Statement No.: [XXXX]
Exhibits: [XXXX]
Dated: 8 February 2024

THIRLWALL INQUIRY

WITNESS STATEMENT OF ROYAL COLLEGE OF PAEDIATRICS AND CHILD HEALTH

1. This is a witness statement from Robert Okunnu, Chief Executive Officer of the Royal College of Paediatricians and Child Health (RCPCH). The RCPCH is providing this statement to the Thirlwall Inquiry to answer the Rule 9 request made on 30 October 2023. The RCPCH is committed to full cooperation with the Inquiry, to ensure that lessons can be learned from the crimes committed at the Countess of Chester Hospital (CoCH) in 2015-16, and to provide assistance as to any changes to the wider NHS which may be necessary to minimize the risk of future harm.

2. Before saying anything else, it is important to state RCPCH's heartfelt sympathies to all those affected by these appalling events, especially the families of the babies who were harmed.

3. This witness statement has been informed by input from my senior colleagues Emily Arkell and Graham Sleight. We are not professional paediatricians. As a result, although we can speak with some professional expertise about the practice of paediatrics/charity management, on areas outside this sphere we have drawn on wider expertise within the RCPCH.

4. It is important to note that we were either not working at the RCPCH in 2015-16 (in the case of Robert Okunnu), or, though working at the RCPCH in that period, Graham Sleight and Emily Arkell had no direct involvement with the operational work of the College's Invited Review work at the CoCH. Robert Okunnu is the RCPCH current Chief Executive Officer (CEO) (interim since

October 2022 and permanent since January 2023) and previously was Director for Membership, Policy and External Affairs (appointed in 2019). Emily Arkell is the RCPCH current Executive Director for Research and Quality Improvement (since April 2019), with responsibility of the Invited Reviews function. Previously she was Head of Policy at RCPCH (appointed 2013). Graham Sleight joined the RCPCH in 2002, working in publications. He became its Head of Governance and Contracts in 2012 and is currently Associate Director of Governance, Committees, Contracts and Procurement.

5. Should the Inquiry request witnesses to give oral evidence to speak to this witness statement, Emily Arkell is best placed to speak to issues regarding the RCPCH's Invited Review services. Robert Okunnu is best placed to speak to general issues regarding the RCPCH such as its governance structures and operational delivery.

6. Those who undertook and supervised the review at the CoCH are either no longer working for the RCPCH or only acted in the review as short-term contractors. Accordingly, our approach in preparing this statement has been based solely on the documentary record that the RCPCH has retained. We have sought to summarise all the relevant documents fairly and with due recognition for the limitations of the available evidence. The RCPCH recognises that the Inquiry may wish to speak directly with the reviewers, or with other senior individuals (such as former College CEOs or Presidents). The RCPCH is happy to facilitate this in any way the Inquiry sees fit.

7. Exhibits are referenced as follows: RCPCH/00(number).

Background

The structure of the royal college and its governance

8. The RCPCH is a charity established by Royal Charter in 1996. Its charitable objectives, as set out in Clause 3 of its Royal Charter, (RCPCH/0544 **INQ0010246**) are:

i) *To advance the art and science of paediatrics*

ii) *To raise the standard of medical care provided to children*

iii) *To educate and examine those concerned with the health of children*

iv) *To advance the education of the public (and in particular medical practitioners) in child health, which means the protection of children, the prevention of illness and disease in children and safeguarding their optimal development.*

9. As of 2024, RCPCH has over 22,000 members, all of whom are child health professionals – almost all paediatricians. About 75% of RCPCH members are based in the UK. Although RCPCH welcomes members from other professional groups (such as nurses and social workers) in its Affiliate category (approximately 355) (RCPCH/0545 **INQ0010247**), it is in no sense a representative body for, say, paediatric or neonatal nurses in the same way as it is for paediatricians.

10. In pursuit of the objectives set out above, RCPCH undertakes a wide range of activities. These currently include running exams and assessments for paediatricians, an extensive programme of research, policy, and advocacy, and a range of work to support improvement of paediatric practice in the developing world. The RCPCH's primary exam, MRCPCH (RCPCH/0546 **INQ0010248**), forms a mandatory part of the training pathway for UK doctors wishing to obtain a Certificate of Completion of Training in paediatrics – it is usually completed about half-way through the paediatric training pathway. (Membership exams for other Medical Royal Colleges perform a similar function.) On completion of MRCPCH, UK trainee doctors move from RCPCH's Junior Member to Ordinary Member status. MRCPCH is also offered to doctors in a number of non-UK countries, where it is widely recognised as a badge of significant professional accomplishment. In 2015-16, the paediatric training pathway had an indicative duration of eight years, but this could vary depending on how many attempts individuals took to pass key assessments such as MRCPCH.

11. Of particular relevance to the work of this Inquiry is the RCPCH's Invited Reviews (IRs) service, which provides consultancy to paediatric services encountering difficulty. It was as a result of one IRs commission that RCPCH became involved in undertaking a review for the CoCH in 2016.

12. Since 1 November 2016, the governing body of RCPCH has been a 12-member Board of Trustees comprising 7 members of the College and 5 non-members, including the Chair. One of the member Trustees is an elected President, who acts as Chair of its Council and Executive Committee. The College Presidents at the times relevant to the Inquiry's work have been Prof Neena Modi (in post 2015-18), Prof Russell Viner (in post 2018-21), and Dr Camilla Kingdon (in post 2021 to date). Dr Kingdon's successor, Prof Steve Turner, was elected in December 2023 and will take office from March 2024. The Chairs of Trustees have been Dame Mary Marsh (2016-21) and Joanne Shaw (2021 to date). Before 1 November 2016, the Trustee function was carried out by a member-only Council, chaired by the President. This Council had up to 51 members.

13. The RCPCH's staff group comprises about 200 staff (in 2016 about 140), led by a Chief Executive Officer. The RCPCH's recent CEOs have been Prof Judith Ellis (in post 2014-2018), Jo Revill (in post 2018-2022), and Robert Okunnu (in post 2022 to date). The CEO reports to the Board of Trustees via the Chair. The CEO manages the activities of RCPCH through a group of Directors (since 2023 known as Executive Directors) who comprise the Senior Management Team (since 2023, the Senior Leadership Team).

14. In 2016, the Invited Reviews team sat within the RCPCH's Research and Policy Division, whose Director was Jacqueline Fitzgerald. Jacqueline Fitzgerald left the College in 2019; her successor, leading what is now the Research and Quality Improvement Division, is Emily Arkell. The RCPCH's staff group is (with rare exceptions such as 4 Clinical Fellows, will be 6 by end 2024) not composed of paediatricians or members of the RCPCH. However, in addition to the staff group, the RCPCH relies on a pool of members and others who volunteer to support its activities – for instance, by sitting on

committees or providing clinical input into examinations. In rare cases, the RCPCH also pays for specific clinical input into individual projects/programmes of work.

Training in paediatrics

15. Part of the RCPCH's role is to oversee training in paediatrics – both in "core" paediatrics and in a set of 17 sub-specialties within paediatrics, as defined in the UK (RCPCH/0547 **INQ0010249**). Full information on the duration and requirements of the paediatric training pathway is set out on the RCPCH website (RCPCH/0548 **INQ0010250**). Further information can be provided to the Inquiry regarding specialties if needed. It sets curricula for these subspecialties via College Specialist Advisory Committees (CSACs). One of the sub-specialties which attracts the most candidates is neonatology. Neonatologists are paediatric specialists whose expertise is looking after newborn infants or those born prematurely. More details on how neonatal care is delivered in the UK will be found in our further witness statement.

16. The paediatric curricula set by RCPCH and its CSACs are ultimately overseen by the General Medical Council (GMC) – as they are for other Medical Royal Colleges. The RCPCH has a more general role in overseeing the training and assessment of UK doctors prior to their receiving a Certificate of Completion of Training (CCT). As its name suggests, the CCT marks the end of formal training in paediatrics, and the point where a doctor would normally be able to apply for NHS consultant roles. As noted above, the RCPCH runs the MRCPCH exam (normally taken by paediatricians midway through their training programme) and is also responsible for the Specialty Trainee Assessment of Readiness for Tenure (START) assessment (marking the end of the training programme).

17. More generally, in carrying out the duties set out above, RCPCH works with a number of organisations across the charitable, governmental, and child health sectors. These include the governments of the four UK nations; the British Medical Association (BMA) and the General Medical Council (GMC); and

NHS England and its equivalent bodies in the devolved nations. In the specific context of neonatal work, RCPCH has a particularly important relationship with the British Association of Perinatal Medicine (BAPM), an independent charity which represents UK neonatologists.

Invited Reviews

18. The RCPCH has run a service of "Invited Reviews" (IRs) for over a decade. These are also known as invited service reviews. Under this programme, a small team of RCPCH-identified experts visit paediatric services that are experiencing specific problems. The team interview relevant individuals at the service, review other evidence, and provide a report giving recommendations. The service was put on a formal footing at the RCPCH, with a Programme Board guiding its work, from 2012. As will become clear in the statement, the Invited Reviews service offered by the RCPCH in 2024 (RCPCH/0550 **INQ0010252**) differs in several ways from that offered in 2016. Many other Medical Royal Colleges provide similar Invited Review services in their own specialties, and these are guided by common standards set out by the Academy of Medical Royal Colleges (AoMRC) (RCPCH/0551 **INQ0010195**). Invited Reviews are commissioned and paid for by the commissioning organisations, i.e. the hospitals or commissioning groups concerned with the provision.

19. By 2016, the RCPCH IR service was undertaking about a dozen reviews a year. It was led by the then Head of Invited Reviews Sue Eardley, who worked at the RCPCH from January 2011 to November 2019. Sue Eardley is not a clinician but, prior to her work at the RCPCH, had extensive experience in health service management, including as Chair of an NHS Trust and through working for the Care Quality Commission. The internal Programme Board that oversaw the IR programme of work was chaired in 2016 by Dr David Shortland (RCPCH/0396 **INQ0010204**-RCPCH/0398 **INQ0010206**), the RCPCH's Vice President for Health Policy. The IR service applied expertise to

improve the delivery of child health services and generates a small amount of income for the College.

Policy and standards

20. The RCPCH's Royal Charter states that, in carrying out its charitable objectives it has power (among other things):

> *4 (viii) to undertake regular audit of training and practice where appropriate in association with other bodies*
>
> *(ix) to act as a consultative body on Paediatrics to our Government, statutory bodies, and to the public.*

It is within the scope of these powers that the RCPCH's policy and standards work generally takes place. This work may be broadly categorised into two areas: proactive and reactive work. It should also be noted that the RCPCH's remit covers the whole of paediatrics rather than being confined to any one sub-specialty such as neonatology. That said, the views of sub-specialties are self-evidently important to the overall picture, and the RCPCH convenes a regular Specialty Board, chaired by the President, at which views on questions of policy and standards can be exchanged. BAPM, the specialist society for neonatology mentioned above, is an active member of Specialty Board. It should be noted, separately, that BAPM has for many years had a service arrangement with RCPCH whereby BAPM purchases RCPCH services for its staff (primarily office space, IT services, and HR support). In RCPCH's eyes, this does not affect BAPM's independence as a representative body for UK neonatologists, which the College has always sought to respect.

21. Within the "proactive" category of work, there are some continuing programmes. For instance, the RCPCH has for many years carried out a census/survey of the UK paediatric workforce (RCPCH/0552 **INQ0010253**) to understand the trends in numbers of various categories of roles. The RCPCH has also at various times initiated pieces of work on paediatric standards and staffing. These have included *Facing the Future* (2010, revised 2015) (RCPCH/0542 **INQ0010244**)

and *Paediatrics 2040* (2021) (RCPCH/0543 **INQ0010245**). A continuing programme of work of particular relevance to the Inquiry is the National Neonatal Audit Programme (NNAP) (RCPCH/0553 **INQ0010254**). The RCPCH has undertaken this programme to audit standards in neonatal care since 2006, funded by the Healthcare Quality Improvement Partnership (HQIP). The HQIP sets the remit for the work which is then undertaken by RCPCH. HQIP is a non-governmental body largely funded by NHS England. Its purpose is to improve the delivery of health services by the use of measurement and data. As a central part of this, it funds a wide range of clinical audits such as NNAP and disseminates their findings.

22. Within the "reactive" category fall a large number of pieces of work prompted by or in collaboration with other bodies. These bodies include the National Institute for Health and Care Excellence (NICE), the Departments of Health in the four UK nations, or other relevant bodies such as NHS Digital. These projects are often ad hoc and time limited: the RCPCH will be asked to provide its view on a specific change, policy, or clinical issue. Sometimes the RCPCH's input will take the form of a written consultation response (for instance, on a NICE guideline), and sometimes there will be involvement via the RCPCH sending a representative to a committee or other body. At a rough estimate, the RCPCH provides around 60 of these ad hoc responses every year. It also encourages other bodies – such as BAPM in the field of neonatology – to undertake such work themselves.

23. Therefore, when the RCPCH is called in to undertake an Invited Review, it has a wide range of policies and standards to refer back to. Some will be its own, and some will be generated by other bodies in the field. The number of standards set out below that the CoCH review referred to is not at all atypical – as is the wide range of bodies that generated them.

RCPCH Invited Reviews information

24. For the purposes of context, we have set out in this statement other Invited Reviews undertaken by the RCPCH across the UK.

This information:

- is based on 'visit dates'
- is from January 2012 up to and including May 2016
- totals 59 reviews (RCPCH/0531 **INQ0012854**)

25. In line with RCPCH Invited Reviews retention policy, all documents older than 6 years are deleted, with the exception of the final report which is archived after 7 years and the deed of indemnity which is deleted after 12 years from issue of report – this is denoted with an * and any information found, from a tracker spreadsheet, has been included.

26. Invited Reviews conducted by the RCPCH can take different forms depending on the request from the service, the below definitions represent the standard types of reviews the RCPCH Invited Reviews Service undertook, and the text is sourced from the '160816 RCPCH Reviews Guide August 2016' document (RCPCH/0001 **INQ0010214**):

Design Review	A request where there is no specific urgent concern about safety but an independent College view is sought over plans for reconfiguration or changes to service provision. Any reconfiguration plans should also be tested against the quality and safety of the current and planned service. It is important that consideration of nursing, therapy and administrative resources should be included in any redesign. A design review request may be for an objective opinion on an existing proposal or a request for expertise to develop a proposal and to fully analyse activity and develop a range of options. If there is an extensive amount of modelling or development work required, RCPCH may suggest individuals or an organisation from a retained list that may be more appropriate to assist either directly or as part of a College response team. The conclusions and proposals arising from the review will be objectively assessed by the College as to whether they deliver appropriate interpretation of College standards.
Individual Performance Review	A request primarily to examine the clinical practice of an individual doctor or doctors causing concern. This may involve case note analysis but would always be carried out in the context of the service in which the individual is working and will include a

	visit and interviews with the doctor under review and other relevant individuals.
Service Review	An invitation to visit and comment upon a current service. This may be the whole paediatric service or a specific element such as safeguarding, neonates or emergency care. It will include meeting the paediatricians, nurses, managers and others who have links with the service. The terms of reference will usually be rooted in the quality, safety and efficiency of that service. The service review model may also be used for investigating incidents where a number of clinicians were involved in a single case or whether the service provides a suitable environment for training, in which case we would work closely with the deanery, Regional Adviser and Head of School.

More details of RCPCH Invited Reviews between 2012 and 2016 can be found in RCPCH/0531 **INQ0012854**).

The below definition was absent from the '160816 RCPCH Reviews Guide August 2016' document. We have reviewed the minutes from the Invited Review Programme Board dated 28 January 2016 but these do not include any detail or information about why the definition was not included. The definition below has been sourced from the 'RCPCH Reviews Process and Guidance Manual (November 2018)' document:

Case note Review	May be standalone or conducted alongside a service or individual review. It provides an objective, college-backed independent report on the management of a case or cases and would usually involve two reviewers. Discussion of the case or cases with the clinician(s) involved may or may not be included depending upon the purpose of the review.

The below definitions are 'one off' or miscellaneous types of review the RCPCH Invited Reviews Service undertook and are not defined within the guides/manuals. They have been defined retrospectively based on the individual request:

Other – Consultancy	A review of service provision at a proposed site.

Other – Options Appraisal	An options appraisal for the reconfiguration of a proposed service.
Training review	An assessment of the sustainability and viability of proposed training sites.

27. Information on all reviews we have conducted and completed after 2016 are available to the Inquiry if requested.

Purpose and operation of RCPCH Invited Reviews

28. Invited Reviews 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 from a team of independent, expert peer reviewers. 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.

29. Invited Reviews aim to provide an opportunity to understand the issues and challenges facing a specific service and to listen and support staff who are invited to participate and their perspectives of delivering care. Invited Reviews also provide an opportunity to identify new ways of working to deliver care to patients and solutions to intractable problems that some services may have faced over a significant period of time.

30. They are commissioned by healthcare organisations to provide independent and objective expert advice on the clinical services they provide, through reliable, trustworthy peer review processes. The RCPCH Invited Reviews Service undertakes the review as an independent organisation, commissioned by the healthcare organisation with both bodies sharing the same core purpose. Detailed information about the process can be found in this Exhibit (RCPCH/0532).

31. Information gathered as part of Invited Reviews is from a number of different sources to facilitate triangulation in the forming of conclusions and recommendations. This includes relevant background documentation provided by the healthcare organisation, interviews with staff, stakeholders, and, where relevant and appropriate, service users (or representative groups). It may also be agreed that it would be helpful for the review team to visit the site(s) where the service(s) under review is provided.

32. Clinical reviewers include a number of clinician specialities, bringing experience and expertise in different areas of paediatric care, including community, acute, neonatal and specialist paediatric provision. Invited Review teams were configured to meet the needs of the type of review and the service(s) involved, reviewers have been typically recruited by the Head of Invited Reviews, via RCPCH communication channels, e.g. Clinical Leads ebulletin (RCPCH-0541 **INQ0010243**) (this was a monthly newsletter to update Clinical Leads of paediatric units about recent policy and NHS developments and was sent to them between November 2012 and March 2020).

33. Review Teams are configured by selecting paediatricians and nurses who had demonstrated specific knowledge, skills and experience requirements and attended relevant training and update sessions. Very often the configuration of Invited Review team members would be dependent on availability to participate in the review. The length of time taken to establish the Invited Review team can take up to a 10 week lead in time which is required for both the Invited Review Team and the healthcare organisations. Normally, Invited Review teams comprise:

- ∞ Two consultant paediatricians (or equivalent e.g. Specialty Doctors of Specialists) from the Invited Reviews Service pool of reviewers, one of which, as the lead, has completed at least two reviews.
- ∞ A paediatric/neonatal nurse with the appropriate clinical expertise, experience and training in relation to the issues and areas for review.

34. In certain circumstances, there may also be a reviewer representing another Royal College, should the terms of reference indicate that this would be helpful. Some reviews used lay reviewers who were deemed to have relevant knowledge and skill and had attended an induction and development day hosted by the Invited Reviews Service.

35. The objectives of the induction and development days for reviewers included:

- Providing an overview and explanation of the review programme scope and practice
- Sharing and consolidating knowledge and expertise
- Strengthening understanding of RCPCH standards
- Facilitating interactive peer-group learning and relationship building
- Providing an overview and context of the regulatory environment and levers
- Increasing strategic awareness of healthcare policy and child health
- Improving negotiation, discussion, communication, interview and interpretive skills

36. Attending the induction and development day was not compulsory for prospective reviewers. We cannot definitively confirm that all reviewers attended the induction and development days that were organised by the Invited Review Team. The induction and development day was approved as continuing professional development (CPD) by the RCPCH Revalidation and CPD Coordinator in line with existing RCPCH CPD guidelines at the time.

37. An Invited Review Manager will be assigned to the review, which in 2016 would have been the Head of Invited Reviews. This is normally a non-clinical member of staff of the RCPCH Invited Review Service with appropriate experience in managing reviews to ensure they ran to the agreed schedule, that all information was properly recorded and shared between the review team and to coordinate the feedback session at the end of the review.

38. The Invited Review process uses clinicians' expert and in-depth knowledge of standards, national guidelines and service models, and recognised best practice in reviewing services to provide advice, recommendations and external assurance around quality improvement. The guidelines and service models used in each Invited Review will depend on the type or review requested and the medical speciality which is being reviewed. This approach is designed to assist healthcare organisations to resolve concerns about child health service provision and work towards sustainable services with improved outcomes for children and young people and support compliant, effective working arrangements for professionals.

39. The scope of the review is defined by Terms of Reference. The Terms of Reference are initiated by the organisation commissioning the review and agreed with the appointed Invited Review team. Invited Reviews differ from inspections from statutory regulators such as the Care Quality Commission as they are commissioned by an organisation where there is a specific issue relating to the delivery of care or design of the service and an external professional perspective would be helpful in resolving this challenge and providing recommendations and solutions for future improvement.

40. The report issued to the healthcare organisation is collectively agreed by the review team, undergoes a quality assurance process and includes findings, conclusions and recommendations. The quality assurance process is a formal and confidential part of the Invited Review process and is conducted by at least two clinicians with expertise in the core area under review who have no perceived or actual conflict of interest. Their role is to provide an objective commentary on the report, including the confirmation that the opinions and interpretation of compliance with standards are appropriate and represent the views of the RCPCH.

41. After the report is issued to the healthcare organisation who commissioned the review, a follow-up seeks information on what actions it has taken to address the report's recommendations. The concept behind this is to create a culture of accountability and demonstrates the quality of the Invited Review service

provided, which goes beyond the provision of a report. Looking at some of the reviews, the RCPCH's position is that the follow up at the time of some previous reports do not meet the current 2023/4 expectations of reviews.

42. Changes to the programme were implemented in 2022/3 to ensure it is delivered in line with the principles set out in the Framework of operating principles for managing Invited Reviews within healthcare published in March 2022 by the Academy of Medical Royal Colleges (AoMRC) (RCPCH/0551 **INQ0010195**).

43. Changes to the RCPCH Invited Review service have also been made in response to the recommendations made following an external review of the RCPCH Invited Reviews Programme. The review was led by Helen Crisp, an independent quality improvement consultant in healthcare. It was commissioned to ensure the quality of service and identify improvements in its delivery to enable it to respond and adapt to the changing landscape of healthcare provision for children and young people. The review took place in late 2020 and early 2021 and further details about it are outlined below.

Countess of Chester Hospital Invited Review 2016

44. This describes the process and delivery of the Invited Review at the CoCH, including the configuration of the reviewers, the commissioning of the review by the CoCH, agreeing the terms of reference and the deed of indemnity.

45. The team for the CoCH review in September 2016 comprised the following:

- Sue Eardley
- Alex Mancini
- Claire McLaughlan
- Dr David Milligan (Lead Reviewer)
- Dr Graham Stewart

46. Sue Eardley was Head of Invited Reviews (an RCPCH employee) between 2011 and 2019. She reported to the then Director of Research and Policy Jacqueline Fitzgerald. The other four reviewers were external professionals contracted on a consultancy basis to carry out the CoCH review. The four external reviewers therefore did not have RCPCH line management reporting hierarchies; they were accountable to Sue Eardley (and, through her, to the Invited Review Programme Board) for performance of their contractual obligations.

47. The Lead Reviewer would be expected to provide clinical leadership throughout the Invited Review, chair the meeting between the reviewers at the end of the final day of the review to discuss findings and any immediate recommendations identified throughout the review and then feed these back to the commissioners of the review at the final feedback session before concluding the onsite review.

48. The reviewers were drawn from a wider pool of reviewers managed by Sue Eardley to be drawn upon for Invited Reviews. Clinicians who expressed an interest in being a reviewer could self-nominate to join the pool. At the time, the role as a reviewer would have been communicated through the Clinical Leads ebulletin which would have been sent to service leads in paediatric units across the UK. They would be invited to express their interest directly to Sue Eardley as Head of the Invited Reviews Service. Depending on the request from a service and the issues covered in a review, reviewers and their skills would be matched to the request by Sue Eardley. Reviewers would be invited to an induction and development day to equip them with the skills, knowledge and expertise to carry out a review (example of an Invited Review induction and development day agenda from 2019 RCPCH/0540 **INQ0010215**).

49. Relevant professional qualifications of the reviewers who reviewed the neonatal unit at the CoCH at the time were set out in Appendix 1 of the final report provided to CoCH (RCPCH/0452 **INQ0012795**) but are summarised here:

    - Alex Mancini was a senior neonatal nurse with over 25 years' experience working in a range of neonatal units. In 2016, she had recently been

appointed as the Pan London Lead Nurse for Neonatal Palliative Care (RCPCH/0390 - RCPCH/0393 **INQ0010198**- **INQ0010201**). INQ0010199 INQ0010200

- Claire McLaughlan was a former Associate Director of the National Clinical Assessment Service (the National Clinical Assessment Service was the predecessor organisation to NHS Resolution which is an organisation that works towards the resolution of concerns about professional practice in healthcare settings across the United Kingdom. She was also a non-practising barrister and a former Head of Fitness to Practise at the Nursing and Midwifery Council (RCPCH/0394- RCPCH/0395 **INQ0010202- INQ0010203**).

- Dr David Milligan was a consultant paediatrician and neonatologist at the Royal Victoria Infirmary and Great North Children's Hospital in Newcastle for 30 years until his retirement in 2013.

- Dr Graham Stewart had been a consultant paediatrician with a special interest in neonatology since 1994. He also had over fifteen years' experience in clinical leadership and management posts (RCPCH/0399- RCPCH/0404 **INQ0010207- INQ0010212**). INQ0010208 INQ0010211

50. Using a team of this size and multi-professional mix was standard practice for an Invited Review of this kind conducted by the RCPCH.

The commissioning of the Service Review

51. The Service review was commissioned by Ian Harvey, Medical Director at the Countess of Chester Hospital Foundation Trust. The first contact from Ian Harvey to the RCPCH enquiring about the Invited Review service hosted at the RCPCH was on 28 June 2016 at 10.02am and sent to a generic 'Enquiries' inbox (RCPCH/0002 **INQ0009615**).

52. Thereafter, there were a series of emails between Ian Harvey and Sue Eardley and it appears there were telephone conversations. However, we do not know

what was discussed or agreed during these conversations or how many conversations happened as we have not found any handwritten notes or other records to reflect those telephone calls. The email correspondence indicates that they spoke to one another on the telephone about the review request which helped inform the briefing sheet which sets out in more detail about the paediatric and neonatal unit at the CoCH, Ian Harvey's medical career, local political issues and media coverage of issues at the hospital plus data that the RCPCH had access to which related to the hospital. The briefing and data sheet would have been used to collate information about the neonatal service and the CoCH to inform the development of the terms of reference. Although we do not know how the briefing was developed and who wrote it, it would appear that the information collated in comprises the results of research via the internet and provided directly by Ian Harvey to Sue Eardley as set out in the briefing and data collection sheet for Invited Review (27/06/2016) (RCPCH/0003 **INQ0009590**)

53. Following the initial contact from Ian Harvey on 28 June 2016, a draft proposal was sent to him on 30 June, after an email from him asking when the document would be sent to him. The time period for developing the proposal and terms of reference of the review was unusually short as it normally takes a number of weeks to draft a proposal and there is often correspondence between the commissioning organisation and the RCPCH to agree the terms of reference. From the RCPCH's perspective in 2024, the proposal and terms of reference of the Invited Review at the CoCH were compiled more quickly than usual. It can take up to 10 weeks to draft and agree terms of reference. It appears that there was no clinical involvement from the RCPCH reviewers or any member of the Invited Review Programme Board in developing them. It also appears that no other staff members, nor members of the Programme Board at the time of the review, were involved in drafting, reviewing or signing them off (RCPCH/0004 and RCPCH/0005 **INQ0009595 and INQ0009596**).

54. From the email exchanges between Ian Harvey and Sue Eardley, he replied to her on the 7 July 2016 to confirm that he agreed the terms of reference. Ian Harvey also informed Sue Eardley that after lengthy network and regulator

consultations, that the neonatal unit would be downgraded on the 7 July 2016, effectively closing the intensive care unit cots pending further data collection and the review and that this may feature in the local press. On 8 July 2016, Sue Eardley forwarded an article contained in Chester Chronicle which featured this story to the Media and External Affairs team and the Policy team at the RCPCH in case any media enquiries were received about the review (RCPCH/0006 **INQ0010255**).

55. According to the email exchanges Sue Eardley contacted Ian Harvey again on the 12 July 2016 to provide an update to him about the Invited Review team, the deed of indemnity and the contract. Sue Eardley also enquired about parental involvement in the review and whether parents of infants who died at the unit would be prepared to participate.

56. On 13 July 2016, Ian Harvey replied: "we made every effort to contact the parents of every baby who had died during the increased incidence period before the story was in the local paper – address and phone number changes meant we couldn't contact all. Part of the conversation was that we would share the findings of the review with them. To my knowledge none has requested seeing the review team." (RCPCH/0002 **INQ0009615)**.

57. During our review of files, we have located a draft terms of reference which is not dated and there appears to be no version control for it (RCPCH/0007 **INQ0010257**). We have also located a confidential copy of the terms of reference for the review (RCPCH/0009). The terms of reference were sent Ian Harvey, Medical Director at CoCH on 2 August 2016 from Sue Eardley (RCPCH/0009 **INQ0009597**):

Contract

58. The first draft of the contract for review was sent on 12 July 2016 with associated correspondence (RCPCH/0010 and RCPCH/0011 **INQ0009598 and INQ0009599**). This is a standard contract for Invited Reviews requested by commissioning organisations.

59. A final version of the contract, including the Terms of Reference, was sent on 2 August 2016, along with a request from more detailed information and data from Badgernet (RCPCH/0012, RCPCH/0013 and RCPCH/0009 **INQ0009603, INQ0009607 and INQ0009597**).

Deed of Indemnity

60. The deed of indemnity which was an agreement between the RCPCH, the Countess of Chester NHS Foundation Trust and the reviewers (Claire McLaughlan, Graham Stewart, David Milligan and Alex Mancini) the purpose of which is to specify the actions and consequences which will result should a particular event or events occur. The deed of indemnity was signed by the RCPCH (David Howley, the Director of Corporate Services) and the Countess of Chester Hospital NHS Foundation Trust (Ian Harvey, the Medical Director at CoCH). This is a standard document signed in any review.

- Draft Deed of Indemnity for the Review (RCPCH/0014, RCPCH/0068, RCPCH/0129 and RCPCH/0134 **INQ0009608, INQ0009594, INQ0009588 and INQ0009589**)

- This is a fully signed copy of the deed of indemnity signed on 5 August 2016 (RCPCH/0015 **INQ0010186**)

Preparation and planning for the CoCH Service Review

61. As part of the preparation for the review, a flyer (information) document was written and sent to all of the people who were invited to participate in the review. This was a normal and standard practice in the preparation for an Invited Review and set out the background to and process of the review. The flyer was sent to interviewees in August 2016 in preparation for the Invited Review which was scheduled to take place on the 1 and 2 September 2016 (RCPCH/0016 and RCPCH/0017 **INQ0009592 and INQ0009593**). Drafts of this have also been

found, but we are not clear who saw these (RCPCH/0018 and RCPCH/0019 **INQ0009586 and INQ0009587**).

62. As part of the review preparation, a checklist was developed for the CoCH to complete and return to the RCPCH in advance of the initiation of the onsite review at the hospital (see the exhibit Trust checklist for preparing for the Invited Review draft version (RCPCH/0020 **INQ0009609**) and final version (RCPCH/0021 **INQ0009610)**. This was a standard practice to ensure that a range of background data and information that the review team required to look at was available and that arrangements for the interviews with participants was organised for the onsite review. The checklist includes a list of suggested participants. It is important to note that the hospital had discretion in deciding who was invited to participate in the review (page 1 and 2 of RCPCH/0021 **INQ0009610**).

63. The checklist included logistical details for the review team and interview rooms. It also included information about the hospital, local plans and audit data, although not an exhaustive list (page 3 and page 4 of RCPCH/0021 **INQ0009610**).

Timetables

64. A timetable was developed for the review at the neonatal unit at the CoCH on the 1 and 2 September 2016. An onsite review of two days is normal and standard practice for a review of this size and would have been seen as reasonable given the terms of reference which were agreed between Sue Eardley and Ian Harvey. A timetable for the RCPCH Invited Review on 1 and 2 September 2016 is set out at RCPCH/0025 **INQ0010171**.

65. The list of interviewees included:

Alison Kelly, Director of Nursing and Quality
Ian Harvey, Medical Director and Deputy CEO
John Gibbs, Consultant Paediatrician
Susie Holt, Consultant Paediatrician

Doctor V Consultant Paediatrician

Murthy Saladi, Consultant Paediatrician

Doctor ZA Consultant Paediatrician

Emma-Jayne Punter, Business Performance Assistant

Gill Mort, Business Performance Manager

Carol Jackson, Nurse Consultant, Transport Team, Liverpool Women's Hospital Foundation Trust

Dr Howie Isaac, Consultant Community Paediatrician

Karen Milne, Safeguarding Children Lead

Paula Lewis, Safeguarding Children Practitioner

Dr Rajiv Mittal, Community Consultant Paediatrician

Huw Mayberry, Trainee Paediatrician

Sudeshna Bohwmik, Trainee Paediatrician

Jenny Loughnane, Trainee Paediatrician

Jill Stratford, Trainee Paediatrician

Gemma Fairclough, Trainee Paediatrician

Maya James, Trainee Paediatrician

Jessica Burke, Trainee Paediatrician

Charlotte Thorne, Trainee Paediatrician

Colin Morgan, Head of School Paediatrics, Health Education North West

Julie Maddocks, Director of North West Operational Delivery Network

Karen Mainwaring, Quality Improvement Lead Nurse, North West Neonatal Operational Delivery Network

Jacqueline Morgan, Neonatal Manager, Wirral

Yvonne Farmer, Nurse/Nurse Practitioner

Eiran Powell, Nurse/Nurse Practitioner

Anne Murphy, Nurse/Nurse Practitioner

Yvonne Griffiths, Nurse/Nurse Practitioner

Sharon Dodd, Specialist Nurse Safeguarding Children

Andrew Higgins, Non-Executive Director

Ruth Milward, Clinical Governance/Risk Management

Sara Brigham, Consultant Obstetrician/Gynaecologist

Jim McCormack, Consultant Obstetrician/Gynaecologist

Gwenda Jones, Midwife

Becky Fryer, Midwife
Lorraine Millward, Midwife
I&S , Patient Representative
I&S Patient Representative

66. The timetable also identified a feedback session at the end of the second day of the review. Participants identified for this session included:

Tony Chambers, Chief Executive, Countess of Chester Hospital
Alison Kelly, Director of Nursing and Quality
Ian Harvey, Medical Director and Deputy CEO

67. During our review of files and folders we located redacted timetables for the Invited Review on 1 and 2 September 2016 (RCPCH/0022 and RCPCH/0023 **INQ0010170 and INQ0009616)**. We do not know why they are redacted and by whom.

68. We also located a version of the interview timetable with handwritten comments by Sue Eardley (RCPCH/0024 **INQ0010187**).

69. It is relevant to note that Lucy Letby was not included in the formal list of interviewees. It appears that the interview with Lucy Letby and Hayley Cooper, who we understand was Lucy Letby's union representative at the Royal College of Nursing, were added to the list of interviewees at the end of the first day of the review (1 September 2016). It is unknown how or when this interview was arranged and by whom it was agreed. It was highly unusual that the interview with Lucy Letby and her union representative was arranged as she was suspended from clinical duties at the time of the Invited Review and her participation in it could have interfered with the process at the CoCH relating to this.

70. In 2016, there was not a standard protocol used by the Invited Review Service at the RCPCH on interviewing staff who are suspended from their substantive positions as part of an Invited Review. To our knowledge, this had not occurred before this review, and so there was no advice set out in the protocols and

practices accompanying the reviewers on this issue. The drafters of this witness statement were not on site at the time, and information can be sought from the reviewers directly. The decision to interview Lucy Letby was unusual and outside the range of usual experiences during reviews.

71. We have made a number of substantial changes to the Invited Review Service at the RCPCH since 2021 following a thorough and robust external review. The Handbook for Healthcare Organisations *advises that if a member of staff is involved in a formal internal human resources process, that they do not participate in the review.* This advice postdates the 2016 review.

Contracts for Invited Reviewers and Quality Assurance Reviewers

72. RCPCH/0026- RCPCH/0036 **INQ0009621- INQ0009631** exhibits the contracts for each member of the RCPCH Invited Review, and quality assurance forms for the clinicians who quality assured the final reports which were returned to the CoCH after the review had concluded. The clinicians who provided the quality assurance for the reports were Jon Dorling and Nic Wilson.

The unpublished version(s) of the report and the underlying materials

73. As part of any Invited Review, a range of background information is analysed. We have been able to identify the following documents in archived folders which relate to the review at the CoCH. The range of documents set out below would not have been unusual. We would also point to the number of different organisations who generate these standards, data, and evidence all of whom operate with different remits and guidelines. These documents included:

    a. A Care Quality Commission review report about the CoCH from 2016 (RCPCH/0051 **INQ0009632**). This report describes the Care Quality Commission's judgement of the quality of care at the CoCH. It is based on a combination of what the Care Quality Commission found when it

inspected the hospital in February 2016 from its 'intelligent monitoring system' information from patients, the public and other organisations. The trust was rated overall as 'good' and services were rated good for safety, effectiveness, well-led and caring. The Care Quality Commission stated that services required improvement for responsiveness.

b. An MBRRACE-UK Perinatal Mortality Surveillance report titled *UK Perinatal Deaths for Births from January to December 2014* (RCPCH/0052 **INQ0009633**). This report has many key findings and is a detailed document with a number of recommendations. The key finding was that significant variation in the rates of extended perinatal mortality across the UK persisted, even after taking into account the effects of chance variation relating to small numbers of births in some organisations and adjusting for the case-mix differences. Amongst organisations responsible for commissioning care, stabilised and adjusted rates varied from 4.9 to 7.1 deaths per 1,000 total births.

c. An excel document with information about the consultants working at the CoCH (RCPCH/0053 **INQ0009634**). This includes their name, date of birth, gender, job title, paediatric subspecialty, General Medical Council number.

d. Activity and capacity demand at the neonatal unit at the CoCH between April 2014 and March 2016 (RCPCH/0054 – RCPCH/0056 **INQ0010155, INQ0010089 and INQ0010094**). This document was written by the North West Neonatal Operational Delivery Network and attempts to determine the cot capacity (beds required for sick babies in a neonatal unit) required to safely deliver the current and predicted demand for neonatal services. It provides an overview of the activity (number of babies admitted to neonatal units) and capacity (availability of cots) of the neonatal units within the Cheshire and Merseyside Neonatal network.

e. The Pan-Cheshire Child Death Overview Panel Protocol (RCPCH/0057 **INQ0010095**). This document sets about the arrangements and processes for comprehensive and multidisciplinary reviews of the death of a child by the Pan-Cheshire Child Death Overview Panel.

f. Cheshire and Merseyside Local Neonatal Unit mortality data from 2014-2016 (RCPCH/0058 **INQ0010096**).

g. Report by the North West Neonatal Operational Delivery Network entitled 'Improvements to services for neonates requiring surgical care' dated September 12 2016 (RCPCH/0059 **INQ0010097**). This report sets out actions to improve the quality of care of neonates who may need care or treatment from the regional neonatal surgical service. The review includes an evaluation of the service and pathways; benchmarked against national quality standards, best practice with assessment of whether the service is truly patient and family centred.

74. We have identified information sources that may have been used by the reviewers as additional background but we cannot say for certain whether the review team used each of these, but they have been found within relevant documents used by the reviewers for this Invited Review. The range of documents set out below would not have been unusual for the volume of relevant sources that an Invited Review could have drawn on. It is also important to note the number of different organisations who would have generated these standards, data, and evidence for different purposes and measurements. These include:

    a. An example of a neonatal discharge summary record (RCPCH/0060 **INQ0010098**)

b. An improvement report by the North West Neonatal Transport Service which focuses on (RCPCH/0061 **INQ0010099**):
    i. Compliance with the National Neonatal Transport Service Specification
    ii. Equity of access and service provision
    iii. Work force challenges
    iv. Financial challenges
    v. Ambulance vehicle provision

c. A neonatal delivery action plan developed by Dr Sara Brigham, Consultant Obstetrician (RCPCH/0062 **INQ0010100**).

d. An email exchange between Sue Eardley and Steve Brearey between 12th September and 4th October 2016. Sue lists requests for further documentation and information to inform the development of the reports (RCPCH/0063 **INQ0010109**).

e. Resuscitation record template (RCPCH/0064 **INQ0010111**).

f. The Pan-Cheshire Child Death Overview Panel annual report 2014-15 and action plan for 2015-16. This contains detailed information about 48 child death in the Pan-Cheshire area between 2014-15 (RCPCH/0066 **INQ0010112**).

g. A document that sets out a pathway to follow when a child dies along with a timeline in the event of a sudden and unexpected or expected death of a child (RCPCH/0067 **INQ0010117**).

75. As part of any Invited Review there is a request to the commissioner of the service being reviewed for all relevant information about the service. We have been able to locate the following documents in archived folders which were supplied to the RCPCH Invited Review Service in advance of the Invited Review on the 1 and 2 of September 2016. As with other lists of evidence provided to the

Inquiry, we have made extensive efforts to provide the full set of relevant documents. However, we cannot guarantee that no documents have been lost between 2016 at the time of compiling this statement.

76. Information and documents provided by the CoCH to the RCPCH to inform the review (RCPCH/0117- RCPCH/0368 **I[INQ0009635 INQ0009643, INQ0009691, INQ0009696, INQ0009697, INQ0009588, INQ0009699, INQ0009701, INQ0009703, INQ0009705, INQ0009589, INQ0009709- INQ0009718, INQ0009724, INQ0009730 - INQ0009732, INQ0009756-INQ0009762, INQ0009764, INQ0009766, INQ0009767, INQ0009774, INQ0009775, INQ0009777, INQ0009787- INQ0009790, INQ0009809-INQ0009813, INQ0009815, INQ0009817, INQ0009819, INQ0009821, INQ0009823, INQ0009833, INQ0009836, INQ0009841, INQ0009842, INQ0009844-INQ0009850, INQ0009852- INQ0009927, INQ0009930- INQ0009969, INQ0009978- INQ0010010, INQ0010073, INQ0010074, INQ0010078, INQ0010082, INQ0010086, INQ0010088, INQ0010011, INQ0010017-INQ0010023, INQ0010025, INQ0010026, INQ0010027, INQ0010030-INQ0010034, INQ0010036, INQ0010037, INQ0010054- INQ0010057, INQ0017464 INQ0010070- INQ0010072**). This folder contains a number of folders and separate standalone documents including:

    a. neonatal unit incidents summaries in 2014-15 and 2015-16 (RCPCH/0118- RCPCH/0124 **INQ0009635 - INQ0009642)**
    b. Datix reports (RCPCH/0117 **INQ0009635**
    c. Urgent Care Divisional Board meeting minutes from April to November 2015 (RCPCH/0125-RCPCH/0135 **INQ0009643, INQ0009691, INQ0009696, INQ0009697, INQ0009588, INQ0009699, INQ0009701, INQ0009703, INQ0009705, INQ0009589, INQ0009709)**
    d. Women and Children's Care Governance Board meetings minutes from April to December 2015 (RCPCH/0136-RCPCH/0145 **INQ0009710- INQ0009718 and INQ0009724**)

e. Urgent Care Governance Board meeting minutes from January to June 2016 (RCPCH/0146-RCPCH/0150 **INQ0009730- INQ0009732 INQ0009756 and INQ0009757**)

f. Cheshire and Merseyside Neonatal Network Clinical Effectiveness Group Meeting Minutes from June 2013 to May 2016 (RCPCH/0151- RCPCH/0164 **INQ0009758- INQ0009762, INQ0009764, INQ0009766, INQ0009767, INQ0009774, INQ0009775, INQ0009777, INQ0009787, INQ0009789, INQ0009790**)

g. Cheshire and Merseyside Neonatal Network Board Meeting minutes from June 2013-May 2016 (RCPCH/0165-RCPCH/0178 **INQ0009809 -INQ0009813, INQ0009815, INQ0009817, INQ0009819, INQ0009821, INQ0009823, INQ0009833, INQ0009836, INQ0009841, INQ0009842**)

h. Details of job plans for the consultants working in the neonatal unit at the Countess of Chester (Ravi Jayarem, Steve Breary, Susie Holt, **Doctor V** John Gibbs, Murthy Saladi) (RCPCH/0179-RCPCH/0186 **INQ0009844- INQ0009850**)

i. Details of agency staff/locums and trainees working at the neonatal unit between 2012 and 2015 and the registrar rota from August 2013 to September 2016 (RCPCH/0187-RCPCH/0194 **INQ0009852- INQ0009859)**

j. Oncall medical rotas from January 2012 to June 2016 (RCPCH/0195- RCPCH/0249 **INQ0009860- INQ0009914**)

k. Details of staff training and attendance (RCPCH/0250-RCPCH/0257 **INQ0009915- INQ0009922**)

l. Policies relating to the delivery and discharge of neonatal care at the CoCH (RCPCH/0258-RCPCH/0266 **INQ0009923- INQ0009927, INQ0009930- INQ0009933**)

m. Information of mortality reviews of babies who died at the CoCH between 23 March 2010 and 24 June 2016 (RCPCH/0267 – RCPCH/0300 **INQ0009934- INQ0009967**)

n. Activity data for the neonatal unit at the CoCH including information about admissions in 2015 and 2016 (RCPCH/0301- RCPCH/0316 **INQ0009968- INQ0009969, INQ0009978- INQ0009991**)

o. Information about neonatal incidents between January 2015 and June 2016 (RCPCH/0317—RCPCH/0335 **INQ0009992- INQ0010010)**

p. Information about the Cheshire and Merseyside Neonatal Transport Service and its performance in 2015 and 2016 (RCPCH/0336- RCPCH/0341 **INQ0010073, INQ0010074, INQ0010078, INQ0010082, INQ0010086, INQ0010088**).

77. A to do list including potential contacts for a case note review and additional information and data to inform the findings of the RCPCH Invited Review (RCPCH/0069 **INQ0010174**).

78. Anonymised mortality cases for review with chronology. There is no context, rationale or explanation why these cases have been selected for review that we can find in the materials selected for review (RCPCH/0070 and RCPCH/0071 **INQ0010168 and INQ0010169**).

79. A list of deaths of babies March 2010 and June 2016 (RCPCH/0072 **INQ0010175**).

Interviews with staff at the CoCH

80. We have exhibited notes by RCPCH reviewers of interviews during the Invited Review on 1 and 2 September 2016 (RCPCH/0073 – RCPCH/0080 **INQ0010118- INQ0010125**). These include:

Interview with Ian Harvey, Medical Director and Alison Kelly, Director of Nursing

81. We have exhibited notes by Graham Stewart who interviewed Ian Harvey and Alison Kelly on the first day of the review. The key points from the interview include:

- ∞ The terms of reference of the review are broadbrush.

- ∞ There has been concern raised about one particular member of staff who has been taken out of clinical practice and that only senior team members are aware of the concerns that had been raised. Support for that staff member and other staff has been provided by occupational health.

- ∞ The neonatal unit was redesignated at a level one unit the same time as the nurse was suspended from clinical duty. There have been some tensions between medics and nurses and the nursing team feels disempowered.

- ∞ Escalation policies are in place and there are debriefs in place after each event.

Interviews with Ravi Jayaram and Steve Brearey

82. When the reviewers interviewed Steve Brearey, consultant neonatologist and Ravi Jayaram, consultant paediatrician at the CoCH on the first day of the Invited Review, they raised concerns about Lucy Letby. The concerns are documented in Sue Eardley's handwritten notes from the interview with the

two consultants on 1 September 2016 and in typed notes by Graham Stewart (RCPCH/0078 and RCPCH/0079 **INQ0010123 and INQ0010124**).

83. Both Steve Brearey and Ravi Jayaram were interviewed together by the RCPCH review team. Steve Brearey set out the background to the deaths of babies at the neonatal unit between June 2015 and 2016 and stated that one of the nurses was present at all of the collapses during that time. He added that at the time, he didn't think it was significant (RCPCH/0079 **INQ0010124**).

84. In the interview notes, it is stated that Ravi Jayaram raised concerns about how the babies had collapsed and said that he wondered if there was something they were missing in the review of all the cases, there was nothing consistent except that Lucy Letby had been on shift during all the collapses and deaths of babies. He added that he spoke to Ian Harvey and Alison Kelly and that they had put Lucy Letby on dayshifts. As a result of this, there had been no more collapses at night but further collapses happened during the daytime when Lucy Letby was on shift (RCPCH/0079 **INQ0010124**). In Graham Stewart's notes, he has recorded that members of both the obstetric and neonatal teams thought that there was 'foul play' in the deaths of babies at the unit (RCPCH/0078 **INQ0010123**).

85. We do not know why the Invited Review team did not stop the review after learning this information. We note that in a feedback session at the end of the second day, the reviewer David Milligan said (RCPCH/0081 **INQ0010197**) "*We considered aborting (the review) and starting again but the Terms of Reference indicated it is important to get the background.*"

86. Regrettably, at the time of the CoCH review, the RCPCH did not have an escalation policy in place for Invited Reviews. This forms part of the lessons learned for the RCPCH, and a clear escalation policy is now in place.

87. We do not have a record of what was discussed by the Invited Review team about aborting the review and how a decision was made to continue or whether there was discussion about escalating this conversation back to senior staff within the RCPCH for a final decision.

Interview with Lucy Letby 1 September 2016

88. We know from our records that Sue Eardley and Claire McLaughlan interviewed Lucy Letby, accompanied by Hayley Cooper, Royal College of Nursing representative at the end of the first day of the review (RCPCH/0076 and RCPCH/0079 **INQ0010121 and INQ0010124**). As mentioned above, this was highly unusual and the view of the RCPCH in 2023 is that this interview should not have taken place. The full notes of the interview are set out at RCPCH-0076 and RCPCH/0079 **INQ0010121 and INQ0010124** but the key points are:

89. Lucy Letby felt that there was a good rapport between the nursing and medical staff at the unit but she was wary of raising concerns with the consultants working at the unit.

    a. There were delayed debriefs following the deaths of infants and other events and that not everyone was invited to join these. She added that nursing staff had pushed for these debriefs.

    b. Debriefs were supported by medical staff but less so by nurse managers and that she had initiated some of the debriefs.

    c. She had been taken off night shifts so that she was more protected on day shifts and she had been told about these rather than being consulted about them. She added that she had been redeployed and told she would have no further contact with the neonatal unit and that she had been referred to occupational health.

    d. She added that consultants were not always supportive of nurses and were slow to refer patients to tertiary centres.

e. Lucy Letby stated that there was a shortage of nurses working on the unit and that on most shifts there was at least one agency nurse and that she would very often do two or three more shifts per month to cover gaps in the rota.

f. Lucy Letby informed Claire McLaughlan and Sue Eardley that she had been on holiday for two weeks from the 30 June 2016 and on her return she met with Eirian Powell and Alison Kelly, Director of Nursing. Eirian Powell informed her that she would be supervised and would require training. Lucy Letby stated that she had no prior warning about this as no practice concerns had been raised with her. She stated that there was no evidence or reason to redeploy her and that she felt vulnerable and was being scapegoated and that "everyone had turned their back on her".

g. Lucy Letby added that she was under the impression that the RCPCH had recommended that she should be redeployed pending the outcome of the Invited Review, as she was of the view that the review would exonerate her and she would be able to return to her substantive post as a nurse on the neonatal unit.

h. As will be seen from the agreed terms of reference for the review, this was not part of what the review team had been asked to do. The RCPCH cannot speak as to why Lucy Letby had this understanding.

Interview with CoCH consultants Doctor V John Gibbs, Murti Saladi, Susie Holt and Doctor ZA (RCPCH/0079 INQ0010124)

90. The key points in this interview included:

- ∞ The consultants felt that there was good team working within the unit and that the nurses had a good line of communication to the consultant team. They felt the neonatal and paediatric unit were a victim of their success – and were 'at arm's length' from the executive team.

- ∞ When talking about the unexplained deaths of babies on the unit, they said that what was striking was that collapses were unexpected and did not respond to resuscitation, some of the babies showed signs of colour changes and central mottling and several of the babies showed strange mottling centrally.

- ∞ They also recommended there should be no re-introduction of staff member until all investigations are complete.

Interview with nurses – Eirian Powell, Yvonne Farmer, Anne Murphy and Yvonne Griffiths (RCPCH/0077 INQ0010122)

91. Claire McLaughlan interviewed a group of nurses on the 2 September 2016. The group included Eirian Powell, Yvonne Farmer, Anne Murphy and Yvonne Griffiths. During the interview, Eirian Powell stated that the trust had taken a line with Lucy Letby and that this was unfounded. Eirian added that she was very upset by the situation and that Lucy Letby had very high standards and good communication skills and was the key person to go to when she needed help. Eirian felt the trust had not been honest with Lucy Letby and others. She added that Lucy was her best friend, was very clever, exceptional and very professional and that she would report any incidents she had been involved in.

92. Eirian also noted that after the death of a baby on the unit, she would organise a debrief within one week of it happening and if any member of staff had one incident in a short space of time, then arrangements would be made to enable them to step back, but that was not always possible.

Interview with Carol Jackson, Nurse Consultant, Transport Team (RCPCH/0073 and INQ0010118)

94. The interview with Carol Jackson, Nurse Consultant, Transport Team at Liverpool Women's hospital Foundation Trust outlined concerns which included:

    a. The time taken before calling the transport team and earlier notification of possible transfers would enable one to be booked to be ready if needed.

    b. There was a silo approach between units in managing the cot availability system[1]. There was no administrative support out of hours and this may be a reason in delays in calling the transport service. Infants are more sick/unwell when being brought back to the CoCH from tertiary centres. She added that there were the correct number of intensive care cots for the regions but felt that these were in the wrong places as Liverpool Women's hospital had reduced the number of cots due to infection risk and staffing and Arrowe Park hospital had increased, but more infants from out of area were being accepted and that the cots weren't being deployed well as staff were too busy to plan properly.

    c. Carol Jackson also stated that infants referred for a transfer tended to be more sick/unwell described by the time the transport team arrived and that they needed a clearer analysis of the condition of the infant so they could transfer them safely.

    d. Carol Jackson also highlighted her concerns about number of sudden collapses at the CoCH.

Interview with Jacqueline Morgan, Neonatal Network Manager, Cheshire and Merseyside (RCPCH/0074 INQ0010119)

[1] As far as we know, the cot availability system would be referring to the number of cots available in paediatric and neonatal services in the region.

95. The interview with Jacqueline Morgan, Neonatal Network Manager, Cheshire and Merseyside stated that:

a. There were no issues at the CoCH except for the lack of accommodation and hotel availability for parents who had babies being cared for at the neonatal unit.

b. There were plans in place to improve cross-trust working and three meetings had taken place since January 2016 to do this. She had a limited view of the relationship between nursing and medical staff at the CoCH and that is seemed to be "ok" and that there were good unit conversations which were documented. Exception reports were proactively provided.

c. There were no concerns expressed about the CoCH and that data about mortality at the neonatal unit would be collected on a quarterly and annual basis.

d. She added that she could not comment on the increase in mortality at the CoCH or other units because it would go up and down and that it had not previously been monitored.

e. Jacqueline Morgan added that at a Clinical Effectiveness Group meeting in January 2016, Steve Brearey, consultant neonatologist and EP (we assume this is Eirian Powell, Nurse) had expressed their concerns about the increase in mortality at the unit (RCPCH/0073 **INQ0010118**)

Parent representatives

96. Parent representatives were interviewed by Claire McLaughlan as part of the review on 2 September 2016 (RCPCH/0075 **INQ0010120)**. A handwritten record of the interview is below. The representatives were I&S and I&S I&S We do not have any details about how the representatives were identified. The interview was short and the key points were made during the interview:

a. Doctors listened to the intuition of parents

b. Care at the CoCH was described as exemplary and specifically the care of parents was as good as the care of the babies.

c. Communication with parents was better at the CoCH than at Liverpool Women's Hospital.

d. There were no concerns about the quality of care provided at the CoCH.

e. Parents felt reassured when care was increased, they were made very welcome to join ward rounds and provided with information and telephone contact numbers after discharge.

f. Parents felt free to raise concerns with nurses and were involved in discussions and decisions about the care of their babies (RCPCH/0075 **INQ0010120**).

Feedback session to Tony Chambers, Alison Kelly and Ian Harvey (RCPCH/0081 INQ0010197)

97. At the feedback session at the end of the review on 2 September 2016, the RCPCH review team, led by David Milligan, provided feedback to Ian Harvey, Tony Chambers and Alison Kelly about their initial findings of the neonatal unit at the CoCH. The verbal feedback included:

a. That the Invited Review team was not sure if the review would give them (the CoCH) the answers they were looking for.

b. That the Invited Review team had considered aborting (the review) and starting again but the Terms of Reference indicated it was important to get the background.

c. A recommendation for an independent case note review of all the deaths by two independent people.

d. Concerns about Lucy Letby's welfare and a recommendation to start a formal HR process.

98. The feedback session also included an update from Claire McLaughlan about the interview with Lucy Letby and the key points included:

a. Lucy Letby was under the impression that the RCPCH had asked for her to be removed from the neonatal unit and that she was under the impression that she would have results from the review within two weeks time.

b. Lucy Letby had asked why she had been moved and thought she had been moved on understanding she was there for all the deaths and that she had something to do with them.

c. Claire McLaughlan also expressed concerns about Lucy Letby's mental health and that she was worried to let her go home by herself and had asked Hayley Cooper to escort her.

d. Claire McLaughlan also emphasised the need for a HR process to start as quickly as possible and that there may be a grievance which may progress to a case for constructive dismissal if nothing was put in place.

e. Claire McLaughlan notes that Lucy Letby "came across slightly strange but we didn't interrogate."

At the feedback session two immediate recommendations were made.

Conclusions of the Service Review

99. We have located a template dated 5 September 2016 outlining very draft findings of the review and potential concerns around a detailed case note review (RCPCH/0037 **INQ0010172**). The key issues in the template are identified as:

a. A request to the RCPCH to review high neonatal death rate which had resulted in unit closure. The template states that these had been 'handled OK with media'.

b. Client indicated they had done case investigations and wanted external view.

c. But we (the RCPCH Invited Review team) "were not equipped as a team to carry out detailed case note review - only 3 (people) in country could do that and it had to happen subsequently delayed and added to the cost of the review."

d. The "*unsubstantiated allegations*" about a nurse being involved did not trigger investigation before arrival, however the team added benefit by counselling the Director of Nursing on policy and implications of no action.

100. The template states that the investigation of neonatal deaths was very inconsistent and the form to record this was poorly designed. It also outlines two lessons learned at the review including:

a. Ensure time for feedback and team gathering at the end; and

b. Managing expectations of the reviewer commissioner if they are expecting a case note review and making sure that the terms of reference reflect this.

101. The second lesson learned is worth noting as it suggests that Ian Harvey was expecting the RCPCH Invited Review Service to carry out a case note review when it initiated the onsite review even though this was not stipulated in the Terms of Reference.

'Closeout' letter

102. It is standard practice at the end of an onsite Invited Review visit to send a 'closeout' letter to the commissioner of the review. The closeout letter details the key findings of the review, any immediate concerns about patient safety and actions needed to manage and minimise these. The letter will also include details of next steps and the timeline for drafting and completing the final report.

103. The CoCH Invited Review 'closeout' letter is dated 5 September 2016 outlining immediate actions for the CoCH following the Invited Review on 1 and 2 September 2016. It includes interim advice and recommended actions whilst the final report was being prepared by within a four to six week timeframe (RCPCH/0041 **INQ0009611**). Key points include:

    a. that on 7 July the LNU facility was revised to operate as a Special Care Unit for infants over 32 weeks gestation, and that one of the terms of reference were to explore whether there were any common factors that might explain the apparent increase in mortality in 2015 and 2016.

    b. the RCPCH Invited Review team was not aware until 1 September that action had been taken in early July to move a nurse from the neonatal unit at the CoCH to other duties, with a requirement that she did not contact colleagues from the neonatal unit. The letter also states that this took place without a formal process nor clear notification to her of the reasons for so doing and that these steps appear to have been taken on the basis of an allegation made by one member of medical staff, supported by his medical colleagues and that some staff were aware of this and the reasons, others were not.

104. Members of the Review team met with the nurse (Lucy Letby) who has been moved, supported by her preferred union representative (Hayley Cooper) and that she was under the impression that the RCPCH review would resolve the situation and enable her to resume duties on the unit. She appeared to be

distressed that there was very little information as to the reasons for her move and appeared isolated and vulnerable.

105. Actions required in the letter include:

1. HR Investigation
   The letter states that it is important that the Trust takes immediate steps to formalise the actions is it taking with the nurse (Lucy Letby).

2. Case review
   The letter states that the pattern of recent deaths at the unit and the mode of deterioration prior to death in some of them appears unusual and needs further enquiry to try to explain the cluster of deaths. The letter adds that a further inquiry was not possible within the terms of reference for the review or from the information received. The letter recommends a detailed forensic case note review of each of the deaths since July 2015 should be undertaken, ideally using at least two senior doctors with expertise in neonatology/pathology in order to determine all the factors around the deaths. The case notes and electronic records should ideally be paginated to facilitate reference and triangulation. This investigation should include as a minimum the following elements:

   a. a full systematic chronology for each case including all interventions, and details of nursing and medical observations and activity

   b. a view on whether escalation of each case at an earlier stage to involve more senior opinion locally or more expert opinion from a regional centre would have potentially made a difference to the outcome

   c. examination (with the relevant paediatric pathologist) of the postmortem findings and any additional information available on their files which might identify cause of death, including rare conditions such as air embolism and severe metabolic derangement

d. details of all staff with access to the unit from 4 hours before the death of each infant. Ancillary and facilities staff should be included

e) Consideration of any other `near mis' cases with similar chronology/presentation where the child survived.

106. The letter stated that four individuals with appropriate expertise and experience had been identified who may be prepared to deliver the case note review on behalf of the CoCH on a private basis. The names of the four individuals who had been identified to potentially deliver the case note review as recommended by the RCPCH were sent separately. (RCPCH/0044 and RCPCH/0041 **INQ0009614** and **INQ0009611**).

107. As a result of this, Dr Jane Hawdon was commissioned to carry out a case note review for the CoCH. This commission was separate from the review the RCPCH had carried out and the RCPCH is not aware (except via later media reporting) of the findings of the review carried out by Dr Hawdon. As Dr Hawdon contracted directly with the CoCH to deliver the confidential case note review, the RCPCH does not have any further details about the report she produced or any recommendations within it because of the highly confidential and sensitive patient identifiable information that would be contained in it.

108. We are unable to identify any records or attempts from the RCPCH Invited Reviews Service to follow up with the CoCH at either three or six months (as was the protocol at that time and as was stated in the closeout letter) after the Invited Review report had been issued to the CoCH. The purpose of this follow-up would have been to review the implementation of recommendations and identify any further sources of support for the CoCH to implement them. We do not know why this did not take place. (RCPCH/0042 -RCPCH/0044 **INQ0009612 - INQ0009614)**.

Draft versions of the report

109. We have located 26 different draft versions of the report (RCPCH/0082 – RCPCH/0105 **INQ0010126-INQ0010148, INQ0010160, INQ0010161, INQ0010149-INQ0010151, INQ0009580-INQ0009581, INQ0009583-INQ0009585, INQ0009635-INQ0009643, INQ0009691**). Some of these drafts have a version control included in their title. We cannot identify any substantive changes relating to the sections about Lucy Letby to the draft versions following review and feedback by the individual reviewers who participated in the Invited Review. We are also unable to identify copies of the review report which have been quality assured by John Dorling (consultant neonatologist) and Nic Wilson (consultant paediatrician and neonatologist) or by Ian Harvey (Medical Director), Anne Murphy (neonatal nurse), Ravi Jayaram (consultant paediatrician) and Steve Brearey (consultant neonatologist), as well as consultants working at the unit who checked it for factual accuracy.

110. Exhibit RCPCH/0103 **INQ0010147** includes comment from Alex Mancini in relation to the concerns which were raised about Lucy Letby during the review. The comment states that:

"However, the significance of this one nurse being rostered on shift at the time of each of the deaths had not been investigated via a thorough process, and is only 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'm making sense, but I think it's important that we recognise that these allegations were only hearsay, and have no substance."

Feedback from the CoCH following the provision of the published and unpublished versions of the report to CoCH

111. An email was sent from Ian Harvey to Sue Eardley providing feedback on the report and additional information about activity, capacity and demand at the neonatal unit and guidelines/guidance for neonatal care at the CoCH (RCPCH/0106 and RCPCH/0107 **INQ0010161 and INQ0010149**). This

additional information was added to the report and mainly focused on mortality data.

112. Draft versions were sent to the client for review and returned with track changes (RCPCH/0108 and RCPCH/0109 **INQ0010150 and INQ0010151)**. We cannot identify the track changes which were made to the document and from checking the draft version returned from Ian Harvey to Sue Eardley, it appears that there were no substantive changes made to the sections of the report relating to the allegations made against Lucy Letby during the Invited Review.

The published version of the final report and the underlying materials

113. An email was sent from Sue Eardley to Ian Harvey dated 28 November 2016 and enclosed a covering letter from Dr David Shortland, Clinical Lead for the RCPCH Invited Review Service and copies of the final reports (RCPCH/0045 **INQ0009617**).

114. This letter outlines the key issues identified during the review and was accompanied by the Invited Review report. The letter enclosed two reports, one including full details of actions taken and one omitting the confidential HR issues (RCPCH/0038 and RCPCH/0039 **INQ0010173 and INQ0010258**).

115. The executive summary of both reports states that the RCPCH Invited Review team found a cohesive and enthusiastic group of paediatricians and a nursing complement that is well led and supportive. Trainees are positive about their experience and the skills they acquire. There is scope for further development of nurses towards specialist or nurse practitioner roles and greater involvement in medical decision making. Recent events have put pressure on inter-team relationships but this is being addressed and morale remains reasonably robust with generally good professional communication between teams.

116. The specific and dedicated section regarding the allegations made against Lucy Letby during the course of the review in RCPCH/0049 **INQ0010259** states that:

"On arriving for the visit the RCPCH Review team was told that Nurse L had been moved to an alternative position around ten weeks previously without explanation nor any formal investigative process having been established. The Review team was told that the individual was an enthusiastic, capable and committed nurse who had worked on the unit for four years. She herself explained to the Review team that she was passionate about her career and keen to progress. She regularly volunteered to work extra shifts when available or change her shifts when asked to do so and was happy to work with her friends on the unit. The Directors understood there was nothing about her background that was suspicious; her nursing colleagues on the unit were reported to think highly of her and how she responded to emergencies and other difficult situations, especially when the transport team were involved. There were apparently no issues of competency or training, she was very professional and asked relevant questions, demonstrating an enthusiasm to learn along with a high level of professionalism.

When the Neonatal Lead made allegations to management, the Director of Nursing considered supervised practice for the Nurse L but the consultants would not accept this and required the nurse be removed from the unit. Senior operational staff on the unit reported being very upset at the situation and the neonatal nurse manager in particular explained the difficulty of wanting to support Nurse L and managing morale and anxiety amongst the other nursing staff who were not aware of the allegation. The consultants explained that their allegation was based on Nurse L being on shift on each occasion an infant died (although not necessarily caring for the infant) combined with `gut feeling`. There was no other evidence or history to link Nurse L to the deaths, and her colleagues had expressed no concerns about her practice.

The decision was taken to redesignate the unit to an SCU from 7th July. Nurse L was on leave for two weeks from 30th June. On her return she was told that she would be supervised for a period and that others were also being supervised. She was not told of the specific allegation but she was made aware that there were concerns that she was on duty for each of the deaths. At a subsequent meeting, accompanied by her Union representative she was

advised that supervision was not possible (due apparently to 'staffing levels') and she would be temporarily redeployed. She was apparently advised again that this would also happen to other members of staff. She was told not to make contact with staff on the unit. Nurse L had incorrectly been told that the RCPCH had suggested that she be redeployed, and that the review would resolve the issue within 2 weeks of the visit. No formal HR process had been put in place for the ten weeks between the redeployment and the RCPCH visit. The RCN support to the nurse had, up to the RCPCH visit, not been very active but it was expected that the nurse would raise a grievance.

In the light of information shared with the Review team, the RCPCH advised the Trust to follow corporate processes in responding to allegations of misconduct by opening an investigation; it was also recommended that a full and detailed independent case note review should be carried out on the deaths, prioritising those that were unexpected.

117. There were 21 recommendations in total contained in the reports. The two most relevant to Lucy Letby and the allegations expressed about her during the review were:

a. Conduct a thorough external, independent review of each neonatal death between January 2015 and July 2016 to determine any factors which could have changed the outcomes. Include obstetric and pathology / postmortem indicators, nursing care and pharmacy input

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

118. We exhibit here the final copies of the reports sent. These included:

a. Copies of the final versions of the reports returned to Ian Harvey following the RCPCH Invited Review at the neonatal unit at the CoCH on 1 and 2 September 2016 can be found here (RCPCH/0046-RCPCH/0050 **INQ0010153, INQ0010154, INQ0010259, INQ0010260**).

b. A copy of the final and confidential report of RCPCH Invited Review at the CoCH. This version includes a separate section about Lucy Letby following the interview with her during the Invited Review by Sue Eardley and Claire McLaughlan.

c. A copy of the final report for dissemination to people who participated in the review. This does not include the separate section about Lucy Letby (RCPCH/0050 **INQ0010260**).

119. The RCPCH recognises that the consultants and colleagues at the CoCH who raised concerns with the review team were dissatisfied with the final version of the report that they were provided with (RCPCH/0050 **INQ0010260**) and understands that they felt let down by the Invited Review process.

120. The 28 November 2016 closing letter to Ian Harvey from David Shortland (RCPCH/0039 **INQ0010258**) which accompanied the two reports made plain the intention that the redacted report was to be shared with the clinicians on the ward (among others who had contributed the review), and that the full report would likely be held as confidential even within CoCH because of the HR issues described elsewhere. As a consequence, the RCPCH's assumption is that the paediatricians on the ward were not aware of the confidential version.

Service Review findings – escalation within the RCPCH

121. During the period following the review visit, there was some flagging of the issues raised by the review to more senior groups within the RCPCH. This would have been normal (and good practice) for an issue of such seriousness.

Council

122. The RCPCH's Council (at that point, the College's trustee body) received a written management report from the then-CEO (Prof Judith Ellis) on 16 October 2016 which included a mention that the review at the CoCH was sensitive (RCPCH/0115 **INQ0009582)**.

Board of Trustees

123. A new Board of Trustees took over from Council as the College's governing body on 1 November 2016. The Board of Trustees received written management reports from the CEO on 7 December 2016 and 14 March 2017 which stated the review at the CoCH was sensitive. The latter update included the CoCH's publication date of the review on 8 February 2017 (RCPCH/0110 and RCPCH/0111 **INQ0009580 and INQ0009581**).

124. The minutes of the Council and Board meetings referred to above do not give any detail about the discussion that took place on the CEO reporting on the CoCH review. Neither do they give any indication of any actions being agreed as a result of the reporting.

Executive Committee

125. The RCPCH's Executive Committee received a written CEO management reports on 13 October 2016, 24 November 2016 and 26 January 2017 which stated the Invited Review at the CoCH was sensitive.

Invited Reviews Programme Board

126. This Board, chaired by the IRs clinical lead Dr David Shortland, was the senior College body most directly concerned with the CoCH Review.

127. On the basis of the evidence we have reviewed, the following general observations can be made about these escalations:

i) We assume that the review was described as "sensitive" due to the allegations of criminality that had been made about Lucy Letby during the course of the Invited Review. We assume that concerns about the issues raised in the review were sufficiently significant to be included in the written CEO report but we do not have details about how this was or who escalated it. We are not aware of any other Invited Reviews being escalated to this level and what processes were in place to identify other reviews which would warrant this level of scrutiny and oversight. In hindsight, we do not think this adequately describes the situation.

ii) There is no evidence that the Board of Trustees or any other senior group was comprehensively briefed by Sue Eardley or the Clinical Lead, Dr David Shortland about the issues raised during the Invited Review and the implications of them. (RCPCH/0112 – RCPCH/0114 **INQ0009583-INQ0009585)**.

iii) There is no evidence that RCPCH shared the report or its findings and recommendations with any external scrutiny bodies, regulators, the police or other authorised individuals for consideration after the Invited Review was completed in 2016. We do not know why the concerns were not escalated with external organisations and whether any consideration about this was given at the time in light of the serious allegations that had been made about Lucy Letby during the review. The evidence indicates that the final reports were shared with the Medical Director, Ian Harvey as he was the commissioner of the Invited Review and the reports became the property of CoCH as agreed in the contract which commissioned the review. At that point, the process moved to the case note review – recommended by the RCPCH report and ultimately undertaken by Dr Jane Hawdon. As noted separately in this statement, RCPCH had no sight of or involvement in that review.

iv) The issues arising from the review were added to the RCPCH's risk register in November 2018 listing Jacqueline Fitzgerald – the then-Director of Research

and Policy - as the risk owner. This risk register was shared first with the RCPCH's Audit, Finance, and Risk Committee and then with the Board of Trustees. By that time, the police investigation into the deaths was under way and Lucy Letby had been arrested. As part of the police investigation, RCPCH was asked by the police for some notes from the Invited Review visit, which were provided.

128. Reflecting on these actions with the benefit of hindsight, we consider that the ability of the RCPCH's Board and other senior bodies to conduct their oversight functions was hampered because they were not sufficiently sighted on the level and seriousness of the concerns that the CoCH review entailed. In practice, this was because concerns were not escalated by the two routes immediately available – via Sue Eardley's then-line manager Jacqueline Fitzgerald, or via the IR Programme Board chaired by Dr David Shortland. At least from the written evidence available to the College now, there is no clear evidence as to why this did not happen. That said, the following factors may have inhibited such escalation:

- Invited Reviews were confidential, and so it may have been difficult to outline the details outside a narrow group without breaching such confidentiality.
- The presumption of some of the review team reviewers – recorded elsewhere in this statement – that the allegations against Lucy Letby were "unsubstantiated". This could have been reflected in how urgent escalation was seen as being.

- Once the review report was delivered to the CoCH in late November 2016, the RCPCH was assured (as referenced in the closing letter) that the recommendation it had made – for a detailed case-note review by an appropriately skilled professional – was under way. In this sense, this could have been seen as the appropriate escalation resulting from the review.

129. One further element of the RCPCH's interaction with the issues raised by the review should be recorded. This concerns direct interactions between the RCPCH and the CoCH paediatricians, who are RCPCH members. On 5 February 2018, Dr Steven Brearey, wrote to the RCPCH's then-President Prof Neena Modi (RCPCH-0407). He raised a number of issues, centred around "the way the college responded to [the CoCH neonatologists'] concerns, particularly after the invited review report was submitted to the trust." He stated that "The report was modified by the Trust before it was shared with the public and the paediatricians". As a consequence, he says, "It is quite possible that if the College had intervened at that stage [i.e. when the Trust shared the report] and provided support to its members, then the police investigation might have started earlier." These were clearly very serious allegations, both about the Trust and the approach the College had taken. He said that the affected parents and paediatricians "could have been supported by the College in a more positive way". The immediate request from Dr Brearey was to ask whether a discussion in person with Prof Modi might be possible.

130. Prof Modi replied by email on 8 February 2018, with copies to Prof Judith Ellis (then-College CEO) and Dr Mike Linney (then College Registrar), (RCPCH-0407). She stated that she was aware of both the CoCH Invited Review and the police investigation, which at that point was under way but had not resulted in any arrests or charges. She said that the College's primary contact was with the Medical Director as the "client" for the Invited Review, and that it would be difficult for the College to intervene because of the police investigation. Nevertheless, she asked what Dr Brearey had meant by "supported by the College in a more positive way".

131. Dr Brearey replied by email later on 8 February (RCPCH-0407). He stated that "all the paediatricians [in CoCH] have concerns regarding the integrity and competence of the 'client', the medical director, who also happens to be our responsible officer. Therefore, the review team maintaining sole contact with him when he has not acted appropriately to our concerns is in some ways making our problems worse and is not in the interests of the parents of affected babies." He also stated that he "was not asking the College to intervene in any

way into the police investigation". He said that his purpose was threefold: to make the College aware of what was happening at CoCH; to highlight the problem of "a college report which had large sections deleted without anyone's knowledge", and to seek advice from a senior neonatologist.

132. In response to this, Prof Modi emailed Prof Ellis and Dr Linney later on 8 February 2018 asking for a discussion on this issue. In compiling this statement, records of that discussion have not been found, but its result seems to have been a letter to Dr Brearey dated 20 February (presumably 2018) (RCPCH-0405). This reiterates that the College was constrained in what it could do because of the police investigation. It did not address the allegations that had been made by Dr Brearey of the Trust altering the report, and nor did it deal with his argument that contact solely between the IRs team and the client (the medical director) was in itself damaging. Instead, it suggested that the paediatricians should use the local channels available to them (i.e. the Trust Board of Directors) both for, "procedural" support and for more personal help in dealing with an exceptionally stressful time. Prof Modi suggested that such communications could be copied to Prof Ted Baker, CQC Chief Inspector of Hospitals and the RCPCH Registrar Dr Linney.

133. In hindsight, the approach taken by the College in these communications with Dr Brearey is congruent with that described above in discussions of escalation to trustees. As a result, the very unfortunate conclusion was reached that the College could not at that point offer direct support to several of its own members who had been involved in an exceptionally difficult situation. The rationales for the College's approach to escalation (paragraph 127) were likely still present in the minds of those dealing with this, and that the police investigation further constrained what could and could not be done.

Education and Training

134. We have been asked to provide information on the training or guidance that was (and is) given to members of the RCPCH on the duty of candour and the duty to report adverse incidents or near misses that may have led to harm

(RCPCH/0539 **INQ0010194**).

135. Progress+ is the curriculum agreed by the General Medical Council (GMC) by which trainee paediatricians must demonstrate competence before they can complete their training and become a consultant paediatrician.

136. Learning outcome seven of both the Progress and Progress+ (Core) curricula include a core capability to apply the principles of the duty of candour and these should be demonstrated in the paediatric clinical mini evaluation, the paediatric case-based evaluation, through clinical leadership assessment skills, the Foundation of Practice examination, the Applied Knowledge and Practice exam and the MRCPCH clinical exam. As with all specialty curricula, the curriculum sits within the framework of the GMC's Good Medical Practice domains, including Domain 2 on Safety and Quality.

137. Paediatricians are required under their license to practice with the GMC to show that they are in good standing with the GMC, which includes their professional duty of candour. GMC guidance states: "*Health and care professionals must also be open and honest with their colleagues, employers and relevant organisations, and take part in reviews and investigations when requested. They must also be open and honest with their regulators, raising concerns where appropriate. They must support and encourage each other to be open and honest, and not stop someone from raising concerns.*" . This is usually reflected in the Terms of Conditions of employment and the Inquiry may wish to seek further advice on this matter from the Medical Defence Union, and with the GMC specifically in context of whether any strengthening is needed on guidance around reporting concerns about colleagues. The GMC also has published guidance jointly written with the Nursing and Midwifery Council (NMC) on what to do if something goes wrong.

138. Following the Inquiry into Hyponatraemia Related Deaths in January 2018, the RCPCH responded to the Department of Health Northern Ireland's proposal for a statutory Duty of Candour and Being Open Framework (RCPCH/0539

INQ0010194). The RCPCH broadly welcomed an organisational Duty of Candour, but held the position that an additional, individual Duty would be cumbersome, duplicative, and disproportionate to meet the stated aims of improving culture and ensuring the quality of services.

Lessons Learned

139. While the Invited Review at the CoCH was delivered and highlighted areas for action, we recognise that there were inadequacies of the Invited Review Service at the time, and of the Invited Review undertaken at CoCH. These are:

a. The lack of due diligence to understand the background to the review and the concerns that had already been raised by clinicians at the CoCH about Lucy Letby.

b. Insufficient clinical involvement and specifically the Clinical Lead for the Invited Review Programme and the Lead Reviewer in meeting with Ian Harvey to discuss the request for an Invited Review and the development of a terms of reference.

c. The speed which the terms of reference were written and apparent lack of oversight and sign off by either the Clinical Lead of the Invited Review Programme or a Director at the RCPCH.

d. The absence of written notes of the conversations between Sue Eardley and Ian Harvey which informed the development of the terms of reference.

e. The interview with Lucy Letby by Sue Eardley and Claire McLaughlan despite her being involved in a human resources process which was being led by the CoCH.

f. The lack of documentation about the discussion between the reviewers on whether or not to proceed with the review and the rationale for the decision to continue to proceed with the review.

g. The need for an escalation policy to aid decision making on when to halt a review if allegations of criminality are raised.

h. The absence of follow up at the specified times of three and six months after the review completed to check on progress in delivering the recommendations.

i. The lack of lessons learned about the review to ensure that the issues that arose during the review at the CoCH were mitigated and practice was changed and adopted into future reviews.

Review of Invited Review Programme

140. A review of the Invited Review Programme was first initiated in the second half of 2019 to interrogate the operation and function of the Invited Review Service more broadly. This was largely because:

- ∞ It is good practice to periodically review functions within the RCPCH to ensure they are fit for purpose and to identify any areas within them that require improvement and/or investment.

- ∞ A new Chief Executive Officer, Jo Revill, started at the RCPCH in June 2018 and Emily Arkell, started as the new Director of Research and Quality Improvement in April 2019.

- ∞ Feedback was received from some College Officers close to the Invited Review Service

- ∞ Concerns were raised by about two Invited Reviews – CoCH and GOSH

- ∞ Concerns about the leadership and management of the Invited Review service.

141. The report of the independent and external review of the RCPCH Invited Review service is exhibited here: RCPCH/0370-RCPCH/389 and RCPCH/0463 **INQ0010176- INQ0010182, INQ0010184, INQ0010185, INQ0010217, INQ0010219, INQ0010223, INQ0010225, INQ0010228, INQ0010229, INQ0010232, INQ0010234, INQ0010236, INQ0010237, INQ0010240.**

142. The external and independent review was carried out by Helen Crisp, Editor of BMJ Quality and her associates, Jan Mackereth- Hill and Jane Jones. The review was wide ranging and a root and branch analysis of the service including:

- ∞ review requests,
- ∞ the process for accepting or declining them,
- ∞ understanding the reasons for healthcare organisations requesting reviews,
- ∞ drafting and agreeing the terms of reference,
- ∞ the review team,
- ∞ the reviewers skills/knowledge/expertise and training,
- ∞ escalation processes,
- ∞ governance processes within the RCPCH,
- ∞ sharing findings from reviews with other College functions (eg policy and service standards development),
- ∞ report drafting,
- ∞ timeliness in liaison with regulators.

143. The external and independent review carried out by Helen Crisp and her associates also included a 'deep dive' into the review at the CoCH neonatal unit in 2016 and GOSH in 2017. The rationale for carrying out a 'deep dive' at CoCH was to understand the circumstances of how the review was accepted and conducted by the RCPCH and to identify any lessons learned from it.

The Crisp Report identified the following lessons learned by the RCPCH on the Invited Review at CoCH:

a) Decision making and process

David Milligan who was the Lead Reviewer was not involved in the scoping of the review or the pre-visit meeting and felt somewhat unprepared for the review. The Invited Reviews acceptance decision making was not risk based at that time and did not provide any scrutiny of the request by staff other than the Head of Invited Reviews. It was also unusual for the RCPCH to turn down requests or signpost to other more suitable organisations. At the time there was no escalation policy to guide the review team in their decision to continue or call off the review.

b) Risk assessment and management

The review team had no guidance on whether to interview a suspended staff member. This could carry a risk of being seen to interfere with other disciplinary and, in this case, criminality and legal concerns. The Invited Reviews team had insufficient guidance on what to consider and to assess the risks if faced with a situation where continuing the review was in doubt. The Crisp review stated that RCPCH should consider its risk appetite to take on reviews involving high mortality rates. An issue such as this should trigger a risk assessment of this aspect.

c) Communication with stakeholders and clients

The Crisp review concluded that the RCPCH report of the review at the neonatal unit at the CoCH provides clear findings and recommendations, but that this could be seen as somewhat 'light touch' in the way the issues are presented. The Invited Review found that local procedures were not thorough and systematic and national guidance for child deaths had not been followed completely. These were serious issues. The reviewers were unaware that the suspicions raised by the hospital paediatric consultants were formally communicated to the commissioner of the report, in this case, Ian Harvey, in the review closeout letter.

d) Outcome and impact of the Invited Review process

The Invited Review at CoCH provided useful guidance for the service and the trust was clearly working to implement the recommendations in the months following. The Crisp review stated that the media coverage the Trust appeared to have been open about the report and its findings. The recommendations in the RCPCH report may have been overtaken by the subsequent police investigations.

Escalation policy

144. As a result of the external and independent review of the Invited Reviews function at the RCPCH carried out by Helen Crisp, an escalation policy was created to provide an extra level of risk management if issues similar to the situation at the CoCH where allegations of malpractice and criminality were made, arose again in a future Invited Review. We have rigorously and robustly tested this using the scenario at the CoCH as an example. We can confirm that if this escalation policy was in place at the time the review took place at the CoCH, it would have recommended that the review team at the very least should have paused the review and considered the information that had been shared with them.

Understanding data – lessons learned

145. We have been asked whether there was anything else that the reviewers could, or should, have looked for to help them understand the data they had about the neonatal service at the CoCH and the reasons for the neonatal deaths.

146. The amount of evidence now available, and the level of detail and insight was not available to the Invited Reviewers at the time the review took place. The framing of the Invited Review process at that time was to fulfil a brief agreed with the client, Ian Harvey. The team undertaking the review was configured to deliver on that brief.

147. Section 4 of the Invited Review report of CoCH identified that there were unanswered questions around the elevated neonatal death rate in the preceding months. The report recommended that CoCH engage an external individual to undertake a detailed clinical review of the cases concerned. To our knowledge, and as far as the evidence reflects, a detailed case note review of such cases as at CoCH was not within the capabilities of the group of reviewers at that time. Guidance has subsequently been updated to include this service.

148. Sue Eardly communicated to the CoCH that she had identified 4 individuals to recommend to undertake a case note review. We have been unable to find any evidence that contains this list of names, despite communication confirming that these will be sent separately (RCPCH/0044 **INQ0009614**). In the closeout internal form (RCPCH/0037 **INQ0010172**) it states the RCPCH was not equipped to carry out a case note review and that there were in fact on 3 in the country that could do it.

149. The closeout letter of November 2016 notes that this recommendation to undertake a case note review had been taken forward (RCPCH/0037 **INQ0010172**). Neither the Invited Review team nor the RCPCH was sighted in that review.

Changes of the RCPCH's Invited Review Service made as a result of lessons learned

150. Significant changes have been made to the operation, management and governance structure of the RCPCH's Invited Review service since the Crisp Review. The changes have been made, alongside other changes as part of the wider review of the Invited Review service, to ensure the service is a robust and rigorous as possible and properly risk managed and as a result of the lessons learned of the Invited Review at the CoCH in 2016.

151. These changes and improvements to the RCPCH Invited Review service include:
    a. The 'Invited Reviews Process and Guidance' has been significantly strengthened. A thorough due diligence process is undertaken when a

healthcare commissioning organisation first enquires and requests an Invited Review to clarify the concerns behind the review and any intelligence about organisational tensions gathered are shared with the review team so that they are well prepared for possible tensions or defensiveness.

b. There is a greater emphasis and consideration about risk management and for the overall programme of Invited Reviews and this is built into the acceptance criteria and risk assessment frameworks used.

c. Consideration and clarification takes place at the acceptance decision making stage about whether an Invited Review is most appropriate method for the specific issues (such as investigation of high mortality rates) or whether to signpost to another organisation.

d. Procedures are systematically followed, to ensure that the Lead Reviewer for a review is involved in the scoping of the review. This helps to ensure that they are aware of nuanced information regarding the background and context for the review, enabling review teams to be mentally prepared.

e. Information about the RCPCH's Invited Review service has been updated and a set of handbooks for a range of stakeholders have been written and placed on the RCPCH website. The handbooks include information about responsibilities and expectations of the review, the process and escalation processes.

f. Developed an escalation policy and tested scenarios through the stages it.

g. New guidance has been developed on the considerations of when to call off a review in the light of events /findings revealed once the review has started,

and/or the steps to record the decision making on continuing or calling off a review in difficult circumstances.

h. Guidance has been reviewed and revised to set out the circumstances in which reviews should not be undertaken if a healthcare professional to be subject to the review is already under professional or legal investigation.

i. A rolling programme of training for reviewers including guidance on making firm recommendations, based on evidence, which do not shy away from serious concerns.

j. Regular updates and progress reports about the Invited Reviews programme are shared with the RCPCH's Executive Committee, Council and Board of Trustees.

k. The Invited Reviews programme is now overseen by the Registrar (a clinician and trustee) who provides senior clinical oversight and responsibility for it (RCPCH/0481 **INQ0010213**).

Statement of Truth

I believe that the facts stated in this witness statement are true. We understand that proceedings may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief of its truth.

Signed: **Personal Data**

Dated: 8 February 2024

Glossary

AH – Alder Hey Children`s Hospital

AoMRC – Academy of Medical Royal Colleges

ANNP – Advanced Neonatal Nurse Practitioner

APH – Arrowe Park Hospital

BAPM – British Association of Perinatal Medicine

BLISS – Charity for neonatal services and families

BMA – British Medical Association

BMJ – British Medical Journal

CCG – Clinical Commissioning Group

CCT – Certification of Completion of Training

CDOP – Child Death Overview Panel

CEO – Chief Executive Officer

CoCH – Countess of Chester Hospital

CPD – Continuing Professional Development

CSACs – College Specialist Advisory Committees

CQC – Care Quality Commission

GMC – General Medical Council HD(U) – High Dependency (Unit)

GOSH – Great Ormond Street Hospital

IC – Intensive Care

IR – Invited Review

LNU – Local Neonatal Unit

LWH – Liverpool Women`s Hospital

MBRRACE-UK – Mothers and Babies: Reducing the Risk through Audits and Confidential Enquiries across the UK

MRCPCH – Membership Royal College of Paediatrics and Child Health

M&M – Morbidity and Mortality (meeting)

NHSFT – NHS Foundation Trust

NICE – National Institute for Health and Care excellence

NICU- Neonatal Intensive Care Unit

NMC – Nursing and Midwifery Council

NNAP – Neonatal Audit Programme administered by the RCPCH

ODN – Operational Delivery Network

O&G – Obstetrics and Gynaecology

RCPCH – Royal College of Paediatrics and Child Health SC(U) – Special Care (Unit)

START – Specialty Trainee Assessment of Readiness for Tenure

STP – Sustainability and Transformation Plan

WTE – Whole Time Equivalent