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 CLOSING SUBMISSIONS ON BEHALF OF THE ROYAL COLLEGE OF PAEDIATRICS AND CHILD HEALTH ("RCPCH")

Introduction

The Royal College of Paediatrics and Child Health (RCPCH) repeats its deepest sympathies to the parents and wider family members whose children were injured, killed or harmed during 2015 and 2016. It also apologises that it was not sufficiently supportive to the paediatricians then working at the hospital.

Application by the Former Directors of COCH

- 1. The RCPCH does not wish to make written or oral submissions on the application made on behalf of the former directors of COCH and the separate request by Sir David Davis MP in his letter of 28 February 2025.
- The RCPCH splits its submissions into the following areas as requested by the Inquiry in its note on closing submissions and further note on written closing submissions:

Part A: Acknowledgment of failings and implementation of changes

3. The first part of this submission provides reflections upon RCPCH's review of the Countess of Chester Neonatal Service and what should or could have been done differently by the RCPCH (and by others, where the RCPCH considers that it has observations to make useful to the Inquiry's decision making). It highlights the steps subsequently taken to remedy the weaknesses in the review process, and to prevent similar mistakes in future. Those who undertook the review in 2016 have provided written witness statements¹, and the majority of them gave oral evidence², which set out in some detail what happened before, during and after the review. This section also seeks to reflect upon the evidence given by others about the RCPCH review.

Part B: Specific submissions in respect of child safeguarding procedures

4. The Inquiry in its further note of 4 February 2025 asks the RCPCH to provide specific submissions on safeguarding duties and obligations for children in hospital, and in respect of how the Sudden Death in Infants and Children ("SUDIC") guidelines operate in hospital settings. The RCPCH seeks to provide assistance to the Inquiry in this regard, as far as it is able.

Part C: Recommendations (and comments upon other recommendations, where appropriate)

5. The RCPCH sets out in these written submissions its suggested recommendations for the Chair based upon the evidence it has provided and those submitted by others during the course of this inquiry as requested pursuant to paragraph 7(iv) of the Note on Closing submissions. These focus upon (a) rectifying the lacunas which have emerged in training, knowledge and education during the Inquiry and (b) to improve neonatal patient safety.

Part A: Acknowledgment, reflections and alterations.

The invited review process for the COCH and where it went wrong

6. As identified in the opening submissions of the RCPCH ³, the written evidence from the RCPCH and the evidence of Professor Turner ⁴, the evidence of Ms Eardley, the Head of the Invited Reviews service for the RCPCH in 2016⁵, the

¹ Sue Eardley [INQ0101348], Claire McLaughlan [INQ0100895], Graham Stewart [INQ0101347], Alexandra Mancini [INQ0102614 and INQ0108410], David Shortland [INQ0099070], Nicholas Wilson [INQ0101080]

² RCPCH Invited Reviewers, Week 9, Day 1, <u>11/11/2024</u> and <u>WHYPERLINK</u> "https://thirlwall.publicinquiry.uk/transcript/07-11-2024-transcript-of-week-8-day-4/" <u>Week 8, Day 4, 07/11/2024</u> ³Opening Submissions of RCPCH [INQ0107954]

⁴ Professor Turner, Week 13, Day 2,12/12/2024, p73 – <u>119.</u>

⁵ Witness Statement of Sue Eardley [INQ0101348] and oral evidence of <u>Sue Eardley Week 8, Day 4,</u> <u>07/11/2024</u>, p131, 13-25 and p132, 1

written evidence from the reviewers⁶⁷, that the reviewers had sought to reflect upon the review and sought to accept (in the vast majority of cases) that things had gone wrong with this review and that it should never have taken place, and once started should have been aborted early. The RCPCH and the reviewers have, as a body, sought to be transparent and clear, and to recognise and acknowledge mistakes. The RCPCH submits that the following conclusions may be reached by this Inquiry.

Inappropriate use of the service review procedure by the COCH

- 7. An invited review is not designed as a regulatory or supervisory visit or inspection. It is a peer review process to examine the safety and efficiency of paediatric services or their configuration [INQ0017463-00010 and INQ0010214]. At the time in question, there was no "standard" set of operating guidelines for such reviews (which have now been issued by the Academy of Medical Royal Colleges [INQ0010195]). The process had been developed to an extent, but the RCPCH was still learning, as identified by Ms Eardley⁸:
- 8. The Invited Review process as deployed for the COCH review involved clinicians with relevant expertise, along with a layperson. As a group, the reviewers were aware of relevant standards of care and governance in hospitals, enabling them to interview staff, patients, managers and others over a short period of time (1-2 days) and then make recommendations. The written evidence of Ian Harvey⁹ states that he suggested inviting RCPCH¹⁰, and in his oral evidence,¹¹ it is suggested that he anticipated that RCPCH would carry out some kind of investigation into the increase in unexpected deaths and collapses, not the kind of service-level peer review that was offered. This is

⁶ Witness statement of Dr Milligan [INQ0102061], Witness Statement of Dr Stewart [INQ0101347], Witness Statement of Ms Mancini [INQ0102614 and INQ0108410] and Witness Statement of Ms McLaughlan [INQ0100895], Witness Statement of Dr Shortland [INQ0099070] and Witness Statement of Dr Wilson [INQ0101080]

⁷ Evidence of Alex Mancini and Claire McLaughlan, Week9, Day 1<u>, 11/11/2024</u> and evidence of Dr Shortland and Dr Wilson <u>Week 9, Day 1, 11/11/2024</u>

⁸ Sue Eardley, Week 8, <u>Day</u> 4, 07/11/2024, p.98,10-17

⁹ Ian Harvey, <u>Week 11, Day 4, 28/11/2024</u>

¹⁰ [INQ0005745],p1

¹¹ Ian Harvey, Week 11, Day 5, 29/11/2024, p3, 21-25 and p4, 1-5

reflected in the evidence of the wider paediatric group¹². The RCPCH would suggest that commissioning such a service review was never going to answer the question of why there was an increase in unexplained and unexpected deaths. Further, there were very many internal discussions at COCH about calling the police and the criminal activities alleged by the paediatricians on 27 June 2016 (set out in some detail in the evidence of Ian Harvey)¹³ including meetings where Letby's criminality was directly raised [INQ00015337, p4, INQ0103104, p44, witness statement of Dr Brearey at paragraphs 248 – 250, discussions with the nursing staff INQ00015537, p4] and plans of action (INQ0005745, p1), suggestions from Dr Brearey to the Medical Director of COCH on 28 June 2016 (INQ0005744,p3), and most importantly the meeting between Stephen Cross, the Head of Legal Services for COCH and the Medical Director (INQ0003360, p1) which recommended that the police needed to be involved at that stage. However, the RCPCH submits that the information given to Ms Eardley¹⁴ was of a more general and less specific nature than had been raised in these meetings.

9. A note from Ian Harvey [INQ0003362] recalls that he advised Ms Eardley of the fact that a nurse had been suspended, and the nurse 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

¹² See for example Dr ZA, paragraphs 73, 76, 80 of her written witness statement [INQ0099097]

¹³ Ian Harvey, Week 11, Day 4, 28/11/2024, p.156-170

¹⁴ Sue Eardley, Week 8, Day 4, 07/11/2024, p.<u>124, 22-24.</u>

had been suspended should "ring alarm bells" (paragraph 49 of the witness statement of Dr Shortland [INQ0099070-0015] and oral evidence)¹⁵. 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 stated, in the evidence given by Prof Turner (current President of the RCPCH¹⁶), and by Ms Sue Eardley then Head of Invited Reviews¹⁷ that a service review was inappropriate given the seriousness of the issues raised by Mr Harvey in his email chain.
- 11. 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 Invited Review Programme Board, it is likely that the review would not have been allowed to take place by RCPCH because of the potential of future police involvement. As Professor Turner said¹⁸:

"....this review went wrong from the start and it – it was unusual. Looking back, it certainly was unusual from the information we have now.

Q: Say that last bit again?

A: So yes, it was an unusual request and unfortunately the due process that we have in this document here [The Invited Review Guide] wasn't followed".

¹⁵ Dr Shortland, <u>Week 9, Day 1, 11/11/2024</u>

¹⁶ Professor Turner, Week 13, Day 2, 12/12/2024

¹⁷ Witness Statement of Sue Eardley [INQ0101348] and oral evidence of <u>Sue Eardley Week 8, Day 4,</u> 07/11/2024

¹⁸ Professor Turner, <u>Week 13, Day 2, 11/11/2024,</u> , p78,21- p79, 24

- 12. Furthermore, the Head of Invited Reviews should have sought advice from the proposed lead clinician (Dr Milligan) or the programme lead for Invited reviews (Dr Shortland) in line with the guidance [INQ0012822], p4 and Eardley/4/7Nov/99/10-100/124] The RCPCH accepts that this did not take place in any adequate way¹⁹. Had it done so, it is likely the review would not have taken place.
- 13. 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. He should have seen those things before reaching that conclusion.

Insufficient due diligence by the RCPCH in advance of the review

14. The RCPCH's view in 2024 (paragraph 53 of [INQ0017463-0018] and Professor Turner's oral evidence²⁰) is that the proposals and terms of reference were compiled very quickly. Ms Eardley accepted that the review was rushed, without the level of care she would usually have put into a proposal. ²¹The Crisp review – an external review commissioned in 2020 by RCPCH into its invited review process which examined in some detail the COCH review as part of its remit [INQ00101783] – also found that at that time the RCPCH seldom turned down approaches for reviews, and there was not any risk-based approach to selecting the reviews undertaken by the RCPCH before accepting the work. The RCPCH also considers that there should have been clinical involvement from either someone on the review team or the Invited Review Programme Board in drafting the terms of reference in the light of the policy - as set out in the Handbook for Reviewers [INQ0012822,p4] which identified this as a

¹⁹ Professor Turner, <u>Week 13, Day 2, 11/11/2024</u> p78,19 – p79,16

²⁰ Professor Turner, <u>Week 13, Day 2, 11/11/2024</u>, p87, 8-21

²¹ Sue Eardley Week 8, Day 4, 07/11/2024,p159,4-160,1

requirement²². 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 2025 is that the reviewer and/or a clinician on the Invited Reviews Programme Board should also have met the Medical Director in advance to talk through the review.

15. The briefing material compiled (primarily by Sue Eardley) from information which the hospital had supplied to RCPCH 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"²³. 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.

Terms of reference which could not be achieved

16. 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." In her oral evidence, Ms Eardley accepted ²⁴ that this term of reference could not have been achieved by way of an invited review and that was made clear by the lead reviewer in the contemporaneous notes made by Ms Eardley to the Clinical Director and Director of Nursing on the first day of the review [INQ0010124]. ²⁵ stated that a service review "could look at organisational and cultural factors which led to an increase in mortality", and

²² Witness Statement of Robert Okunnu 08/02/2024, [INQ0017463, para 139] and oral evidence of Professor Turner, Week 13, Day 2, 11/11/2024, p77 - 80

 ²³ Professor Turner, Week 13, Day 2, 11/11/2024, p86, 25 – p88, 6
 ²⁴Sue Eardley Week 8, Day 4, 07/11/2024, p153, 1-25-p154, 9
 ²⁵ Sue Eardley Week 8, Day 4, 07/11/2024, p109/13-112/12

that she agreed that there was a difference between looking at why there is an increase in mortality was a different to looking at how a clinical service was functioning. It can be inferred that Ms Eardley considered that this term of reference was dealing with general "service level" matters, whereas the hospital inferred it would be dealing ²⁶. Ms Eardley accepted that she had not been asked before or since to look at why death rates had increased.²⁷

- *Misunderstanding between the hospital and the RCPCH about the terms of the review* 17. One of the most significant problems raised by the absence of detailed discussions between the Medical Director and the RCPCH was that the former considered that the review would be a case note review. Mr Harvey accepts in his witness statement ([INQ0107653], paras 343/828) that there was no provision for the IR reviewing case notes expressly set out in the terms of reference [INQ0010172] and what the RCPCH considered that they were going to do. In his oral evidence, Mr Harvey accepted this.²⁸
 - 18. The COCH supplied the "staffing rota" [INQ0010072] to the reviewers as part of the pack sent to them in advance of the review (and this 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 deaths²⁹) consider that would not have put them on notice of concerns about potential wrongdoing by a member of staff (see for example, Ms Mancini at 50 [INQ0102614]). Ms Mancini's oral evidence³⁰ was that she had identified a correlation between Letby and the deaths from the documents but they had not

²⁶ As implied by Mr De La Poer's KC's question to Ms Eardley at <u>Sue Eardley Week 8, Day 4,</u> <u>07/11/2024</u>, p110,12-24

²⁷ Sue Eardley Week 8, Day 4, 07/11/2024, p111,5-14

²⁸ Ian Harvey, <u>Week 11, Day 5, 29/11/2024,</u> p4, 6-21

²⁹ Discussed in detail with Sue Eardley in her evidence – <u>Sue Eardley Week 8, Day 4, 07/11/2024</u>, p165,2 – 165,21

³⁰ Alex Mancini, <u>Week 9, Day 1, 11/11/2024,</u> p118,4 –120, 24

been aware of any suspicions of the Countess of Chester hospital³¹. This was confirmed in their oral evidence³².

The review

The review should have been abandoned on the first morning

- 19. It was only on the morning of the first day of the review that the reviewers as a group became aware of the exact nature of the concerns raised by the paediatricians. ³³ Three of the reviewers, (Ms Mancini, Dr Stewart, Ms McLaughlan) found out 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], p1 - 3.). Ms Eardley also said that the Medical Director made it clear that he wanted an invited review before any police contact, and he had been advised of such by a senior colleague³⁴.
- 20. 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 those first 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

³¹As précised by Professor Turner, <u>Week 13, Day 2, 11/11/2024</u>, p91,20 – 22, 5

³² See also: Sue Eardley Week 8, Day 4, 07/11/2024

 ³³ Sue Eardley Week 8, Day 4, 07/11/2024, p170,20 – 173, 4
 ³⁴ Sue Eardley Week 8, Day 4, 07/11/2024, p197,1 – 199,1

collapses in the day. The notes make it clear that <u>after</u> this change in Letby's shifts both paediatricians considered that there had been "foul play" [INQ0010123]. The reviewers discussed aborting the review (there is no contemporaneous note of this discussion but the reviewers seem to agree that this took place³⁵, ³⁶ Dr Milligan in the contemporaneous notes from the second day of the review [INQ0010125] and his written evidence [INQ0102061-003], says that the review was not aborted because it was important to get the background ³⁷.

- 21. Some of the reviewers consider in their written and oral evidence 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]) and Alex Mancini, Week 9, Day 1, 11/11/2024. 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". Ms Eardley in her oral evidence accepted that the review should have been stopped after the conversations with Drs Brearey and Jayaram³⁸.
- 22. The RCPCH agrees that it was not the role of the reviewers to act in a forensic manner, but that given the issues raised, the RCPCH Invited Review Board should have been contacted for advice. Further, any RCPCH review that examined allegations of criminality would have been entirely inappropriate and might have prejudiced any subsequent disciplinary or criminal investigation by the appropriate bodies.
- 23. The RCPCH guidance for reviewers ([INQ0010214] at paragraph 7.7) stated that if issues of criminality become known, the review should be completed in

³⁵ For an example, see Sue Eardley Week 8, Day 4, 07/11/2024, p113, 6-25 and p132, 1: paragraph 84 of the witness statement of Alex Mancini [INQ0102614-0019]

³⁶ <u>Sue Eardley Week 8, Day 4, 07/11/2024</u> and witness statement of Graham Stewart [INQ0101347]

 ³⁷ INQ0014605,p6- and <u>Sue Eardley Week 8, Day 4, 07/11/2024</u>, p191,7-p192,15
 ³⁸ <u>Sue Eardley Week 8, Day 4, 07/11/2024</u>, p178, 23

respect of its original remit, but the reviewers should not investigate other issues or those relating to the potential criminality. The reviewers did not readjust the term of reference and/or make any other changes to avoid prejudicing future investigations³⁹.

The reviewers should have advised the COCH to call the LADO

- 24. At no time did the reviewers say to COCH that the police should be called (Eardley/8/7/11, p116/1-117/8). They considered that this was the decision which was "*right at the time*"⁴⁰. Given the discussion held internally by reviewers at lunchtime on the first day of the visit, as to the methodology that could be used to harm babies in this context and the serious discussions to abort the review, the LADO should have been contacted at this stage. ⁴¹ Ms Eardley in her oral evidence agreed that this discussion should have led the reviewers to abort the invited review and let the police come in⁴².
- 25. The RCPCH accepts that it did not have an escalation policy in place or any guidance on what to do when 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. Given what was alleged, the RCPCH considers that at the very least, the LADO should have been involved to provide advice.

 ³⁹ Professor Turner, <u>Week 13, Day 2, 11/11/2024</u>, p95, 12 – p96,6
 ⁴⁰ <u>Sue Eardley Week 8, Day 4, 07/11/2024</u>, p117,8-9

⁴¹ Sue Eardley, notes of review 1 September 2024 INQ0010124 and Sue Eardley Week 8, Day 4, <u>07/11/2024</u> p183,15 - 184,25

⁴² Sue Eardley Week 8, Day 4, 07/11/2024, p184,20 – 185,1

- 26.Ms Alex Mancini (the nurse reviewer) and Ms Claire McLaughlan (the lay reviewer) interviewed Letby on the afternoon of 1 September 2016 ([INQ0010121], handwritten notes, and [INQ0014602] transcript). This was a late addition to the schedule, made following the earlier meeting with Drs Brearey and Jayaram. Ms Eardley says that this was discussed and agreed upon by the review team because they considered that proceeding with an interview in a limited way was "not unhelpful⁴³", and because it was felt that it seemed unusual that she was not included in the list of people to interview. ⁴⁴ Ms Eardley accepted that this was wrong in her evidence. ⁴⁵There 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 2025 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 advantages⁴⁶. Several of the reviewers now agree that this interview should not have taken place.
- 27.Ms Mancini and Ms McLaughlan in their written evidence disagree with the College that they should not have interviewed Letby (as did Ms Eardley by inference) on the basis that they did not consider at the time that the interview took place that her behaviour was misconduct as all they knew was that she had been taken off clinical duty without an HR process having taken place⁴⁷. Both reviewers considered that Letby had been left "in limbo" in the absence of any proper investigation. Both Alex Mancini [INQ0102614] and Claire McLaughlan ([INQ010895 – 0012], paragraphs 36 and 37), (the lay reviewer with an extensive background in NHS processes and standards) considered

⁴³ Sue Eardley Week 8, Day 4, 07/11/2024, p175,21 – 176,10 ⁴⁴Sue Eardley Week 8, Day 4, 07/11/2024, p186,1-187, 13

⁴⁵Sue Eardley Week 8, Day 4, 07/11/2024, p186,23 – 187,14 ⁴⁶ Professor Turner, Week 13, Day 2, 11/11/2024, p96, 15 – 16 ⁴⁷ Sue Eardley Week 8, Day 4, 07/11/2024, p124/11-12-128/4

that the hospital had not followed their own HR procedures. Taking someone off clinical 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 consider that the hospital had failed in its duties to the babies, the unit and Letby by not undertaking a formal process. 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".

- 28. The RCPCH submits that it does appear that the staunch support for Letby expressed by the nursing staff during their interviews [INQ0014603, page 1]⁴⁸ 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 presence on shift correlated strongly with incidents of babies showing sharp deterioration or dying (para 143 of [INQ0101348-0036]).
- 29. 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

⁴⁸ See also <u>Sue Eardley Week 8, Day 4, 07/11/2024</u>, p193,20 – 194,19

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.49

Ms McLaughlan's qualifications

30. It would appear that various individuals at COCH and elsewhere sought to rely upon and/or sought to use Ms McLaughlan's gualification as a barrister (albeit unregistered) as leading them not to require legal advice or to consider that there was some kind of forensic investigation that was to take place. Ms McLaughlan's role on the review team was a lay reviewer with understanding of issues in nursing and hospital management - not as a lawyer, and she was not part of the RCPCH team presented as a lawyer or providing legal advice⁵⁰. The issues in this case do raise questions about how people with such qualifications should present themselves and the understanding of wider society of what such a qualification means (or does not mean).

Findings of the review and the report produced by the RCPCH

(a) The findings of the review did not assist in resolving the situation facing the COCH (and never could have)

- 31. 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 [INQ0010197-0001].
- 32. The review findings identified that the RCPCH review team was 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 [INQ0010172-0001]. lan Harvey, the medical director, on the first morning of the review said that he expected that this would be a case-note review and the review team on the first morning made it clear that they intended

 ⁴⁹<u>Sue Eardley Week 8, Day 4, 07/11/2024</u>, p197, 1 – 199, 1
 ⁵⁰ Claire McLaughlan, Week 9, Day 1, 11/11/<u>2024</u> p3 1-25

to conduct a service review and were not able to investigate the details of the increase in unexpected deaths and collapses⁵¹.

- 33. 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 clinical activities on the neonatal unit and that this had been done without a formal process nor clear notification of why this had happened.
- 34. The evidence of Ms Eardley emphasised that the review made a recommendation for a case-note review of the deaths. By doing this, the review team was encouraging investigation of the deaths and was not taking a view on whether or not there was cause for concern about the unexpected deaths and collapses⁵². The letter of 5 September 2016 from the RCPCH identified two immediate actions⁵³, one of which was to undertake an independent disciplinary investigation. Ms Eardley accepted that they should have told COCH to call the police and not follow this disciplinary process, which whilst useful in a situation of a potential employment dispute, was not as helpful as it could have been to resolve the issue (or, indeed, to prioritise patient safety)⁵⁴. Whilst the invited review did identify that a case-note review and an HR investigation should take place in respect of the allegations made about Letby, it is submitted that these recommendations were drafted in an opaque manner, and did not clearly identify the need to call in the LADO/other agencies. Whilst explanations were provided about this by Ms McLaughlan⁵⁵, the RCPCH would submit that the opacity was unhelpful.

(b) The findings of the review did not involve calling the police

⁵¹Sue Eardley Week 8, Day 4, 07/11/2024, p170/20 – p171,11

⁵² Sue Eardley Week 8, Day 4, 07/11/2024, p194,24 – 196,25

⁵³ INQ0009611,p2

⁵⁴ <u>Sue Eardley Week 8, Day 4, 07/11/2024</u>, p201, 11 – 204,12

⁵⁵ Claire McLaughlan, Week 9, Day 1, 11/11/<u>2024</u>, p29,20-24

35. The actions set out by the RCPCH did not include calling in the LADO, the police or advising regulatory bodies of the concerns that had been raised. These recommendations should have been made^{56.} The contemporaneous notes made by Ms Eardley suggest that Ian Harvey told them that "he could not see how to conclude without calling the police....unless there is something to satisfy the medical staff from this review, they will call the police"⁵⁷. The inference which Ms Eardley drew was that the police would be called, as the review did not disclose other reasons for the deaths. That was also the inference that Ms McLaughlan drew. Yet this was not spelt out in the RCPCH invited review report. The RCPCH's position is that it should have advised the Medical Director and the Designated Doctor for Child Protection and/or Safeguarding to follow their safeguarding policy and to call the Police and/or the LADO. The RCPCH cannot compel a body to take action (paragraph 9.7 of the Guide to Invited review, [INQ0010214]), but it could have provided advice.

(c) The quality assurance process raised issues about Letby's criminality but these were not then acted upon by the RCPCH or relayed to COCH.

36. 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". Again, such questions (in the College's view) should have prompted serious discussion of escalation of the COCH clinicians' concerns.

(d) The review identified gaps and difficulties with the running of the Unit, but did not grapple with the issue of the increase in mortality.

37. 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;

⁵⁶ Professor Turner, <u>Week 13, Day 2, 11/11/2024</u>, p100, 10-25, p101 1-5

⁵⁷ Witness Statement of Sue Eardley [INQ0101348, para.80]

and six were directed at the neonatal network involving transport to and from other NHS units. The make-up of these recommendations therefore underlines again that this was a service rather than a forensic case-note review.

Failure to follow up the review.

- 38. 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". Although the case-note review by Dr Hawdon was in hand by the time the report was issued to COCH at the end of November, there should have been more follow-up by the College as to implementation, in line with these statements.
- 39. 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 [Sue Eardley Week 8, Day 4, 07/11/2024, p103 2-4]. 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."

- 40. Ms Eardley did⁵⁸ ask Ian Harvey (as commissioner) that the full report be seen by the clinical leads (i.e. Drs Brearey and Jayaram). He told her⁵⁹ that they had seen it. However, Ian Harvey only shared the *redacted* report with these individuals. They did not therefore have an immediate opportunity to see the unredacted report's erroneous statement that the clinicians' suspicions about Letby were based solely on "gut feeling". [INQ0010150, page 9], As a result, Dr Harvey proceeded to conclude, and to communicate to management and board colleagues, that the only substantiation for the clinicians' suspicions was "gut instinct". This was factually wrong and would have been corrected had the unredacted report been seen at the fact-checking stage by Dr Brearey and Jayaram. The failure by Mr Harvey to show the full report to Drs. Brearey and Jayaram thus denied these two paediatricians the opportunity to correct factual information in the "unredacted" version.
- 41. There should not have been two versions of the report. The RCPCH considers that the very need for redaction should have put Ms Eardley and the reviewers on high alert that what they were doing was (a) unusual and (b) should not therefore be occurring. The HR concerns which prompted the redaction should not have outweighed the safeguarding concerns around the harm to babies.
- 42. 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 at meetings with the Council and Board of Trustees 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 considers that

⁵⁸ INQ0009617.pdf

⁵⁹ INQ0009617.pdf and Sue Eardley Week 8, Day 4, 07/11/2024, p219, 8-11

describing the reviews as "sensitive" did not do justice or accurately set out the situation at COCH and the issues which this visit and report had raised (paragraph 127 of [INQ0017463-0050]).

Conclusion

43. 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. 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. With hindsight, however, there are lessons which can be (and have been) 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 the follow up to check progress in delivering recommendations after a review has concluded.

The disclosure of the report and the way the report was treated by COCH

44. The RCPCH's submission is that the review was not used by the COCH leadership in the manner that the RCPCH intended. In particular, the report was mischaracterised 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. Furthermore, Ian Harvey failed to disclose the full unredacted report to clinicians and only the redacted report was available, missing key allegations against Letby. It is suggested by the RCPCH that Ian Harvey's explanation of why he failed to provide the full report to the clinicians was not plausible. He said that he felt that as it raised HR issues about Letby, that the RCPCH had said not to disclose this (see [INQ0003403-001] and Ian Harvey transcript, Week 11, Day 5, 29/11/2024, p71,7-14. This is not what was said in any email or other discussion that can be remembered or recorded. Furthermore, the contract between COCH and the RCPCH [INQ00009597] (page 2) identifies that everyone who contributed should see the full, unredacted review and in fact Ian Harvey said in an email [INQ0009617] that he had shown the report to the relevant clinicians [Week 11, Day 5, 29/11/2024, p197, 9-16]. The RCPCH could therefore not have known (until told by the clinicians in early 2017) that the clinicians had not seen the full report. As they had not seen the full report, they could not comment upon the accuracy of those passages concerning Lucy Letby and therefore did not have a chance to correct the error in the report. It is the RCPCH's position that Mr Harvey should have shown the full report to the clinicians, and that not doing this was wrong and contrary to the advice reflected in the written record of his interactions with the RCPCH.

- 45. The COCH sought to use the report to say that "proper investigations had been undertaken", and that the allegations against Letby were "unsubstantiated" ([INQ0003138], board minutes 10/1/17). The impression given to the group of consultants (which appears to be shared by most of them) was that there was nothing to show that the deaths were untoward or suspicious⁶⁰. Ian Harvey accepted in evidence that the investigations commissioned were neither designed nor aimed at finding criminal activity, and that it was not acceptable to have said that the allegations were unsubstantiated on the basis of those reviews⁶¹.
- 46. These assertions about the "unsubstantiated" allegations were wrong, and furthermore, it is suggested, led to people considering that there was "no evidence that babies had been harmed"⁶². Counsel to the Inquiry asked Mr Harvey whether he did realise and/or communicate that the review was not able to exclude the fact that Letby had harmed the babies because he did not listen? He denied this (Week 11, Day 4, 28/11/2024, pp198-201) but the RCPCH would submit that this is precisely what happened.
- 47. COCH should have been under no illusion that the RCPCH report could have explored the detail or causation of the mortality of the babies from the first day of the review (Week 11, Day 5, 29/11/2024,p4/8 4/13).
- 48. Furthermore, Ian Harvey told others that the RCPCH had not revealed any "immediate concerns" (information given to the QSPEC committee of the

⁶⁰ Thirlwall 081024 Day18-1008.ecl, Mcguigan, p115,23-116,2

⁶¹Ian Harvey, <u>Week 11, Day 5, 29/11/2024, p186 9-15</u>

⁶² Written evidence of Dr McGuidan as an example, paragraph 15

COCH, 19/9, [INQ0004141], p2.) That was simply wrong, as (a) they had said they could not deal with this, and (b) there were plainly issues in the unredacted which were raised which were significant and relevant. Ian Harvey should have reported the need for formal action in respect of Letby for misconduct to the internal committees of the hospital, and to refer matters to the relevant professional bodies (see [INQ0003120]). He should have sent the report to NHS England, the CQC and the local neonatal network in unredacted form, and promptly upon its receipt. Ian Harvey did not tell the relevant regulatory body of the RCPCH's view that there should be a misconduct investigation (Week 11, Day 5, 29/11/2024, p35).

49. Dr Brearey has stated in writing⁶³ that the police investigation could have begun sooner had the full unredacted RCPCH report been received by the paediatricians. Having listened to the evidence, the RCPCH does not consider that this is a conclusion which can be reached on the evidence. There is no doubt that Drs Brearey and Jayaram, if they had seen the "full" report would have been able to correct the factual inaccuracies set out within it. However, given the discussions which preceded the RCPCH report, and the reluctance of the board and senior team to refer matters to the police despite the RCPCH report identifying the need for a relevant misconduct investigation, it is respectfully suggested that this would not have made a material difference.

Changes made by the RCPCH following this review and the evidence of the impact of those changes

50. It is important to set out what invited reviews are and what they are not: invited reviews are a valuable quality assurance and improvement tool, utilising expert independent peer review to provide healthcare organisations with an opportunity to adopt a proactive approach in seeking assurances on care provided, address areas of concern and identify scope for quality improvement and to help assure patient safety, address issues of concern at an early stage and improve the quality of care in children and young people's health services.

⁶³ INQ0006669

They support, but do not replace the processes of the health and social care regulatory bodies or the healthcare organisation's own procedures for addressing and managing patient safety, clinical performance, and service provision. Invited reviews are not designed to investigate suspected criminal activity.

- 51. The RCPCH witness statement sets out the changes made after reflecting upon the COCH review⁶⁴. 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. It led to a significant change in the approach to invited reviews. During the period in time when the Crisp review was being undertaken and then reported upon (2020 – 2023), the Invited Review process was paused. Revised processes were established and the governance and oversight of the service has been overhauled.
- 52. The RCPCH has also incorporated the Academy of Medical Royal Colleges⁶⁵ updated framework of operating principles for reviewing organisations undertaking invited reviews into its current practices and procedures (issued in March 2022).
- 53. In summary, there is considerably more senior clinical and Executive Director oversight in the whole invited review process including: consideration of request, initial feedback following review, report, escalation and follow up.
- 54. The Crisp review made a number of recommendations for changes in procedures and made criticisms of the COCH report which included:

⁶⁴ Witness Statement of Robert Okunnu [INQ0017463, para 150-151] and Professor Turner, <u>Week 13, Day 2,</u> <u>11/11/2024</u>

- 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.
- 2. There was no escalation policy for advice as to whether to continue with a review.
- 3. There was no guidance on interviewing staff members who had been suspended.
- 4. 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.
- 55. Following on from this, the RCPCH has remodelled its invited review service. For the purposes of the Inquiry, the most salient changes are that the RCPCH has:
 - (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. A new 'discovery stage' has been built into the

overall invited review process. This includes a process of due diligence to enable the service requesting the review to distil why they are asking for a review and for the RCPCH invited review service to understand why the service is requesting a review. This process can take up to 10 weeks to complete.

- (g) 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.
- (h) The Lead Reviewer is now involved in scoping the review.
- (i) 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.
- (j) Regular updates are given to the RCPCH Executive Committee and Board of Trustees about reviews.
- (k) The review programme is now overseen by the Registrar of the RCPCH, who is a clinician and trustee, for senior clinical oversight [INQ0010213].
- (I) A new escalation process has been developed and implemented. The process has been developed with clinical input and provides additional senior clinical and Executive Director support to an invited review team if and when issues arise during a review and provide a decision framework for halting a review.
- (m)Clinicians are integral, integrated and involved throughout the whole invited review process. There is an Invited Review Programme Oversight Group (IRPOG) providing the operational day to day management of the service which comprises both staff and clinicians including the clinical lead and deputy clinical lead for the programme, the Assistant Registrar and Registrar. Both the deputy clinical lead and Assistant Registrar are new roles created since 2020 and bring additional clinical input, experience and knowledge to the IRPOG. The IRPOG input to the review process at key points ensures appropriate clinical and Executive Director oversight. These are at the following times: consideration of request, initial feedback following review, report, escalation and follow up.
- (n) There is also an Invited Reviews Programme Board which has been strengthened and which includes the College's Registrar and Assistant

Registrar on this board. The role of the Registrar is to lead cross-cutting programmes of work, such as the Invited Reviews Programme, and to provide clinical leadership to properly manage the risk of delivering reviews. The Assistant Registrar provides additional support to the Registrar as well as providing senior clinical leadership to the &Us Network which works to ensure the voices of children and young people and their families makes a real difference in child health and healthcare by working with the RCPCH and its members to shape policy and advocacy, inform education, training and practice and develop quality improvement programmes.

- (o) Risks associated with the invited review service are recorded as part of the corporate risk register (CRR) and is a standing agenda item at each Invited Reviews Programme Board meeting. Risk reviews include adjustments required to mitigations. After each review, and as part of ongoing review, any changes identified to risks are discussed with IRPOG and agreed changes to processes and invited review documentation are implemented to mitigate.
- (p) The invited review service has established formal agreements with the four nations' relevant regulatory, inspectorate or body involved in patient safety and quality improvement which set out how and when the RCPCH informs each about invited reviews it has undertaken in its nation. As far as we are aware, the RCPCH is the only medical Royal College that has these agreements in place. It has, on at least one occasion referred an organisation to the relevant regulatory body following an invited review.
- (q) There is a dedicated process for follow up after a review has concluded and a report has been shared with the service, with a formal requirement for follow up and a requirement for the organisation to identify what steps it has taken and when.
- 56. A review was recently completed to assess progress in delivering the 86 recommendations contained in the Crisp review and implementation of the Academy of Medical Royal Colleges' framework of operating principles. The resulting paper⁶⁶ set out actions taken and assigned RAG (red, amber or green)

⁶⁶ [Reference/INQ to come]

ratings to demonstrate progress. Fifty-six were assessed as green and had been delivered, implemented and adopted in operational delivery of the invited review service. Sixteen were assessed as amber which were recommendations which were in progress or subject to ongoing internal discussion and decisionmaking processes. Fourteen recommendations were assessed as red and most of these are linked to the long-term strategy for and development of the invited review service.

Part B: Safeguarding

- 57. The RCPCH (in section C below) accepts that the current processes in respect of both Sudden Infant Death and the process for escalation set out in Working Together to Safeguard Children (2023), including referrals to the LADO, when cases of concern about staff appear, from the majority of evidence to be unknown to the majority of paediatricians and those working in hospitals. This inquiry has clearly shown up failures in this, and the RCPCH makes a series of recommendations to improve knowledge and understanding below. The RCPCH acknowledged these deficiencies in the evidence given by Dr Kingdon⁶⁷.
- 58. The RCPCH is not a trade union so it does not "represent" its members in respect of their employment or professional obligations. However, it is responsible for the training curriculum for all paediatricians and provides other forms of training and guidance as part of its role as a membership organisation. It has sought to answer questions 3(a)-(c), (g), k), and questions 4 and 5 (headed B and C) of the note of 4 February 2025⁶⁸.

RCPCH internal safeguarding procedures

⁶⁷ Dr Kingdon, Week 13, Day 2, 12/12/2024, p171, 3 – 172, 4

⁶⁸ Insert x Ref to the note.

59. In respect of the RCPCH as an organisation, it has a Safeguarding Policy produced in 2023⁶⁹, which deals with the internal work that the RCPCH does with children and young people. The Safeguarding Policy sets out the RCPCH's expectations on all RCPCH staff working with children and vulnerable adults. There is an Associate Director of Safeguarding role which provides internal development and quality assurance processes of these policies and procedures. There is a designated Trustee for Safeguarding who attends the Safeguarding Governance Group meetings, and who receive reports and send reports to the Charity Commission and other bodies which amount to serious safeguarding incidents.

RCPCH guidance to clinicians/others and training materials

- 60. The RCPCH does not have direct safeguarding obligations to doctors, but it is responsible for setting the curriculum for paediatric training (although this is delivered within hospitals and community child health settings).
 "Safeguarding" is a core element of paediatric clinical training and is examined by the College as a core "competency". This includes training on leadership⁷⁰. The College also has other advisory materials which it provides to assist staff in this area (but these are not to be read as substitutes for, or instead of the Trust or organisation's own safeguarding policy).
- 61. It also offers safeguarding training at various stages of a doctor's career, on a voluntary basis, the content of which is reviewed regularly. The RCPCH works in partnership with eLearning for Healthcare to provide 10 Level 3 safeguarding children modules, one of which is Management of Sudden Unexpected Death of a Child, which is available to all members. The content includes the role of health professionals following an unexpected child death (including legal requirements) and information about Child Safeguarding Practice Reviews. RCPCH also works in partnership with Advanced Life Support Group (ALSG) on their safeguarding provision and one of their Child Protection in Practice modules is called Child Death Review. This covers parental concerns, joint

⁶⁹ INQ to follow.

⁷⁰ Dr Kingdon, Week 13, Day 2, 12/12/2024, p175,20 – 176,17

agency responses and history, examination and investigation. Furthermore, in February 2025 the RCPCH launched a new face-to-face course entitled 'How to Manage: When a child dies – the role of the paediatrician', where the statutory processes and the opportunity to share practice to promote learning from deaths and how to best support families will be explored.

- 62. Alongside setting the curriculum, the RCPCH has a "Child Protection" resource on its website with various information which members (and the general public) in many cases can access. This includes documents which doctors and others can refer to if they have safeguarding concerns.
- 63. First, The Child Protection Companion⁷¹ is a handbook which is available to all RCPCH members and is an online resource which aims to provide a clear explanation of how paediatricians are involved in the multi-agency safeguarding processes and to help them to recognise, investigate, assess and manage cases of child maltreatment. It includes "Good Practice" Recommendations and "Implications for Practice" sections.
- 64. The Child Protection Companion also includes a series of systematic reviews of evidence about various forms of abuse and maltreatment suffered by children, which draws together all the scientific literature on this subject for example, setting out the emotional, behavioural and development features which are indicative of neglect. This is available to members, or institutions who choose to purchase access, online. There is no such a scientific literature review for deaths in babies on the RCPCH website, however, some of the reviews will be relevant for that age group (head and spinal injuries: burns: retinal findings). Alongside this, it provides specific resources for various aspects of child protection from expert witness guidance to child protection for anaesthetists, to resources for children who are looked after. Additionally, the RCPCH produces a "Purple Book" which sets out the physical signs of child sexual abuse and outlines good practice in relation to paediatric child sexual

⁷¹ Child Protection Companion, 2013 [INQ0108020]

abuse. Again, there are no specific guidance in these set of resources about concerns about staff.

65. The RCPCH also has "competencies" which it expects various grades of paediatricians to be able to display⁷².

What safeguarding duties and procedures apply where a member of staff has a suspicion or concern that another member of staff may be harming a baby who is in hospital?

The statutory background

66. Section 11 of the Children Act 2004 ⁷³ provides that NHS England, an Integrated Care board, an NHS Trust or Foundation Trust, must make arrangements (s11(2)) for ensuring that "their functions are discharged having regard to the need to safeguarding and promote the welfare of children" and "any services provided by another person pursuant to arrangements made by the person or body in the discharge of their functions are provided having regard to that need". Each person and body to whom this section applies must, in discharging this duty, "have regard" to any guidance issued by the Secretary of State (in this case the Secretary of State for Education, and not the Department of Health and Social Care) (s11(2) of the CA 2004). Have regard means, in this context to follow unless there is good reason not to do so (R (Munjaz) v Mersey Care NHS Trust [2005] UKHL 58 [2006] 2 AC 148: R(X) v Tower Hamlets [2013] EWCA Civ 904 [2013] 4 All ER 237 at 32 – 42). Section 16E of the Children Act 2004⁷⁴ provides that safeguarding partners (which includes the ICB) must make arrangements for organisations and agencies to work together to exercise their safeguarding functions. These arrangements must be published and scrutinised and reported upon as to their effectiveness on an annual basis (s16G of the Children Act 2004). Chapter 2 of Working Together to Safeguard

⁷² https://childprotection.rcpch.ac.uk/resources/roles-competencies/

⁷³ https://www.legilsation.gov.uk/ukpga/2004/31/section/11

⁷⁴ These changes were introduced as a result of the Children and Social Work Act 2017 and came into force in March 2018.

Children⁷⁵ sets out the requirements for "*prompt, effective responses*" where a child is identified as suffering or likely to suffer significant harm⁷⁶.

- 67. All NHS Trusts are "relevant agencies"⁷⁷ that is, agencies whose involvement the safeguarding partners consider are required to safeguard and promote the welfare of local children. They therefore have to follow not just the national guidelines, but also the local safeguarding partnership arrangements (if identified as a relevant agency)⁷⁸. The organisation therefore should (a) have a clear understanding of its responsibilities in relation to safeguarding children locally and how to discharge them (b) share information and (c) ensure arrangements are implemented and applied.
- 68. As employees/contractors within a Trust, all those who work in hospitals are therefore required to "have regard" to the need to safeguard the welfare of children and follow the guidance issued by the Secretary of State (absent exceptional circumstances to do otherwise). This guidance expressly states that the local authority social services sets out the process for referrals and that contact details should be signposted clearly⁷⁹. Paragraph 150 of the current Working Together Guidance says:

"Anyone who has concerns about a child's welfare should consider whether a referral needs to be made to local authority children's social care and should do so immediately if there is a concern that the child is suffering significant harm or is likely to do so."

69. Where a referral is made, Working Together has a flow chart as to what happens next – i.e. assessment of referral and then identification of next steps⁸⁰. The section on child protection in Working Together⁸¹ identifies that

⁷⁵https://assets.publishing.service.gov.uk/media/669e7501ab418ab05592a7b/Working_Together_to_s afeguard_children_2023.pdf.

⁷⁶ Paragraph 40 of the 2023 edn of working together (see note 37 above).

⁷⁷ Under the Child Safeguarding Practice Review and Relevant Agency (England) Regulations 2018, No 789, Schedule 2 www.legislation.gov.uk/uksi/2018/789/made

⁷⁸ Paragraph 70 of Working Together : s16G(4) of the Children Act 2004

⁷⁹ Paragraph 149 of Working Together to Safeguard Children

⁸⁰ Page 75 of Working Together to Safeguard Children.

⁸¹ Section 3, pages 79 onwards, paragraphs 212 et seq.

children who need protecting may include those who are harmed by "others". Paragraph 214 of Working Together makes it absolutely clear that whatever the form of abuse, the needs of the child come first when determining what action to take.⁸² If there is "reasonable cause to suspect that a child is suffering or is *likely to suffer significant harm*"⁸³, then a strategy discussion should take place between the local authority, health and other relevant bodies, to determine the child's welfare⁸⁴. The health body cannot carry out a s47 investigation (that is the role of the local authority) but can and should assist with it⁸⁵.

- 70. All NHS Trusts/hospitals/other health services should have in place arrangements to reflect the importance of safeguarding⁸⁶ including clear whistleblowing procedures, a culture that enables issues about safeguarding to be addressed and clear escalation policies for staff to follow if they consider that their concerns are not being addressed. All staff should be given a mandatory induction which includes familiarisation with child protection responsibilities and the procedure to be followed if there are any concerns⁸⁷.
- 71. Furthermore, current Working Together Guidance identifies that organisations working with children and families should have "clear policies for dealing with allegations" against people who work with children. An allegation is defined⁸⁸ as that a person has:
 - (a) Behaved in a way that has harmed a child or may have harmed a child
 - (b) Possibly committed a criminal offence against or related to a child
 - (c) Behaved towards a child or children in a way that indicates they may pose a risk of harm to a child
 - (d) Behaved or may have behaved in a way that indicates that they may not be suitable to work with children.

⁸² Paragraph 214 of Working Together

⁸³ The statutory test under s47 of the Children Act 1989

 ⁸⁴ Page 86 of Working Together
 ⁸⁵ Pages 87 – 90 of Working Together

⁸⁶ Paragraph 222 of Working Together

⁸⁷ P107 of Working Together 2023, paragraphs 222

⁸⁸ Paragraph 223 of working together

- 72. All county/unitary local authorities should have particular officers, or a team of officers known by the LADO to be involved in the management or oversight of allegations against those who work with children, who should have suitable qualifications⁸⁹. A local authority should have arrangements to provide advice and guidance to employers and agencies on how to deal with allegations against those who work with children, and every employer should ensure they have clear policies which set out the process for making an allegation and the advice available⁹⁰. Any allegation against people who work with children should be reported immediately to a senior manager within the organisation, and the LADO informed by the employer within one working day of all allegations that come to an employer's attention. If the person is subject to oversight by a professional body, the LADO should advise on whether referral to that organisation should be made⁹¹. As most staff working in a hospital will be undertaking regulated activity (if they work directly with children) then a referral may need to be made (and in some cases must) be made to the Disclosure and Barring service – this applies whether a referral has been made to the LADO or not⁹².
- 73. Alongside these general responsibilities, all staff working in healthcare settings should receive training to ensure they attain the competencies appropriate to their role and follow relevant professional guidance⁹³. A suite of documents produced by various organisations set out those competencies and responsibilities which include:

(a) Safeguarding children and young people: roles and competencies for healthcare staff. This was developed by a number of different Royal Colleges and others (including the RCPCH) and sets out 5 levels of competency for minimum training requirements for staff (even those who work with adults). All staff who work in a hospital have to undertake Level 1 training: Level 2 is for non clinical and clinical staff who may have small

⁸⁹ Paragraph 224

⁹⁰ Paragraph 226 of Working Together

⁹¹ Paragraph 226 of Working Together

⁹² See Regulation activity in relation to children: scope (factual note) and the Safeguarding Vulnerable Groups Act 2006 (as amended) and Making Barring Referrals to the DBS

⁹³ Paragraph 236 of Working Together: Professor Sir Stephen Powis sets out these responsibilities in more detail at [INQ0017495 – 0191]

amounts of contact with children: Level 3 is all clinical staff working with children, and Level 4 is those who are named professionals. Level 5 is for Designated professionals. These are professionals employed by the ICB to provide advice and expertise to organisations in health – including hospitals, and the ICB. As Dr Kingdon identified in her evidence⁹⁴ (see paragraph 93 below), her understanding of the training is that it is only at Level 4 the role of the LADO is mentioned.

(b) Professional Guidelines. For doctors, the current guidance is "*Protecting Children and Young People: The Responsibilities of all doctors*". This document identifies as a key principle that medical professionals must within their competence deal with child protection issues and get advice from a named or designated professional or lead clinicians if they are not sure how to meet those responsibilities⁹⁵. Where a doctor has concerns about a child or young person who may be at risk or abuse or neglect, then they must act on those concerns⁹⁶. Paragraphs 32-38 of the Guidance is absolutely clear that you must tell an appropriate agency such as social services, NSPCC or the police, if you are concerned that a child or young person is at risk of harm. The guidance says:

"You do not need to be certain that the child or young person is at risk of significant harm to take this step. If a child or young person is at risk or is suffering abuse or neglect, the possible consequences of not sharing relevant information will, in the overwhelming majority of cases, outweigh any harm that sharing your concerns with an appropriate agency might cause."

74. Where these concerns are not followed up, an individual should take them to the next level of authority if they feel the concerns have not been acted upon appropriately⁹⁷. This guidance is used by the GMC as part of its suite of Good Practice Guidance and so would be examined if any regulatory proceedings were undertaken as to the standard of competence expected of a doctor.

⁹⁴Dr Kingdon, <u>Week 13, Day 2, 12/12/2024</u>

⁹⁵ Principle 1(h) of Protecting Children and Young People

⁹⁶ Paragraph 5 of Chapter 2 of the Protecting Children and Young people guidance

⁹⁷ Paragraph 42 of Protecting Children and Young People: GMC guidance

- 75. The third document is "Safeguarding children, young people and adults at risk in the NHS Safeguarding and Accountability Framework"⁹⁸. Prepared for use by Trusts and NHS England, it aims to set out the "safeguarding roles and responsibilities of all individuals working in providers of NHS funded care settings"⁹⁹. This framework largely sets out the various responsibilities at different levels but makes it clear that information "must be shared to protect children, or to prevent or detect a crime"¹⁰⁰. The Framework identifies that information must be shared with the LADO where it is considered that a member of staff poses a risk to children or might have committed a criminal offence against one or more children¹⁰¹.
- 76. Providers must demonstrate safeguarding at every level (including Board Level)¹⁰², and this includes identification of a named nurse, doctor and midwife for safeguarding children (and those in care) and also arrangements for dealing with allegations against staff. All staff must be trained commensurate with their role, and safeguarding included in every induction programme. The named professional's role¹⁰³ is to provide advice and expertise for others, to ensure supervision and training is in place, and work with the safeguarding lead, the ICBs and others.
- 77. As outlined above, there are a number of parallel sets of guidance about the duties owed by various individuals working in healthcare settings. These can, however, be boiled down to answer the question about the processes to apply in cases of suspicion as follows:
 - (a) Staff member has suspicion (and the RCPCH says it does not matter who has the suspicion – every person has a responsibility to report concerns).

⁹⁸this iteration December 2022 [INQ0014736], but has been produced since 2013

⁹⁹ INQ0014736-005, paragraph 2.1

¹⁰⁰ this is related to data sharing with other organisations, but the principle behind such data sharing is to protect children [INQ00014736 – 0011]

¹⁰¹ Paragraph 3.5.6 of 2022 Safeguarding and Accountability Framework [INQ0014736 – 0013]

¹⁰² Paragraph 4.2.1 of 2022 Safeguarding Framework [INQ0014736 – 0014]

¹⁰³ Paragraph 4.3 [INQ0014736-0015]

- (b) Staff member reports concerns to either (a) professional colleagues (a) senior manager (b) Named Doctor, Midwife or Nurse (c) Head of Safeguarding for the hospital/Trust (d) Board members with responsibility for safeguarding. The correct local process should be made clear to all staff as a part of their induction training. The written evidence of Dr Isaac¹⁰⁴ shows that he was told nothing about the rises in mortality until November 2016. His evidence was that he did not have enough knowledge of the child deaths to challenge the executive team¹⁰⁵, showing that even where individuals are in positions of responsibility, this does not necessarily mean they feel equipped to manage these highly specialist areas of paediatric care. The RCPCH also notes other evidence which suggests that executives fear challenging boardroom decisions and that senior managers only want good news so that the system needs to be sufficiently robust and candid for people to be able to speak up¹⁰⁶.
- (c) In cases where this is ignored/not taken further, the staff member goes to the Freedom to Speak up Guardian and/or one of the more senior individuals identified above (or in their line of management) to state their concerns. This may be necessary in more cases than should be usual given the difficulties with speaking up identified by a number of the witnesses to the Inquiry.
- (d) In the alternative, the staff member is entitled to contact the local authority LADO with their suspicion without needing to report to those people at (b) or (c).
- (e) Such disclosure should be written down and documented and information shared with other agencies if needed (although once it has gone to the LADO, their role is largely organising and co-ordinating the other bodies).
- (f) If there are concerns the LADO is not acting, then the Director of Children's Services should be contacted.
- (g) None of this precludes the police being called in cases of a crime.

¹⁰⁴ INQ0102621

¹⁰⁵ INQ0102621,para 27

¹⁰⁶ INQ0017906, Helen Donnelly, paragraphs 15 – 18

78. The RCPCH submits that this process applies to any members of staff, contractor or other person who works or provides services for a healthcare organisation.

Process for sudden and unexpected baby death

- 79. Dr Kingdon's evidence to the inquiry¹⁰⁷ was that in cases where the death was unexpected, it would not usually be the case that in Dr Kingdon's unit (which is a Level 3 unit, dealing with the most unwell of preterm babies) that they would necessarily use the JAR/SUDIC approach, and that there may need be a "rethink"¹⁰⁸ of how those guidelines are used in neonatal settings. It does appear that because of the clinical uncertainty as the precise reason why a baby has collapsed and died, and the very "at risk" nature of some babies, that JAR/SUDIC processes are not always called upon in practice, in the most specialist of neonatal units. The coronial system (and, now, the medical examiner system) are often used instead. The RCPCH considers that the Inquiry should make a recommendation (set out below) to ensure that these three systems work together and to set clear "triggers" for the various kinds of investigation. Furthermore, given that Dr Isaac (the safeguarding doctor -INQ0102612, paragraph 28) said that mortality rates for the NNU were never discussed in safeguarding meetings, it would appear that the SUDIC and safeguarding system at COCH were run as separate, or parallel systems.
- 80. The current legal processes for child death reviews, including sudden and unexpected infant deaths are set out in Working Together to Safeguarding Children 2023¹⁰⁹. This is supplemented by two other sets of guidance, DHSC and DfE joint guidance on the operational process of child death reviews (2018)¹¹⁰ and joint Royal College guidance specific to sudden and unexpected

 ¹⁰⁷ Dr Kingdon, <u>Week 13, Day 2, 12/12/2024</u>, p177, 11 – 188,13
 ¹⁰⁸ Dr Kingdon, <u>Week 13, Day 2, 12/12/2024</u>, p188, 8

¹⁰⁹https://assets.publishing.service.gov.uk/media/669e7501ab418ab055592a7b/Working together to safeguard children 2023.pdf

¹¹⁰ https://assets.publishing.service.gov.uk/media/637f759bd3bf7f154876adbd/child-death-reviewstatutory-and-operational-guidance-england.pdf

death in childhood (SUDIC) (2016)¹¹¹. The RCPCH is not a "statutory partner" who must follow the process laid out in Working Together. In healthcare, the Integrated Care Board, NHS England, a NHS trust and foundation trust are such partners. Section 16M-16Q of the Children Act 2004 set out the parameters of such child death reviews¹¹². The Children Act sets out that the local authority area (including the local ICB) is obliged to pay for the reviews, and the child death review partners are under (amongst others) the following obligations:

- (a) The child death review partners must make arrangements for the review of each death of a child normally resident in the area (s16M(1)) – which can be delegated form one local authority or ICB to another (s16P).
- (b) They must make arrangements for analysis of information about deaths (s16M(3)) but this is for the purposes of identifying any matters relating to death relevant to welfare of children in the area AND to consider whether any action should be taken in relation to matters identified (s16M(4)(a) and (b)).
- (c) There are compulsory powers available to provide information to the child death review partner (including by obtaining an injunction) s16N.
- (d) The child death review partners must have regard to any guidance given by the Secretary of State in connection with the functions set out in s16M and s16P.
- 81. The position therefore is that it is the ICB, and not the relevant practitioners from a trust who are under a responsibility to review the deaths.
- 82. Chapter 6 of the current version of Working Together to Safeguard Children (paragraph 376 et seq) is statutory guidance on the workings of the child death review panels which are the bodies who are responsible for reviewing the deaths of all children. The current guidance identifies that the process covers children, regardless of the cause of death (but does not cover those who are

¹¹¹ https://www.rcpath.org/discover-pathology/news/new-guidelines-for-the-investigation-of-sudden-unexpected-death-in-infancy-launched.html

¹¹² These were introduced in March 2018, so were not in place at the dates examined by the Inquiry

stillborn). A flowchart¹¹³, sets out the practical process to be followed, and paragraph 394 onwards set out in narrative form that flowchart.

- 83. The Child Death Review Process has "statutory and operational" guidance issued in 2018. This should be "*read and followed*" by all those working within health and coronial services¹¹⁴. This has a flowchart¹¹⁵ which sets out the entire process and also a flowchart which sets out the immediate decision making and notifications, followed by investigation and information gathering¹¹⁶. Paragraph 2.1.3 identifies that if the death is from external causes, the circumstances are unclear, or safeguarding concerns or problems with care or service delivery are suspected, further investigations will be needed¹¹⁷. One can see that is subtly different to the circumstances which trigger the JAR process (whether this is intentional or not is not clear¹¹⁸).
- 84. Working Together also cross refers to the guidelines for sudden unexpected death in infancy and childhood, published in 2016, which the statutory and operational guidance from 2018 seeks to use for the process involving sudden unexpected deaths¹¹⁹. This guidance¹²⁰ provides that SUDIC encompasses all cases in which there is a death or collapse leading to death of a child "*which would not have been reasonably expected to occur 24 hours previously and in whom no pre-existing medical cause of death is apparent*". The guidance states that "*while many of these guidelines may be applied if required, they are therefore not necessarily intended to be applied to cases with a previously diagnosed medical condition in which a medical certificate of cause of death can be provided*". As can therefore be identified, in order for the SUDIC process to be operated the death must be medically unexpected and without a pre-existing medical cause of death. As Dr Kingdon identifies, identifying whether

¹¹⁷ INQ0012899, p20, paragraph 2.1.3

¹¹³ Figure 2 of p150 of Working Together to Safeguard Children 2023

¹¹⁴ INQ0012899-0014

¹¹⁵ INQ0012899-0017

¹¹⁶ INQ0012899-0020

¹¹⁸ INQ00016982, portions of which are exhibited by the Inquiry

¹¹⁹ INQ00012899 – 11

¹²⁰ INQ00016982 _0013

there is or is not a pre-existing medical cause of death in babies born before term can be difficult, as babies can become unwell very quickly and medical investigations may be inconclusive.

85. The guidance does, however "recommend"¹²¹ that SUDIC is used for all unexpected infant deaths, and that where a medical cause cannot be found, then they should be seen as SUDIC unexplained pending an inquest. The guidelines refer to certain "unusual" clinical situations ¹²², which includes where an infant deteriorates rapidly and possibly dies of septic shock, where if the death is due to sepsis, no SUDIC process is required, but otherwise the case should be discussed with the coroner and the SUDIC process initiated. The guidelines in fact state this about newborn infants¹²³:

> "When a newborn infant suddenly collapses and dies on a neonatal unit, consideration should be given as to whether a joint agency response is required. In most situations this would not be appropriate."

86. The guidelines are designed to support child death review teams to carry out their statutory obligations whilst also providing ongoing support to the family¹²⁴. The RCPCH recognises that the three separate guidance documents may be interpreted differently in different local settings, and that the SUDIC guidance is overdue for review and update. RCPCH is working with fellow Royal Colleges and is looking to NHSE to provide resources to facilitate this update. When doing so, RCPCH will seek to reduce the duplication and silos in this space. The RCPCH also agrees with the view of Dr Garstang¹²⁵, that child death review processes have weak levels of accountability with an ICB not really holding trusts to account about this. As outlined below, the RCPCH considers that more should be done by ICBs on this issue but also on child health more broadly.

Forms re baby death

87. The relevant forms to be filled in where it is decided that a Joint Agency Response is required are lengthy. They are likely to take a day's work if filled in

¹²¹ INQ00016982 - 0014

¹²² INQ00016982 - 0015

¹²³ INQ0016982 – 0016

¹²⁴ INQ0016982 – 0020, para 1.4

¹²⁵ INQ001026,24, paragraph 12.2

thoroughly and comprehensively because the type and amount of information is significant and involves detailed notes of many aspects of a child's life which will also include liaison with the family and often other clinical professionals who may have provided care to the child/mother (in the case of neonatal deaths). The RCPCH is not aware of any work being done to shorten this form, and would suggest that efforts to do so must carefully consider how to ensure that all relevant and appropriate information is captured, and that the impact of any changes is carefully monitored.

Administrative support in clinical and leadership roles and leadership by doctors in hospital settings

- 88. As identified by many of the clinicians at this inquiry¹²⁶ and by Dr Kingdon in her evidence¹²⁷, those in leadership roles within hospitals do not automatically receive leadership training and if they do wish to undertake such courses, usually have to pay for it themselves. Whilst clinical leadership competence frameworks are common to all doctors' training, and the Faculty for Medical Leadership and Management sets out leadership standards in the faculty of medical leadership, it is not clear from Professor Smith's evidence whether these standards then "wither on the vine"¹²⁸. Professor Smith in her evidence recognised that the quality of training provided to those who move from clinical to managerial roles (or ones with both functions) do not always receive training and development in such management skills and the provisions of such is variable¹²⁹.
- 89. Whilst time for administrative work is allocated under a clinician's contract if they have clinical roles, this is frequently insufficient given the complexity and wide-ranging nature of the roles that have to be undertaken. As this inquiry shows, many of the clinicians were undertaking their administrative tasks in the evening or in their own free time¹³⁰. There is not, as far as the RCPCH is aware, any "standard" set of administrative support provided for any particular clinical

¹²⁶ Dr Kingdon, <u>Week 13, Day 2, 12/12/2024</u>

¹²⁷ Dr Kingdon, <u>Week 13, Day 2, 12/12/2024</u>

¹²⁸ Witness Statement of Professor Smith [INQ0101380], paragraphs 41 – 50

¹²⁹ Professor Smith, <u>Week 14, Day 3, 09/01/2025</u>, p68,8 – 69,10, and page 92

¹³⁰ Week 5, Day 2, 08/10/2024 as an example at p98, 8 – p101,10 re Dr McGuigan.

role, and the experience of the RCPCH is that it is not guaranteed or always provided. If it is provided, it is often a ward clerk or other person who provides general administrative support to the ward, and not just to those in leadership roles. The preferable solution, of a senior clinician having access to dedicated administrative support, is certainly not universal. Professor Smith in her oral evidence¹³¹ stated that it is common for clinicians to have 25% protected time for management, but in fact all their time is spent undertaking clinical duties and the management is being done "in their own time".

Part C: Recommendations

90. The RCPCH has made recommendations in its written and oral evidence. Summarising these into themes, they focus upon the need to (a) ensure and secure patient safety (b) give sufficient and adequate priority to neonatal and paediatric service provision within the NHS so that patient safety aims can be fulfilled. Various other bodies have or will be making recommendations, some of which have been discussed at the Inquiry. Where it is relevant and pertinent to the work of the RCPCH, views upon the practicability or operability of those recommendations have been set out in these submissions.

Ensuring patient safety

SUDIC Guidelines

91. The evidence presented showed some confusion between when to use the SUDIC guidance and when to follow the Child Death Overview Panel (CDOP) and the guidance set out in Working Together (in its various iterations) to support that. The RCPCH would suggest that there should be a common document, circulated and used by all which unambiguously identifies the range of times when SUDIC and the CDOP should be used (emphasising as is required given the evidence in this case, that this includes deaths in hospitals) and that this needs to be provided by a national body (the RCPCH suggests NHS England and its counterparts in devolved administrations) to avoid confusion and to create coherence.

¹³¹ Professor Smith, <u>Week 14, Day 3, 09/01/2025</u>, p150

92. The RCPCH agree with the evidence of Dr Garstang that the SUDIC guidance issued by the RCPCH in November 2016 is "woefully out of date" [Week3, Day 4,26/09/2024, p158, 15-16 and 159/18]. In particular, the RCPCH notes Dr Garstang's comment that this guidance says that it does not "normally apply" to a neonatal unit. By comparison, as Dr Garstang identifies, the Welsh Guidance (INQ01069187) makes it clear that deaths in hospital settings should be considered under the multi-agency guidelines they have in place. The RCPCH has agreed to carry out this work [Dr Garstang, Week3, Day 4,26/09/2024, p182, 23] but requires funding to be able to carry this work out. Sir Stephen Powis in his evidence to the Inquiry (whilst not on this specific point but on the drafting of documents and materials in respect of SUDIC more generally) "commits" (Thirlwall 170125 Day58-0117/p80/3-12.ecl) to provide more clarity to these documents and guidance. The RCPCH submits that the Inquiry should make a recommendation of funding of such an update if NHS England does not agree to do so specifically.

Awareness and understanding of Working Together and the role of the LADO

93. The Local Authority Designated Officer (LADO) has been a function in existence since 2004. The majority of those who gave evidence to this inquiry, many of whom had worked in paediatric care for a number of years were not aware of the terminology or the role of the LADO¹³². This is somewhat of a surprise to those who work in social services or education to whom the role is familiar and frequently used. Dr Kingdon, past President of the RCPCH in her evidence¹³³ identified that the Level 3 Child Protection Training undertaken by all paediatricians and all those working directly with children does not refer to the LADO at all. Such is only referred to if one was the named doctor for child protection or the designated doctor, both of which identifies the role of the LADO. This Inquiry has clearly identified that this is a deficiency in the training of paediatricians by all NHS trusts. The Inquiry is asked to recommend that all safeguarding training sessions run for those who work with children or in paediatric services and the intercollegiate competencies framework for those

 ¹³² See for examples: McGuigan <u>Week 5, Day 2, 08/10/2024</u>,p85- 4-13, then p85-14 – p87, 17
 ¹³³ Dr Kingdon, <u>Week 13, Day 2, 12/12/2024</u>, p171,5-172-25

working with children should have a knowledge and understanding of the escalation processes outlined in Working Together to Safeguard Children, including the role of the LADO, and what they do and this is included routinely in training for both paediatricians but also nurses and clinical and nursing directors (as the RCPCH considers that if Dr Harvey and Ms Kelly were more familiar with this, they may have wished to have consulted them given the issues which arose with Letby).

94. The RCPCH is taking steps to address this lacuna in the following ways:

- (a) The RCPCH has a role (along with other royal colleges) ¹³⁴in the development of an intercollegiate competency framework which is designed for all healthcare staff which ranges from non clinical staff to experts (Safeguarding Children and Young People: Roles and Competences for Healthcare staff (December 2019)). It is raising with the other colleges the need for that document to reflect the role of the LADO. The RCPCH would ask that the Inquiry recommends that this document (and others which are used to provide training for clinical staff and others working in hospitals) make this role clear.
- (b) The RCPCH also has a specific safeguarding competency framework for paediatricians [INQ number to follow] at Level 3. This does not refer to the LADO, and it should do so. Safeguarding training modules are being revised to include reference to and an understanding of this role, and the updated Intercollegiate Document will make additional references to the LADO and greater awareness of the escalation processes set out in Working Together to Safeguard Children. The RCPCH will provide the Inquiry with the updated materials when they have been produced.
- (c) The RCPCH is consulting with the General Medical Council to explore if the role of the LADO should be included on the general paediatric training curriculum (called Progress +).

¹³⁴ INQ0012911_1,19,30.pdf

- 95. Alongside this, the vast majority of evidence from paediatricians and other staff was a lack of familiarity with Working Together and what it said about safeguarding generally, and the need to raise concerns at the level of suspicion and the general failure to understand that the allegations against Letby should be treated as safeguarding concerns. The evidence from the RCPCH reviewers is instructive as despite being experienced in devising safeguarding policies (such as Ms Eardley) and working in different parts of the country and in different posts, they were not aware of how to manage allegations made about staff with whom they worked and all said they had not received training about this. The RCPCH would also identify that the doctors (even those working in safeguarding) for COCH seemed to consider that issues in neonatology were not necessarily matters for them and were not part of any general safeguarding discussions¹³⁵.
- 96. Again, whilst this document is very familiar to those working in social services or education settings, it appears that in hospitals it is not frequently cited or used save for those working as Designated or Named Doctors and there is a general lack of understanding in how to manage such allegations as they arise, with a focus upon the Safeguarding and Accountability Framework which is an NHS England document¹³⁶. Knowledge and understanding of what constitutes an allegation and what should then happen was poor in this case. As has been littered through the evidence¹³⁷, individuals considered that there needed to be proof, or variations on that before the police /LADO should be engaged.

Co-ordination of data in neonatal settings

National Neonatal Audit Programme, the NMPA and the PRMT

97.As described by Dr Kingdon in her evidence¹³⁸, the National Neonatal Audit Programme (which the RCPCH is commissioned to deliver) provides an invaluable role in identifying and spotting concerns and trends every three

¹³⁵ Dr Isaac [INQ0102621] paragraph 28

¹³⁶HYPERLINK "https://thirlwall.public-inquiry.uk/transcript/17-01-2025-transcript-of-week-15-day-4/" Week 15, Day https://thirlwall.public-inquiry.uk/transcript/17-01-2025-transcript-of-week-15-day-4/, <u>17/01/2025</u> p77, 1-78-,11

¹³⁷ The RCPCH would suggest in nearly all the evidence given by clinicians engaged in the Letby case.

¹³⁸ INQ0017493.pdf at paragraphs 23

months¹³⁹ and derives its data from an electronic database that every neonatal service in the country (used) to use.¹⁴⁰ It reports ten outcomes measures, which include mortality (but are not limited to them), and which enables a national picture of the quality of neonatal care to be assessed and examined on a relatively contemporaneous basis, and which has a high "clinician buy in" ¹⁴¹.

- 98. However, the roll out by NHS England of electronic health records (which the RCPCH considers is necessary), has not considered whether those health records are compatible or speak to the system which is used for NNAP. A software "patch" that would enable data to flow between the two systems has not yet been developed and so currently nursing and medical staff are required to manually enter data into the audit system. This reliance on frontline clinical staff undermines the reliability of the audit data. The RCPCH considers, as expressed by Dr Kingdon that this is a "very, very serious missed opportunity" because NNAP really, really has got an opportunity to be a lever for *improvement.*¹⁴². The Inquiry is asked to make a recommendation to NHS England for such a data "patch" to be prioritized within 3 months of the Inquiry report being published (given that it has already been a year since these problems were identified). The Paediatric Intensive Care Audit Network¹⁴³ in their evidence identifies that the collection of high-quality neonatal data with robust data analysis is vital to keep babies safe but does not recommend any new data system beyond that which already exists by way of the NNAP and MMBRACE.144
- 99. Dr Kingdon also gave evidence about the other data systems which are used in NHS Trusts, and in particular the National Maternity and Perinatal Audit (NMPA). Dr Kingdon recommended the need to link these and the NNAP records together, in order to create adequate data flow¹⁴⁵. The RCPCH and

¹³⁹ Dr Kingdon, <u>Week 13, Day 2, 12/12/2024</u>, p150, 1-25

¹⁴⁰Dr Kingdon, <u>Week 13, Day 2, 12/12/2024</u>, p151, 16-156, 14

¹⁴¹ Dr Kingdon, <u>Week 13, Day 2, 12/12/2024</u>, p150, 12

¹⁴² Dr Kingdon, <u>Week 13, Day 2, 12/12/2024</u>, p151, 8-11

¹⁴³ INQ0010439.pdf

¹⁴⁴ <u>INQ0010439.pdf</u> at 30 – 31

¹⁴⁵ Dr Kingdon, Week 13, Day 2, 12/12/2024, p152, 24

neonatologists would like to see cohesive data collection and the NMPA collection becoming "more mature" so one can analyse and link the records of mother and babies. This would increase the quality and accuracy of the information that NNAP is able to derive from the dataset. The Inquiry is asked to make a recommendation that NHS England seeks to cohere the datasets.

100. The other tool of significance is the PMRT- the perinatal mortality review tool. As was said in the opening submissions of the RCPCH¹⁴⁶, this has been in place since 2018 and provides a set of "real-time" information which as Professor Knight said in her evidence ¹⁴⁷ was the subject of good compliance, with nearly 100% of deaths notified within that time¹⁴⁸. Hospitals have access to the online viewer of this data which shows the number of deaths and the characteristics of deaths, which is compared to hospitals against an average rate to the group which they belong, and which allows the hospital to consider if any variation they are seeing are from a common cause or a special cause variation. The tool can show where there is unusual special cause variation. [Marian Knight, Week 14, Day 1 07/01/2025, p21-24, p29-32, p33-36]. As Professor Knight said, it is important that there is someone trained at the hospital who can understand the data and can review every death and to show to the clinicians working at the hospital what has been happening (p33-36 and p57-60). Again, the Inquiry is asked to recommend that every unit has someone who is trained to be able to understand and analyse this data, and who has the time to do so, alongside an effective escalation route to senior management (and to the ICB) to ensure that an action plan is in place. The combination of the data from the PRMT (which only provides information on deaths within 28 days after a live birth), the NNAP and the NMPA should be viewed and analysed together by every Trust, by the regional Neonatal Operational Delivery Network (ODN) (and by every ICB in scrutinizing those trusts) to see patterns.

Medical Examiners

¹⁴⁶ Written opening submissions of RCPCH [INQ0107954]

 ¹⁴⁷ Professor Knight, <u>Week 14, Day 1, 07/01/2025</u>
 ¹⁴⁸Professor Knight, <u>Week 14, Day 1, 07/01/2025</u>, p8, 14-20

101. The Inquiry received written and oral evidence about the system of medical examiners¹⁴⁹. Dr Fletcher, the National Medical Examiner agreed with Dr Garstang¹⁵⁰ that prior to 9 September 2024 not all child deaths were being examined by the medical examiner system. It is therefore fairly early days to identify how the system is working in respect of paediatric cases, but as identified by Dr Garstang in her statement (paragraph 4.2)¹⁵¹, many Medical Examiners know little about SUDIC, JAR or child deaths, so may not have the expertise when to intervene. Dr Fletcher in his evidence¹⁵² identified that he has requested three medical examiners with neonatal and/or paediatric pathology backgrounds to liaise with the British Association for Perinatal Medicine (BAPM), to provide guidance for their colleagues and to update the Good Practice documents issued by the National Medical Examiner service to ensure that child and neonatal deaths are specifically considered and to create an e-learning module for BAPM to disseminate about the national medical examiner system. That is all laudable, and the Inquiry is asked to follow up and recommend that these are implemented. However, the RCPCH (through Dr Kingdon) ¹⁵³ considers that on a regional basis there should be Medical Examiners who are paediatric and/or neonatal specialists given the particular complexities of such, or who can consult such colleagues (and have a quick answer), a view shared by BAPM. ¹⁵⁴

Reporting of Insulin and C Peptide

102. The RCPCH supports the recommendation made by the British Association of Perinatal Medicine (BAPM), Bliss Charity and the NPPG¹⁵⁵ made in December 2023¹⁵⁶ to improve standardisation of measurement, reporting and communication of serum insulin and C peptide test results. The Inquiry is

¹⁴⁹Week 13, Day 2, 12/12/2024, INQ0108659.pdf, INQ0014570.pdf

¹⁵⁰ Witness Statement of Garstang [INQ0017975] para 2.8 and 4.2, and <u>Week 13, Day 2, 12/12/2024</u>, p47, 23-48,17

¹⁵¹ Witness Statement of Garstang [INQ0017975] para. 4.2

¹⁵² @HYPERLINK "https://thirlwall.public-inquiry.uk/wp-content/uploads/2024/12/Thirlwall-Inquiry-12-December-2024.pdf" <u>Week 13, Day 2, 12/12/2024</u> p49, 5-p50,14 ¹⁵³ Dr Kingdon, Week 13, Day 2, 12/<u>12/2024</u>, p183, 13-18

¹⁵⁴ para. 74 [INQ0012962]

¹⁵⁵ INQ0012962.pdf, para. 73

¹⁵⁶ INQ0012959

asked to make a recommendation that the Association for Quality Management in Laboratory Medicine work with BAPM provides a series of standardised set of processes for measuring and reporting of insulin and how reporting of results suggesting overdose of insulin is transmitted to health professionals.

Recommendations in respect of improving neonatal and child health services.

Child health services

- 103. As Dr Kingdon said in her evidence¹⁵⁷, the RCPCH considers that neonatal and paediatric services are not given sufficient or adequate priority within hospitals or community settings. "Weigh less, worth less" is, the RCPCH submits, unfortunately true when it comes to funding for and awareness of neonatal and paediatric services at a hospital, ICB and government level. Moreover, the lack of focus upon children has resulted in poorer health outcomes for children and young people and there has been chronic underinvestment in paediatric services over the last ten years¹⁵⁸. The RCPCH's most recent figures identify that there are over 50,000 children who have waited more than a year for health treatment, with 14% of children in community health services waiting over a year¹⁵⁹. Of particular relevance to this inquiry, the prevalence of life limiting and life-threatening conditions in childhood has increased by 40% between 2001-2019, and a significant increase in children with a large number of comorbid chronic conditions. ¹⁶⁰
- 104. 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. Given that the expert

¹⁵⁹ <u>https://www.rcpch.ac.uk/resources/transforming-child-health-services-england-blueprint</u> p10.

¹⁵⁷Dr Kingdon, Week 13, Day 2, 12<u>/12/2024</u>, p191, 20

¹⁵⁸ Transforming child health services <u>https://www.rcpch.ac.uk/resources/transforming-child-health-services-england-blueprint</u>, page 4

¹⁶⁰ https://www.rcpch.ac.uk/resources/transforming-child-health-services-england-blueprint p16.

evidence in this case has identified that the focus in most boards is on the financial bottom line (or that weighs heavily in decisions)¹⁶¹, a lack of such focus means that children slip down the priority list¹⁶².

- 105. The RCPCH's *Transforming Child Health Services in England: A Blueprint*¹⁶³ recommends that children should be explicitly prioritised in Integrated Care Systems to ensure their visibility. The RCPCH makes the following recommendations within this document, which, it is submitted, the Inquiry may wish to adopt:
 - (a) All Integrated Care Boards (ICBs) should be assessed by looking at their performance in respect of children and young people. This would include the CQC inspecting and assessing ICB against specific performance for children and young people. Research undertaken by the RCPCH ¹⁶⁴ shows that 50% of ICBs did not explicitly reference children and young people with major and long term conditions, and less than half identified specific actions that would be undertaken in their plans for babies, children and young people. Only 33% of trust surveyed by NHS providers, ¹⁶⁵ consider that the ICB had adequately prioritised children's health services, with 82% stating that they could not meet current demands for child health services.
 - (b) NHS England produces annual "Priorities and Operational Planning Guidance". ¹⁶⁶Every ICB has to provide a plan to NHS England as to how they are going to meet those priorities. The 2025/2026 priorities do not include any data or focus on children and young people, save the need (which is essential and urgent) to increase access to children and young person's mental health services. There is no specific waiting time standards imposed for children's care. There should be.

¹⁶¹ See for example the failure to use agency staff to cover gaps etc in this inquiry

¹⁶² Lyn Simpson, NHS Improvement [INQ01014143], at para 49 recommends a neonatal champion role at executive and non-executive level

 ¹⁶³ RCPCH *'Transforming Child Health Services in England: A Blueprint',* September 2024: <u>https://www.rcpch.ac.uk/resources/transforming-child-health-services-england-blueprint</u>
 ¹⁶⁴ Transforming child health, p14

¹⁶⁵ The organisation which represents hospitals and other bodies which provide care

¹⁶⁶ https://www.england.nhs.uk/operational-planning-and-contracting/

(c) Develop a National Outcomes Framework for Children's Health. This is self-explanatory. The RCPCH understands that "priority thickets"¹⁶⁷ and "top-down" imposition of targets do not work. This is not about that, but about looking at how community provision, holistic care alongside hospital care can be improved and assessed over time.

Patient safety

106. The RCPCH gave oral submissions about the Patient Safety portal it operates within its opening submissions¹⁶⁸. It agrees with the extensive evidence about the need for cultural change, psychological safety for team working and clarity of values, standards and incentives and consistencies of behaviours¹⁶⁹.

Child health workforce

107. As outlined in the written and oral submissions of the RCPCH¹⁷⁰, and the evidence of Dr Kingdon¹⁷¹, there are significant workforce pressures across paediatrics and neonatology. The evidence of the RCPCH and BAPM is that understaffing in neonatology is routine and chronic and is reflected in the wider health service. The witness evidence of Dr Adams of BAPM¹⁷² identifies that the neonatal critical care review report¹⁷³ found insufficient capacity in neonatal units, and workforce gaps¹⁷⁴. The further work undertaken by the neonatology speciality review¹⁷⁵ led to a national report into neonatology with 21 recommendations¹⁷⁶. These included more intensive care beds and other reorganisation of services. The Getting It Right First Time neonatal workforce report from 2023, identified shortages across medical and nursing staff and

¹⁶⁷ As described in the Witness Statement of Mary Dixon [INQ0102624] and the Witness Statement of Sir Robert Francis, part 2 [INQ0101079]

¹⁶⁸ Opening Submissions of RCPCH [INQ0107954]

¹⁶⁹ See for example Professor Smith's written evidence [INQ0101380 -0036-0040], paragraph 101 onwards

¹⁷⁰ Opening Submissions of RCPCH [INQ0107954], Dr Kingdon, Week 13, Day 2, 12/12/2024, Professor Turner, <u>Week 13, Day 2, 11/11/2024</u>

¹⁷¹Dr Kingdon, Week 13, Day 2, 12/12/2024

¹⁷³ INQ0012352

¹⁷⁴ As set out at Dr Adams [INQ0014572 – 003] para. 18

¹⁷⁵ National findings [INQ001241] and Dr Adams, [INQ00014572-0012 - 0014]

¹⁷⁶ INQ0012417, Paragraph 92 – 93 of Dr Adams [INQ00014572]

allied health professionals, the need for improving staffing for clinicians and allied health professionals, with better education and career structures. ¹⁷⁷ The RCPCH welcomes the three-year delivery plan for neonatology and maternity care and the information provided about this by Dr Adams, and Ms Weaver Lowe. ¹⁷⁸ The neonatal critical care service delivery plan of 11 March 2024 sets out what is expected, and introduces the welcomed role of neonatal safety champions and sets out what is expected in neonatal units: it also recognises that there should be sufficient time for clinical consultants and education leads to work on and review CDOP and PMRT data. Obviously, the effective implementation of this plan is vital¹⁷⁹.

108. Fundamental to a good culture is having sufficiently well-trained staff who operate to set standards and who are provided with adequate support. When staff are working beyond their capacity, good culture can be hard to come by¹⁸⁰. 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 heavy¹⁸¹. As very many have said in this inquiry, that culture must be candid, support improvements, and ensure sustained change without imposing blame. The RCPCH is fully supportive of the work of the NHS England maternity and neonatal outcomes group and the work undertaken in respect of Getting It Right First Time that emerges from this in order to differentiate the "signals from the noise", in an understaffed and underfunded system this is more challenging¹⁸².

¹⁷⁷ INQ0012418, Dr Adams [INQ00014572 – 0029] para. 29

¹⁷⁸ Witness statement of Lousie Weaver Lowe [INQ0018081,004, para f] and neonatal workforce data set out [INQ0009252]

¹⁷⁹ The neonatal critical care service delivery plan is set out at [INQ0018029], also set out in the witness evidence of Louise Weaver Lowe [INQ0018081, paragraph 49 - 51] and the witness statement of Dr Ngosi Edi Osagie [INQ0108888].

¹⁸⁰ Benneyworth, HSSIB, Week <u>14, Day 2, 08/01/2025</u> p24-25

¹⁸¹ National Training Survey 2024 Results (gmc-uk.org)

¹⁸² For discussion of the outcomes group see INQ0106962, Dr Edile Murdoch at INQ0106962-007, para 15 – 17

- 109. The RCPCH also notes that there is no statutory "safe staffing "levels in England in comparison to Wales and Scotland where there is legislation about level of minimum staffing¹⁸³.
- 110. Paediatric waiting lists in England 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 year¹⁸⁴.
- 111. The RCPCH recommends a review of the modelling on children's health which underpins the NHSE Long Term Workforce Plan. At present, the Plan does not provide for any increase in children's nurses ¹⁸⁵ and does not provide a coherent plan for the child health workforce.
- 112. The RCPCH recommends specific investment in the neonatal workforce, including medical, nursing, allied health professionals, pharmacy and psychology, to achieve the required national standards needed to improve safety, and to train and develop the workforce to retain our valued staff. The evidence from this inquiry ¹⁸⁶ shows unequivocally the need for such investment.

Funding

113. Children's health services are not adequately funded. The RCPCH recommends increasing investment in children's health services, in line with the recommendations set out in the RCPCH's *Transforming Child Health Services in England: A Blueprint*¹⁸⁷. Children are a quarter of our population, but do not have sufficient funding commensurate with that demography. The Blueprint makes a number of recommendations which the Inquiry may wish to follow:¹⁸⁸

¹⁸³ As noted by Dame Ruth May in her witness evidence [paragraph 103: INQ0012643]

¹⁸⁴ https://www.england.nhs.uk/statistics/statistical-work-areas/rtt-waiting-times/

¹⁸⁵ Dr Kingdon, Week 13, Day 2, 12/12/2024,

¹⁸⁶ See BAPM evidence

 ¹⁸⁷ RCPCH '*Transforming Child Health Services in England: A Blueprint*', September 2024: <u>https://www.rcpch.ac.uk/resources/transforming-child-health-services-england-blueprint</u>
 ¹⁸⁸ RCPCH blueprint, p13. <u>rcpch_child_heath_blueprint_2024.pdf</u>

- a) Introducing a Children's Health Investment Standard to address the investment gap between child and adult health services. This would follow the existing blueprint of the Mental Health Investment Standard, a mechanism which compels systems to increase their spending on specific services by a greater proportion than their overall spending, so they move towards a fairer distribution of spending based on need and demand for services.
- b) Ensuring all national health funding commitments include a specific proportion that is allocated to children's health services. Children and young people must be recognised as a distinct group, and their health needs must be explicitly considered in all national health reform initiatives.

Bereavement and listening to parents

114. Specialist bereavement support in neonatal units is patchy, with many units not having specific psychological or trained nurse oversight as a matter of routine. The heartbreaking evidence of the parents to this Inquiry should show why such is essential and must be provided. The RCPCH notes the evidence of Ms Murphy¹⁸⁹ that the different schemes and guidance read by different organisations (for example the SWAN scheme, the Bliss Charter, the SANDS liaison advisers), are all saying identical things¹⁹⁰. The evidence of Bliss ¹⁹¹speaks of inadequate staffing, and the need to do more for neonatal care is congruent with that of the RCPCH.

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

¹⁸⁹ Ms Fiona Murphy, Week 15, Day 2, 14/01/2025, p151

¹⁹⁰ Ms Fiona Murphy, Week 15, Day 2, 14/01/2025, p156.

¹⁹¹ INQ0014063 at paragraph 25, and raised with the RCPCH at INQ0012321

115. 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 guidance¹⁹²). There is no reason a similar person could or should not be present in NHS Trust boards to ensure appropriate oversight of children's health.

Duty of candour

116. The RCPCH also responded to the consultation regarding the organisational duty of candour. The RCPCH does not consider that an individual duty of candour is required if an organisational duty is to be introduced. Such a duty would be cumbersome, duplicative and disproportionate.¹⁹³

Martha's Rule

117. The RCPCH welcomed the implementation of Martha's Rule – which gives the right of a patient family or any staff member 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. 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]). In a blog published in February 2025, the RCPCH set out that "there are special considerations to making sure this (Martha's Rule) works for children and young people. While most adult patients in acute hospital settings will have access to face-to-face critical care expertise, this is not routinely the case in paediatrics, due to the way paediatric critical care is organised. Some pilot sites have set

¹⁹² NHS England » Executive lead roles within integrated care boards

¹⁹³ https://www.rcpch.ac.uk/resources/duty-candour-northern-ireland-consultation-

response#:~:text=The%20RCPCH%20broadly%20welcomes%20an,to%20meet%20the%20stated%2 0aiMs

up pathways where different paediatric teams are able to provide reciprocal support with urgent reviews. Others with the right blend of skills have set up pathways which allow predominantly adult-focused critical care colleagues to provide urgent escalation reviews for children provided they are appropriately trained. For any model, virtual support and advice from paediatric critical care networks are likely to be crucial - indeed these models will be explicitly tested in the three paediatric critical care networks which are taking part in the pilots. Support for neonates is similarly a conundrum: while similar critical care network approaches may work, there are potentially more limited options when it comes to "in-house" shared expertise. The RCPCH policy and patient safety teams remain actively involved in the design process for this" ¹⁹⁴

Regulation of healthcare professionals

- 118. 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 welcomes the proposed harmonisation of regulation in principle outlined by the DHSC in their evidence but would need to see the detail prior to being able to comment in an informed manner. ¹⁹⁵. The Inquiry may also wish to consider if the current system of regulation is in fact effective in improving patient safety.¹⁹⁶ The RCPCH notes the evidence of the previous Parliamentary and Health Service Ombudsman as to the overlapping regulatory system and the uncertainties in responsibilities that can cause.¹⁹⁷
- 119. The RCPCH has submitted a formal response to the DHSC consultation on the regulation of NHS senior managers, a copy of this response has been submitted to the Inquiry. The RCPCH does not consider that it is in the best place to answer how such regulation should work, and whether it is regulatory

¹⁹⁴ On Martha's Rule - patient safety spotlight | RCPCH

¹⁹⁵ William Vineall, DHSC, <u>Week 15, Day 3, 15/01/2025</u>, p79,7 – p83,7

¹⁹⁶ Dr Benneyworth in her evidence identified that health arm's length bodies about collaboration between arm's length bodies but the results of this are not clear. Week 14, Day 2, <u>08/01/2025</u>, p29. Dr Benneyworth also said that the complex regulatory landscape hinders, rather than helps, individual trusts from making improved safety decisions.

¹⁹⁷ Witness Statement of Rob Behrens, [INQ14599, para. 84] and report at INQ0014545

oversight – or rather clarity of accountability - which needs to be made clear. The RCPCH recognises the wider potential benefits and impacts on patient safety that such an initiative could bring for both patients and the NHS workforce and notes that care must be taken to ensure that an introduction of regulation is proportionate, adequately resourced and carefully implemented so as to avoid the unintended consequences of a reduction in uptake of important senior management roles within the NHS.

CCTV observation of Neonates

- The Inquiry has specifically asked about this as a recommendation. The 120. 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. It has listened to the evidence from NHS England¹⁹⁸ as to pilots and will work with them to provide feedback as to their efficacy. The RCPCH notes the evidence of Dame Ruth May (previous Chief Nurse for NHS England) who sets out the need for continuous monitoring and the impact that this may have on the right to privacy of families and the evidence of Dr Ngozi Edi Osagie, the clinical director for neonatology in this regard¹⁹⁹.
- 121. 'The Use and impact of surveillance-based technology initiatives in inpatient and acute mental health settings: A systematic review'²⁰⁰ investigates the use of surveillance technologies in inpatient mental health settings,

²⁰⁹ Sir Stephen Powis, Week 15, Day 4, 17/01/2025

¹⁹⁹Witness Statement of Dame Ruth May [INQ0012643, para. 83] and Dr Ngozi Edi Osagie first Witness Statement of [para. 74 INQ0108888]

²⁰⁰ <u>The use and impact of surveillance-based technology initiatives in inpatient and acute mental</u> <u>health settings: A systematic review | medRxiv</u>

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.

- 122. The RCPCH has kept abreast of the evidence to the Inquiry on CCTV, and in particular of NHSE's evidence where pilots have been suggested. The College will continue to monitor this and where appropriate, feed into any consultation, review or considerations of widespread use of CCTV in neonatal services.
- 123. 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 26 February 2024 On behalf of the RCPCH