas, with lack of compliance with the British Association of Perinatal Medicine (BAPM) standards in respect of staffing [INQ0001954-004:INQ0001954-0009], although the COCH was less understaffed than was the case in other comparable units at that time. There was insufficient consultant presence to safely

cover the paediatric wards including the Neonatal Unit [INQ0001954-0010] and insufficient junior and training doctors available, with too much cover from locums [INQ0001984-0011), which again was a usual picture. Again, as was usual, leadership was seen as remote from the unit [INQ0001984-0014] with no specific children's champion on the board (which as is identified later, is again a common problem).

38. In respect of leadership and governance, the report found that the unit only partly had a culture of safety and governance. The Inquiry may wish to note that attendance was not high at the monthly women and children's care governance board which considers all incidents, reports, policies and causes for concerns and the Urgent Care Governance Board did not cover neonatal issues in depth. Furthermore:
    (i) There was no clear responsibility for follow up of lessons learned by the mortality and morbidity panel (4.4.4 INQ0001954 – 0016).
    (ii) Two of the cluster of deaths were not reported (4.4.5), and the neonatal unit was not as systematic as it could be in reporting into the relevant data reporting systems – such as Datix (4.4.5 – INQ0001954 – 0016).
    (iii) The internal review of deaths lead by the neonatal lead consultant did not use a recognised process nor did it involve the governance lead or risk manager. (4.4.8 [INQ0001954 – 0016 – 0017].
    (iv) The death/near miss reviews process required further strengthening to raise all deaths as a serious incident, with a prompt review by relevant clinical staff and then appropriate further action taken – including whether to request an internal or external review with a clear forum for recommendations being actioned and with review by the relevant governance board of incidents that were not investigated, and also a mechanism to inform the relevant CCG of all deaths.(INQ0001954-0017, 4.4.9).
    (v) Concerns with data gathering – which the RCPCH identify is a national concern. There were different systems for care, incident and death reporting and the data differs between them – with the two systems (NNAP and MBRRACE) in use having different requirements for reporting details and the MBRRACE study requiring further details and data again (4.4.11 – INQ0001954-0018). The RCPCH identifies that this is something it sees frequently country wide with differing data requirements and multiple systems creating a fragmented and less than coherent system for reporting.
    (vi) The senior management team of the hospital had not realised how busy the neonatal unit was and only identified such when the data had been formally reviewed (4.4.12 – INQ001954-0018).
    (vii) Not all the cases underwent a postmortem despite this being recommended by BAPM in 2011. Where postmortem examinations had taken place, they did not include systematic tests for toxicology, blood electrolytes or blood sugar (INQ0001954 – 0024).

(viii) There was at that time no nationally agreed template for mortality and morbidity reviews in obstetrics and neonatology (INQ0001954-0019).

(ix) The review team were concerned that the Child Death Overview Panel (CDOP) was not alerted to the cluster of deaths (some had been reported to Welsh authorities) and there was not a rapid response meeting within 5 working days of notification (by the CDOP), and the CDOP was asked to consider whether its processes could have detected the cluster of deaths and initiated external review more swiftly. (4.4.25 [INQ0001954-0020).

**The RCPCH's invited review service conclusion concerning the cluster of deaths**

39. The Review team did explore whether there were any identifiable common factors or failings which may have explained the increase in mortality in 2015 and 2016 in their report (INQ0001954-0024) identified that there had not been a systematic exploration of the deaths, following root cause analysis processes. There had also not been direct oversight from the COCH clinical governance group. The main recommendation was to have a detailed case note reviews of all the deaths by two independent expert.

**Questions for the Inquiry**

40. The Inquiry may wish to consider if the RCPCH report should have grappled more squarely with the situation with which they were faced and particularly with the allegations made by the consultants. The RCPCH accepts that the report did not do this. The reviewers agree that this was not their role. What does appear to have happened is that this review was seen by those in positions of responsibility at COCH as a mechanism to forestall or to delay consideration of the issues raised by the COCH clinicians, and in particular to forestall escalation of those issues to the police.

41. In as much as the review identified that there was no systemic mechanism for reviewing the deaths internally within the COCH, the RCPCH would point to the perinatal mortality tool which has been in place since 2018 (described at INQ0006757-0002, at paragraphs 4). If this had been in place at the time of the COCH cluster of deaths, would a pattern have been found earlier? The RCPCH can do no more than speculate that at the very least it provides a national standardised tool to which clinicians can refer when assessing deaths. The Inquiry may also wish to consider whether the real time data viewer provided by MBRRACE-UK to all trusts from May 2019 (paragraph 36 of INQ00067567 – 0010 – 0011) would have assisted in identifying the concerning trends?

**Follow up from the review.**

42. The guide to the review service [INQ0010214] and the letter sent on 5 September 2016 [INQ0005272] both identified that there would be "follow up with the COCH at either three or six months after the report had been issued to the COCH to review the Trust's

implementation". Ms. Eardley considers (paragraph 30 of her witness statement INQ0101348-0008]) that the RCPCH were told that a case note review had been commissioned. She therefore considers that the relevant follow up was in effect undertaken and that the Trust was seeking to mitigate safety concerns.

43. The rationale for not referring matters to any external scrutiny body, regulators or the police is described by Ms. Eardley (and the other reviewers) as being because the relevant invited reviews process put the ball into the court of those who had commissioned the service. Paragraph 9.7 of the Invited review guidance in place in 2016 (INQ00010214_0012) says:

> "*The College has no statutory authority to require action following an IR and can only give advice and recommendations to a client. Any action taken following the IR is the responsibility of the client. Where concerns are raised over safety or staffing the College would expect the client to notify the regulatory authorities promptly of the review, recommendations, and action plan. If during the review or follow up period, the college deems that action taken in response to concern the IR programme board reserves the right to authorise further action which may include reporting the findings directly to the appropriate regulatory or commissioning authority. The Chief Executive of the client organisation would always be notified if this were being considered."*

44. The RCPCH is of the view that the Head of Invited Reviews should have checked and made sure that the final report (unredacted by the Trust) was supplied to clinicians working on the unit. A way should have been found to address the HR concerns about the apparent process failings regarding Letby while dealing fully with the seriousness of the consultants' concerns. The RCPCH should not have accepted that the confidential version concerning Letby should be seen solely by the senior executives at the Trust. Those who had raised concerns should have had sight of the report. The RCPCH is deeply sorry that this did not happen and understands that the COCH paediatricians feel let down by this process. There should not have been two versions of report.

45. The RCPCH did identify that the COCH review was seen as "sensitive" to both the RCPCH's Council and the Board of Trustees (the trustees were the successor body to the Council from 1 Nov 2016) in 2016 (INQ0009582 and INQ0009580 and INQ0009581). There does not appear (albeit that the notes are limited) to have been any discussion by Ms. Eardley about (a) aborting the review (b) the lack of an escalation process with the RCPCH or (c) the interview with Letby. The RCPCH considers that these issues should have been discussed with the Invited Review Programme Board and then the trustees and they should have been fully briefed by either Ms Eardley or David Shortland (the Programme Board lead at the RCPCH) at the time to the trustees. The RCPCH consider that describing the reviews as sensitive did not do justice or accurately set out the situation at COCH and the issues which this report had raised (paragraph 127 of INQ0017463-0050).

**Reflections**

46. The Allitt review in 1994 (p11 of the Inquiry's table of previous inquiry reports) identifies that the actions of Beverley Allitt should lead to heightened awareness in all those caring for children of the possibility of malevolent intervention as a cause of unexplained clinical events. This possibility appears to have been forgotten over the past thirty years, or not emphasised in training and development. Although some of those at the RCPCH (Dr David Shortland) plainly identified similarities with the Allitt case, it seems clear that this warning was not observed as carefully as it could have been by some of those involved in events at the COCH. The fact that experienced clinicians did not consider this as plausible does indicate that as a profession, clinicians may need to think that "It could happen here."

47. The evidence submitted by the RCPCH accepts that a number of mistakes were made in the commissioning and in the review procedure itself and its aftermath. (It should also be noted that, towards the end of her statement, Ms Eardley's reflections accept a number of the points made below by the RCPCH [para 180 of INQ0101348-0046] ). Every reviewer at the RCPCH, all distinguished individuals in their own field, acted, it is submitted, with good faith and sought to do the best that they could on the information that they had. No-one has criticized the report for the professional observations it contains. With hindsight, however, there are lessons which can be learnt about what a review can and cannot do, and how and what steps should be taken in advance of a review, about the parameters of a review, and how the RCPCH should behave after a review. In particular, the RCPCH identifies that:

    (a) The review team could have done more to understand the background to the review and to ask probing questions of the Trust about the concerns raised and why the review had come about, as the information shared by the Trust seems to have been lacking frankness.
    (b) There should have been involvement by the Clinical Lead for the Invited Review Programme and the Lead Reviewer to meet with the Medical Director of COCH to discuss the terms of reference given the potential issues which were raised. Whilst there was some brief discussion, there should have been, it is considered, more involvement and investigation with the medical director of the COCH and the Lead for the Invited Review Programme or the Lead Reviewer. Such discussion may have disclosed or led to the conclusion that either a review was not apposite for the problems at COCH or a different review approach was necessary.
    (c) The lack of a pre-meeting of the reviewers (some consider there was no pre-meeting: others that there was a meeting only the night before) which could have led to further disclosure of the concerns raised by COCH to Ms. Eardley and a discussion of whether the review was or continued to be appropriate.
    (d) The evidence of the reviewers does explain why, from their point of view, they proceeded with the review and what was the rationale for it. The RCPCH's view is that whilst their

rationale is explicable, with the benefit of hindsight the review should have been aborted or should not have taken place.

(e) It would have been helpful for the reviewers to have had an escalation process in place at that stage to discuss matters with the Programme Board of the RCPCH, and it would also have been useful to have had a clear written record of why the review continued.

(f) The RCPCH should have had an escalation policy in place of how to manage situations like the one faced at COCH.

(g) The RCPCH should have provided more guidance on whether to interview a suspended staff member and the team of reviewers should have had more information to assess the risks it faced.

(h) The RCPCH understands the rationale given by Ms. Eardley about not following up with the COCH on a formal basis as she knew that a case note review was taking place. However, there were a number of other recommendations – particularly concerning the recruitment of staff and operation of the transport network – which could and should have been followed up. In particular, given the failure to follow the relevant CDOP processes, there should have been further follow up to make sure that this had taken place.

(i) The report was too "light touch" given the issues it had raised about the relevant CDOP procedures not having been followed thoroughly.

(j) With hindsight, it is easy to see that the review team and RCPCH should have fully considered all options for escalation, regardless of whether there was a process in the handbook. The RCPCH considers that the issues were not as clear in September 2016, but out of an abundance of caution it considers that there should have been more proactive follow up in late 2016/early 2017.

(k) Whilst the review was considered to be sensitive, and had obviously raised difficult questions for the reviewers, there was (until the "Crisp Review" in 2020) no 'lessons learnt' exercise to provide guidance for the future , nor a steer from the Programme Review board as to how to approach such reviews. That should have taken place promptly.

(l) It may have been appropriate to ask the COCH to send the case note review to the RCPCH and for it to be reviewed by those who had undertaken the September 2016 review.

(m) The RCPCH report should have been disclosed fully and promptly to the paediatric and nursing teams working at COCH.

**Changes made by the RCPCH following this review**

48. The RCPCH witness statement sets out the changes made after reflecting upon the COCH review. The RCPCH commissioned an independent audit of the invited review service in 2020 – known as the Crisp Review [INQ0010176 – INQ0010240]. This included a general review of the service and a specific review of the COCH review.

49. This made a number of recommendations for changes in procedures and made criticisms of the COCH report which included:

    (a) That the decision made to accept the review was not risk-based and should have more carefully considered if, given the information supplied by COCH, this review was the correct course of action.
    (b) There was no escalation policy for advice as to whether to continue with a review.
    (c) There was no guidance on interviewing staff members who had been suspended.
    (d) The report was “light touch” in the way that the issues were presented, given that national guidance for child deaths had not been followed and that local procedures for assessing mortality were not thorough.

50. Following on from this, the RCPCH:
    (a) Introduced into the Handbook for Healthcare organisations that if a member of staff is involved in an internal HR process which is formalised, then they will not participate in the review (paragraph 71 of INQ17463-0024 and paragraph 151(i) of INQ0017463 – 0062).
    (b) Introduced a specific document in March 2023 setting out the escalation process to be followed if reviewers have concerns [INQ0012813] and providing detail of how to behave in specific situations.
    (c) Provided new guidance on considerations of when to call off a review in the light of findings made and steps to record the decision making if a review is called off (or not).
    (d) Provided more detailed guidance and training to reviewers including significantly strengthened guidance (paragraph 151 of INQ0017463-0061).
    (e) Provided more detailed information and a set of handbooks about the review service on the RCPCH website including responsibilities about the end outcomes of the review and the escalation processes.
    (f) Put into operation a due diligence process when a review is requested, and further clarification of the reasons for the review. There is also greater briefing of the review team.
    (g) Included a case note review as part of the invited review service – so that there did not need to be two reviews as happened with COCH.
    (h) There is now greater consideration to risk management, which is built into the criteria for acceptance of review, including assessing if an invited review is the most appropriate method.
    (i) The Lead Reviewer is now involved in scoping the review.
    (j) A rolling programme of training for reviewers including guidance on making firm recommendations, based upon evidence which do not shy away from serious concerns is now undertaken.
    (k) Regular updates are given to the RCPCH Executive Committee and Board of Trustees about reviews.

(l) The review programme is now overseen by the Registrar of the RCPCH, who is a clinician and trustee, for senior clinical oversight [INQ0010213].

**The views of Dr Brearey**

51. The RCPCH is aware that Dr Brearey has stated that a police investigation could have begun earlier if they had seen the full report from the COCH [letter from Dr Brearey to Professor Modi 5/2/18 [INQ0006669] It is for the Inquiry to determine if this is the case as the RCPCH does not have sight of all the relevant material from a number of sources.

**Part Two: General points and principles**

52. The Inquiry has requested that core participants address some specific topics, which the RCPCH has sought to do below. The RCPCH would contend that, as its overarching submission, it considers that children's healthcare needs have systematically not been prioritised by national decision makers. The Department for Health and Social Care's Major Conditions Strategy (published by the previous government and currently paused) was starkly focused on adult care and until recently NHS England's annual operational planning guidance has focused mostly on how the system should deliver for adults.

53. Paediatric services are usually only a small part of service provision within hospitals, and it is therefore easy for these services to be given less focus in a system where resources are stretched and where paediatric care is not seen as a priority. The NHS indicators currently used to measure national performance (such as timings for cancer care, elective care and waiting times) are not focussed upon children. This means that at a Board level, children are less likely to be the priority in respect of financial decision making or to be examined as part of oversight or scrutiny of boards. As identified below, the RCPCH wrote in 2021 to ask for ringfenced funding in neonatal units, which has not materialised.

**Advice and help for medical staff**

54. The Paediatric training pathway operated by RCPCH has a "core pillar" focussing on patient safety. Safeguarding training is mandatory throughout paediatric training, and many paediatricians will spend their working lives dealing with safeguarding concerns. As identified by all the reviewers, none of them had specific training about dealing with suspected malfeasance of staff. Because most safeguarding alerts and concerns relate to and involve concerns about children from family members or others in their lives, it may well be (but this is speculative and not based upon any survey evidence) that staff malfeasance in circumstances like those at COCH is not considered to be likely. As is known about other areas where abuse of trust takes place, organisations often find it difficult to understand or recognise that an individual who is ostensibly providing care could also be committing harm.

The Inquiry may benefit from evidence from experts in organisational psychology to explore these issues further. This is not to suggest that those in clinical positions in this case sought to put reputation above concerns for the best interests of children – but that people do think of it, and how it would affect them personally.

55. The team that visited the COCH were all highly specialist practitioners with considerable experience in hospital care, and in setting and assessing standards in such settings. The fact that none of them can remember ever having training about this issue may be of note to the Inquiry and may reflect that this was not something which was referenced during training.

56. As can be seen from the situation faced by the RCPCH at the time, there was no clarity either within their internal policies or experience of facing this situation. The review team did what they considered was right at the time, but it is suggested that they did so without any formal assistance or help. There are a wide number of regulatory bodies which could be engaged across issues and systems, and it is sometimes confusing to know who to contact and why. The RCPCH would indicate however, that there is a designated safeguarding lead attached to every hospital who is the first port of call to raise concerns and who then can call the Local Authority Designated Officer (LADO), and whose role it is to record and monitor how those allegations are being investigated. The Chronology suggests that such a referral was only made in the case of Letby on 27 March 2018 (INQ0079684). The Inquiry may wish to investigate why it took so long for this process to take place, and whether there needs to be greater awareness of the functions and role of the LADO.

57. There is a standardised process of child death review set out in Working Together and backed by primary legislation (s16Q of the Children Act 1989) and guidance (Child Death Review Statutory and Operational Guidance (2018)) and a designated doctor for child deaths. A child death review analysis is meant to identify matters relating to the death relevant to the welfare of children, public health, or safety and to review all deaths of children.

**Management in the NHS and Regulation: Whether senior managers were held accountable for decisions made and was this good enough to keep babies safe and should the current position be improved and should accountability of senior managers be strengthened**

58. The witness statement of Dr Kingdon [INQ 0017493], immediate past President of the RCPCH identifies that the governance and management of hospitals is complex, and the number of bodies potentially involved is numerous. The RCPCH has advocated for a children's lead at the highest level of every NHS organisation (INQ0012284). Every Integrated Care Board (ICB) must have an executive lead for children and young people who should provide visible leadership for them (as identified in statutory guidance[1]). There is no reason a

[1] NHS England » Executive lead roles within integrated care boards

similar person could or should not be present in NHS Trust boards to ensure appropriate oversight of children's health.

59. Furthermore, Dr Kingdon (at paragraph 10 [INQ0017493]) considers that the structures in place are more reactive, than proactive. The RCPCH describes below the proactive safety culture which it considers needs to be created for every paediatric team from the work that it has undertaken and considers that there must be a switch to a culture that proactively seeks to minimize harm prevention rather than responding when things have gone wrong. The RCPCH's view generally (as the body who represents paediatricians in all four UK nations – and internationally) is that hospital leaders/managers are supportive of patient safety initiatives, but they judge this in the context of the monies available. If there is a need to spend significant resources, it can be more difficult for the money to be found or allocated for that (paragraph 15 of Dr Kingdon's statement [INQ0017493 – 005]).

60. As Dr Kingdon identifies, there is no standardised mandate on how to ensure that effective hospital governance or management is in place. In England, the CQC can ask for a written report on how an organisation monitors and assesses the quality and safety of its services, and the patient safety framework (although at the time of writing, the CQC itself is subject to criticism for not undertaking sufficiently rigorous assessments) [2].

**NHS Managers and regulations**

61. The RCPCH supports the formal regulation of NHS managers (INQ0012287) but does not consider that it is in the best place to answer how such regulation should work, and whether it is regulatory oversight – or rather clarity of accountability - which needs to be made clear.

**Culture: The culture in hospitals and neonatal units and the possible oral evidence on those topics**

62. The culture of hospitals is, the RCPCH submits, informed by the leadership of the institution, and the way in which interactions take place between staff, between staff and patients and in the actions and behaviours of those working in the hospital. It would identify six factors that are necessary to ensure safe care is provided which are:
    (a) Staffing
    (b) Resources
    (c) Having the right data and information
    (d) Establishing a safety culture
    (e) Ensuring accountability and shared responsibility throughout the organisation.
    (f) Timely response to concerns.

[2] Review into the operational effectiveness of the Care Quality Commission: interim report - GOV.UK (www.gov.uk)

**Staffing**

63. Fundamental to a good culture is having sufficiently well-trained staff who operate to ambitious standards and who are provided with adequate support. When staff are working beyond their capacity, good culture can be hard to come by. The 2024 GMC National Training Survey shows 19% of paediatric trainees are at high risk of burnout, with 51% also rating the intensity of their workload as heavy or very heavy[3]. An in-depth snapshot of neonatal services conducted by the RCPCH and Getting it Right First Time (GIRFT) in 2020 reported 10% of neonatal units had gaps in medical staffing with 5% of these shifts covered by locums. Gaps were highest for Tier 1 and Tier 2 staff on the weekday (14%), with 15% of neonatal units having gaps in nurse staffing[4]. There were also twice as many gaps in medical and nursing rotas in Neonatal Intensive Care Units compared with Local Neonatal Units and Specialist Care Units and a wide regional variation in medical and nurse staffing gaps were noted. The National Neonatal Audit Programme (2022) identifies that:
"*The continuing decline in neonatal nurse staffing levels is a matter of serious concern to those providing and commissioning neonatal services, given its association with increased mortality" (INQ0012293).*

64. Paediatric waiting lists have grown at double the rate of adult waiting lists over the last two years, and the number of children waiting over 52 weeks for care has increased by 60% for elective services, and 94% for community health services, in just two years. There are now more than 50,000 children who have been waiting for outpatient care for over a year[5].

65. There is a shortage of consultant-led care in many paediatric units and a national shortage of neonatal nurses. In the 2020 neonatal snapshot[3], Allied Health Professionals (AHPs) and other support services were unavailable in less than half of neonatal units during the week and were almost completely absent at weekends. Only one-fifth of Neonatal Intensive Care Units and a tenth of Local Neonatal units/Special Care Units had a psychologist available to support families during the weekday, and no services were available at weekends.

66. Community paediatricians have declined by a third alongside significant waits for community therapy. Community paediatricians most often take up Named and Designated roles for safeguarding within a trust or Integrated Care Board and are therefore responsible for safeguarding training and appropriate escalation of child protection issues. The reduction in community paediatricians has also led to concerns in relation to succession planning for Named and Designated Doctor roles.

[3] National Training Survey 2024 Results (gmc-uk.org)
[4] Snapshot of neonatal services and workforce in the UK | RCPCH
[5] https://www.england.nhs.uk/statistics/statistical-work-areas/rtt-waiting-times/

67. This national picture of understaffing was reflected at COCH. The RCPCH Invited Review of COCH identified a 21% deficit in staffing on the Unit at the time when the deaths took place. Patient safety is at risk of being compromised when units deviate away from national guidance on safe staffing and if there is poor compliance with BAPM medical standards.

**Resources**

68. Boards, managers, and central government needs to make sure that appropriate financial resources are available to secure the necessary staff. Paediatric hospital services are under immense financial pressure, with over 400,000 children in May 2023 on the waiting list for consultant treatment [INQ0012295].[6] This was the highest increase in waiting since records began, with a growth of over 160,000 children between April 2021 – January 2024[5]. This will have a direct impact on neonatal care, particularly in those units reliant upon general paediatricians to supervise and have clinical oversight. It is inevitable that a system at breaking point (or in the words of the Secretary of State, Mr. Streeting, a system which is "broken") may find it difficult to introduce and implement patient safety systems (INQ0012285).

69. The RCPCH welcomed the publication of NHS England's Long Term Workforce Plan (LTWP) in June 2023, and its central aim of putting staffing on a sustainable footing and improving patient care, but cited concerns on the lack of reference and specificity to the child health workforce. There is a significant disparity in a 92% increase in places for adult nursing, with a 0% increase in numbers of child nursing places.

**Data and metrics**

70. As identified above and below, there are a series of reporting mechanisms for serious incidents and "never events" (INQ0012296) – the aim of which is to identify patient safety issues which are preventable. The RCPCH considers that data flow between maternity and neonatal systems is inadequate, and clinical information collected in maternity settings is often not carried across to neonatal care. There is the National Neonatal Audit Programme (NNAP) organised by the RCPCH which provides especially useful national information. There is also a National Maternity and Perinatal Audit (NMPA), which has been set up by a group of organisations concerned with this care (including the RCPCH) to allow the reporting of neonatal outcomes of maternal care, as an audit tool. The RCPCH considers that if this were adopted nationwide, it would be a source of rapid and reliable data and would enable improvement in both maternity and neonatal care.

[6] Analysis undertaken by the RCPCH using the NHS England monthly data for March 2023 in respect of paediatrics [INQ0012295_004]

71. Alongside the NNAP, there has been a Perinatal Mortality Review Tool in place since early 2018 which seeks to analyse every single stillbirth and neonatal death. The RCPCH considers that the NNAP and the Perinatal Mortality Review Tool are the two most important tools to scrutinise deaths and identify trends. Sir David Spiegelhalter in his witness statement also identifies the use of real time monitoring systems (paragraph 5 of INQ0008966-0006). It is understood that the investigation by Dr Kirkup into East Kent Maternity Services also makes this recommendation.

**Patient safety and how it could improve**

**(1) Greater central government attention and oversight.**

72. The RCPCH has advocated (in 2021 – INQ0012290) for ring-fenced funding to meet a number of needs within neonatal units, including more resources to analyse data and the appointment of a Neonatal Safety Champion (INQ0012290) – but not all of those proposals have been put into practice. We do, however, note that there is now a National Clinical Director for Neonatal Care. There is now also a champion for Women's Health (Professor Dame Lesley Regan) and a Patient Safety Commissioner (Dr Henrietta Hughes), although the focus of these two posts is not on neonatal care.

(2) **Staffing processes, frameworks and working as a team.**

73. The RCPCH identifies that a robust, systematic approach to raising concerns within the workplace that is widely promoted, combined with clear signposting to independent external support and advice, supports clinicians to speak up. It is noted that national recommended roles to promote 'speaking up', including freedom to speak up guardian, guardian of safe working hours and wellbeing ambassadors are active in the workplace[7].

**(3) Embedding patient safety into all aspects of care, including training.**

74. It is necessary for a culture of safety to be inculcated as it does not exist in the ether. This relies an organisation prioritising, resourcing, and implementing patient safety. An essential pre -requisite of this is having good interaction between individuals and within the group who share the same values and beliefs and who feel able to speak up. Culture does not exclusively come from those who lead, but to sustain a culture of safety, leadership must be focussed upon it. The RCPCH safety portal (see paragraph 75 below) sets out six leadership practices to develop a culture of safety:
    (a) Establish a vision for safety.
    (b) Build trust, respect, and inclusion.
    (c) Engage and develop a board.
    (d) Prioritize safety in the selection of leaders.
    (e) Lead and reward a just culture.
    (f) Establish organisational behavioural expectations.

[7] https://www.rcpch.ac.uk/sites/default/files/2023-07/thrive_paediatrics_roadmap_2023.pdf

The inquiry may wish to ask if all these practices were present in COCH in 2016? And if not, why that was not the case. BAPM has developed guidance to support service leaders and healthcare professionals to understand and evaluate its culture in neonatal care (INQ0012282).

75. As identified, all paediatric care must be focussed upon examining whether patients are safe, how they can be made safer and what data are needed to carry out this assessment. The RCPCH has a "Patient Safety" Portal which provides resources and information about:
    (a) Patient safety fundamentals – i.e. providing resources, the NHS patient safety syllabus, courses, and conferences.
    (b) Learning from others – which provides a collation of reports and alerts on adverse events.
    (c) Creating systems which are safe – by improving understanding of the interaction between people, technology, and their environment.
    (d) How to build a safe culture - these resources include a paediatric patient safety podcast launched in January 2024.

76. The confidential inquiry into maternal and child health (CEMACH) report from 2007[8] found that there were preventable factors in 26% of reviewed cases – most of which relate to poor communication and delayed recognition of a deteriorating child. The RCPCH consider that there are ten safety risks for children in healthcare:
    (a) Medication error
    (b) Failure to recognise deterioration.
    (c) Failure to recognise life threatening illness early.
    (d) Hospital acquired infections.
    (e) Preventable pain and distress
    (f) Tissue injury
    (g) Failure to recognise early and manage procedural or surgical complications.
    (h) Unnecessary admissions, investigations, and procedures.
    (i) Psychological harms or not providing a positive experience of healthcare.
    (j) Failure to recognise safeguarding concerns only.

77. All ten of these factors need to be identified and communicated about, so that poor outcomes and patterns can be spotted by teams, and as far as possible, errors minimized. NHS England has patient safety training materials and there is a national patient safety syllabus, the basics of which all staff should cover. The Inquiry may wish to examine whether these syllabuses are good enough and whether they provide sufficient training in the issues raised by this inquiry about harm perpetrated by staff. Dr Kingdon in her witness evidence (INQ0017493-0009) identifies that whilst there are systems at a high-level, front-line staff may not have sufficient training.

[8] Why children Die: A pilot study – www.publichealth.hscni.net

78. The Infected blood inquiry in its conclusions has recently identified the need to learn from similar industries in the work undertaken on patient safety in this country.[9] Alongside this, the Manchester Patient Safety Framework was a tool that helps health organisations to understand a safety culture and evaluate what actions may be needed to change their own culture (INQ0012276).

79. The RCPCH would indicate that there are a number of sources from which recommendations come concerning patient safety. They include Regulation 28 reports to prevent future deaths, the work of the Health Services Safety Investigations Body which will issue reports along with SHOT (reports concerning injuries sustained during blood transfusion), MHRA alerts and NHS Patient Safety Alerts Committee. As well as these bodies there is the NHS England process "Getting it Right First Time" (GIRFT) which includes data gathering and discussion examining national and individual trust data. Further, there is a new central service to record patient safety events in the NHS to enable there to be one place to record and then be able to analyse them, and NHS National Patient Safety Team case studies. All of these would include events concerning children but not specifically related to them, and whilst all are invaluable, the RCPCH would suggest that there needs to be a way to ensure that clinicians involved in day-to-day treatment have a way to digest and learn from these many sources.

80. The National Confidential Enquiry into Patient Outcomes (NCEPOD) is a charity commissioned by the Health Quality Improvement Partnership and Health Foundation which examines standards at places of care through confidential surveys and appraisals of provision. It produces reports on common themes which have been identified throughout reviews. The RCPCH considers that this work is invaluable and needs to continue but again it is important that the information in these reports is then implemented.

81. Most importantly, patient safety requires communication, and professionals being willing to share where things have gone wrong, alongside a shared understanding in a team that is not hierarchical. The inquiry may wish to explore what the workplace culture was like at COCH, and whether hierarchy impeded or prevented warning signs being seen or noticed.

**Creating a restorative culture**

82. The RCPCH cannot speak for the families involved with COCH and their view as to whether or not there was a restorative culture in action, but it would suggest that the powerlessness identified in the Kirkup report (and the Bristol and Liverpool inquiries), and the Ockendon review causes harm to patients and to other staff. Many of the reviews and reports set out by the Inquiry (in no order, Liverpool, Bristol, Ockendon, Kirkup, Infected Blood, Mid Staffordshire) all focus upon the need to move from a retributive culture to one which is

[9] Volume_1.pdf (infectedbloodinquiry.org.uk) at p237 – 240

restorative in nature. Whilst the introduction of the NHS England Patient Incident response framework and its guidance on engaging patients focusses upon preventing compounded harm, it is suggested that there is some way to go before this is embedded as a way of dealing and managing with incidents which take place.

**Martha's Rule**

83. The RCPCH welcomed the implementation of Martha's Rule – which gives the right of a patient or family to request a clinical review in the event of a suspected deterioration or grave concern, with a second opinion from an ICU/HDU doctor at the same hospital. Given the staffing pressures in children's services nationally as described above, effective implementation of Martha's Rule will require significant improvement in staffing, as the RCPCH have set out above (INQ0010327_0002). To ensure that the rapid clinical review is effective, it must be undertaken by those with paediatric training (which the Patient Safety Commissioner agrees [INQ0012337]

**Response to concerns**

84. Dr Kingdon considers that, in the context of a busy general hospital, there is often a lack of communication back to the paediatric department when concerns are raised (paragraph 30 of INQ0017493-0010). This lack of response can undermine confidence if any action is being taken, and there are no national standards or mandate about timelines for responding to concerns raised. It can also be unclear to identify to whom individuals go to report concerns. The RCPCH would suggest that having a national standard or mandate about both consistency of response and timeliness of such – whether the concern is raised by patient, family members or staff.

**Regulation of healthcare professionals**

85. There are currently nine regulators which cover diverse groups in the NHS. This is confusing and can also cause problems with implementing patient safety. Research also suggests that there are some 126 organisations which exert some regulatory influence within the NHS provider organisations (INQ0012289). The RCPCH considers that there would be benefit to considering if there could be harmonising of the standards of regulation to have a common set of standards as far as that is possible. The Inquiry may also wish to consider if the current system of regulation is in fact effective in improving patient safety.

**CCTV observation of Neonates**

86. The Inquiry has specifically asked about this as a recommendation. The RCPCH does not hold a position on the use of CCTV in healthcare settings. It is the RCPCH's view that CCTV must always be for a specified purpose which is in pursuit of a legitimate aim and necessary to meet an identified pressing need. There are added complexities when it comes to use of CCTV in a paediatric setting because of child rights considerations. The key children's rights

consideration for clinical settings considering implementing CCTV surveillance in a paediatric ward is whether the increased level of protection justifies the breach of a child's right to privacy. There is very limited data available about how the installation of CCTV impacts clinical staff and parents outside of mental health settings.

87. 'The Use and impact of surveillance-based technology initiatives in inpatient and acute mental health settings: A systematic review'[10] investigates the use of surveillance technologies in inpatient mental health settings, examining their implementation, best practices, user experiences, and impact. The review includes 27 studies covering technologies including CCTV. The findings indicate mixed and complex experiences among patients, staff, and carers, with quantitative evidence on the impact of these technologies on safety, care quality, and cost-effectiveness being inconsistent or weak.

88. The Inquiry's questionnaire and subsequent analysis from the Nuffield Trust on the subject will doubtless provide a great deal of useful feedback, and RCPCH is happy to collaborate with other stakeholders on developing a more robust evidence-base around this.

89. The RCPCH wishes to end this submission as it began: to express our deepest sympathies to all those who lost babies or whose babies were injured, and whose lives were irreparably damaged by what happened at COCH.

Fiona Scolding KC
Landmark Chambers
30 August 2024
On behalf of the RCPCH

[10] The use and impact of surveillance-based technology initiatives in inpatient and acute mental health settings: A systematic review | medRxiv