Witness Name: Ian Trenholm

Statement No.: 2

Exhibits: 223

Dated: 4 April 2024

THIRLWALL INQUIRY

SECOND WITNESS STATEMENT OF IAN TRENHOLM

I, Ian Trenholm, Chief Executive of the Care Quality Commission, Citygate, Gallowgate, Newcastle upon Tyne NE1 4PA, will say as follows: -

1. I am employed by the Care Quality Commission (CQC) as Chief Executive, a post I have held since August 2018.

2. I make this further statement in response to the request from the Thirlwall Inquiry (the Inquiry) dated 6 November 2023, made under Rule 9 of the Inquiry Rules 2006 (SI 2006/1838). I adopt the abbreviations or acronyms deployed in the Rule 9 Request where appropriate. I am duly authorised to make this statement on behalf of CQC.

3. Save where it is stated otherwise, because I joined the CQC in August 2018, much of what is set out in this statement is based on the documentation available to me rather than being within my own direct knowledge. This statement is to the best of my knowledge and belief accurate and complete at the time of signing. Notwithstanding this, it is the case that CQC continues to prepare for its involvement in the Inquiry. As part of these preparations, it is possible that additional relevant material will be identified. In this eventuality the additional material will of course be provided to the Inquiry and a supplementary statement will be made, if required.

4. This statement has been prepared following consultation with current and, where necessary, former colleagues at CQC in order to provide as accurate an account as possible on behalf of CQC.

Registration of Countess of Chester Hospital NHS Foundation Trust

5. Countess of Chester Hospital NHS Foundation Trust is registered with CQC as a service provider. Under this registration, the Trust operates two locations, Ellesmere Port Hospital and The Countess of Chester Hospital (CoCH).

6. The Countess of Chester Hospital was registered with CQC on 01 April 2010.

7. From this location, the provider is registered to provide the regulated activities of Assessment or medical treatment for persons detained under the Mental Health Act 1983, Diagnostic and screening procedures, Family Planning, Maternity and midwifery services, Surgical procedures, Termination of pregnancies and Treatment of disease, disorder or injury. (IT/77 [INQ0017321])

CQC's approach to engagement with Countess of Chester Hospital

8. Paragraphs 15 - 140 below provide an overview of information provided to CQC from 01 January 2015 to 23 October 2023 in relation to neonatal services at the CoCH and the police investigation. The chronology also includes any actions undertaken by us and details of our inspection activity throughout this time period.

9. As set out on CQC's website, https://www.cqc.org.uk/provider/RJR, inspections of the CoCH were undertaken by CQC in February 2016, November 2018, February 2022, July 2022 and October 2023. Neonatal units were inspected as part of the Children and Young Persons services at the February 2016 and the October 2023 inspections.

10. CQC's guidance '*How CQC monitors, inspects and regulates NHS Trusts'* provides an overview of how we monitor NHS Trusts. (IT/12 [INQ0010478]) This remained the position until our move across to the Single Assessment Framework, detailed at paragraph 73 of my first statement. Information on how we will monitor NHS Trusts under our new Single Assessment Framework is available on our website. (IT/78 [INQ0017395])

11. Throughout the statement we will refer to two types of meetings, management review meetings (MRM) and engagement meetings. MRMs are internal CQC meetings for teams to discuss and record decisions made.

12. Engagement meetings take place between the NHS Trust and CQC operational staff. They would normally include the relationship holder and/ or Inspector, the Inspection Manager and, dependent on risk, the local Head of Inspection. The purpose of engagement meetings is to enable CQC to monitor and act on patient safety concerns, monitor risk, and performance, and to seek assurance about any actions the Trust is taking to ensure safe care and treatment.

13. Following the inspection of an NHS Trust, our usual process is to hold regular engagement meetings with the Trust's senior team. These meetings, carried out at regular intervals, are an opportunity to monitor progress on required improvements and service developments, as well as to discuss emerging themes and trends – including the mitigation of risks and the Trust's approach to leadership and governance. In addition, our processes also include meeting regularly with other regulators and key stakeholders, such as commissioners, to share information as to the Trust's performance, as well as the safety and quality of its services for its patients. This was the case in relation to Countess of Chester Foundation Trust pre and post all our inspection activity.

14. All available records relating to both MRMs and engagement meetings have been exhibited throughout the statement.

Chronology of CQC's monitoring and inspection activity at Countess of Chester Hospital

15. On 21 July 2015, Inspectors held an engagement meeting with the Trust to introduce the new Inspector and Inspection Manager who would be responsible for monitoring the Trust. (IT/79 [INQ0017285]) This meeting was not our first interaction with the Trust as a commission, but between the new Inspectors forming the CQC Relationship Holders and the Trust.

16. In the lead up to the planned inspection in February 2016, we received a Provider Information Return (PIR) from the Trust. Within the PIR we ask providers to supply us with data, and some information on how they ensured their service was safe, effective, caring, responsive and well-led. The purpose of a PIR is to help us identify areas to

explore in more detail as part of a comprehensive inspection of a service. Judgements about the overall quality of services and ratings of a service are not based on a PIR, but on information gathered across the whole inspection process. The PIRs returned by the Trust, in relation to Children and Young People's services are in. (IT/80 [INQ0017346]; IT/81 [INQ0017351]; IT/82 [INQ0017347]; IT/83 [INQ0017417]; IT/84 [INQ0017438]; IT/85 [INQ0017282]; IT/86 [INQ0017283]; IT/87 [INQ0017284]; IT/88 [INQ0017348]; IT/89 [INQ0003288]; IT/90 [INQ0005445])

17. Ahead of the scheduled inspection in February 2016, an engagement meeting was held with the Trust. This would have been a routine scheduled meeting and likely focused on the logistics of the inspection, including planning interviews. We have no available record of what was discussed at this meeting.

18. On 16 December 2015, in advance of the planned inspection, we received feedback on the CoCH from the Royal College of Nursing. The feedback included:

> *There are concerns about nurse staffing at this Trust. Numbers are not adequate and nurses who are off sick are frequently not replaced – the Trust is currently relying on nurses to work extra hours without pay, which is not a sustainable approach to securing the safe staffing levels patients need.*
>
> *There are some issues around how effectively the Trust's management engage with staff side representatives and staff in general. For example, it is known that the Trust are planning to become a 'model hospital' but there is not a widespread understanding amongst staff about what this means in practice.*
>
> *There is a perception that feedback by nursing staff to managers is often not acted on, with RCN having had contact with nurses seeking support and advice who are reluctant to raise issues more formally as there is a belief that it will not result in change.*
>
> *However, we do note that the executive team carry out walkabouts every month, which is raising their profile amongst staff at the Trust. This is something that could be built on.* (IT/91 [INQ0017429])

19. We also received feedback from the Health and Care Professionals Council in relation to three fitness to practise hearings where the allegations occurred at, or involved an individual employed by, the provider between the dates 1 April 2013 and 11 December 2015. (IT/92 [INQ0017329])

20. In preparation for the inspection, we made a data request to the Trust on 15 February 2016. Data Requests are requests for documents and records which are made prior to an inspection and which support the inspection planning and contribute to the corroboration of evidence collected onsite during the inspection. One of those data requests related to Paediatric Incidents. The data provided included information on incidents occurring in the neonatal unit; including deaths. In the 2016 report, this data was used to support the findings presented in the Incidents section of the Safe key question. (IT/93 [INQ0017331]; IT/94 [INQ0017355]; IT/95 [INQ0017356]; IT/96 [INQ0017357]; IT/97 [INQ0017358]; IT/98 [INQ0017345]; IT/99 [INQ0017352]; IT/100 [INQ0017353]; IT/101 [INQ0017354]); IT/223 [INQ0017801] [1]

21. On 16 – 19 February, 26 February and 4 March 2016 (the "2016 inspection") CQC carried out a routine inspection of CoCH. We published our report on 29 June 2016. (IT/102 [INQ0017433]) We inspected neonatal services at this inspection.

22. As part of the inspection process, we held a listening event on 9 February 2016 for people who had received care and treatment at either the CoCH or Ellesmere Port Hospital. The event was designed to hear people's views about care and treatment received at the Trust. Intelligence shared with us through this route is intended to be shared internally within CQC to inform the inspection planning process. Some people may also have shared their experiences by email and telephone. Review of available records do not indicate that further feedback was provided in this manner.

23. As part of the inspection, we also carried out an out-of-hours unannounced visit on 26 February 2016. There were no particular triggers for this visit. It was common for members of the inspection team, within a two week window following the main visit and authorised by the relevant Head of Inspection or Deputy Chief Inspector, to return to gather further evidence to inform the report. This would often include urgent and emergency care services which can have notably different risk and staffing profiles out of hours.

24. We also undertook a further unannounced site visit as part of this inspection between 3pm and 8pm on 4 March 2016 at the CoCH. There were no particular triggers for this visit. During that unannounced visit, neonatal services were inspected at 16:05pm. (IT/103 [INQ0017339]) Inspection notes from other core services inspected as part of

[1] All other data requests, though not specific to the Children and Young Person's core service are available to the Inquiry should it require to see them.

this inspection are exhibited. (IT/104 [INQ0017333]; IT/105 [INQ0017340]; IT/106 [INQ0017288]; IT/107 [INQ0017290])

25. The inspection team that undertook the 2016 inspection is listed in paragraphs 26 - 58. Not all records relating to the inspection team are held electronically. This is particularly the case where individuals had been employed by CQC's predecessor and moved to CQC when we were established in 2009. Where this is the case, we have been unable to retrieve the qualifications held for those members of the team.

26. Elizabeth Childs acted as Inspection Chair. Her professional qualifications are listed as Registered General Nurse, Registered Children's Nurse and Executive Coach. Her role at this inspection was to work with the Head of Hospital Inspections to ensure CQC regulatory requirements were met, to ensure impartiality, provide external credibility, ensure the skills and experience of inspection team members were used in the most appropriate way to deliver a robust and thorough inspection, lead briefings and corroboration meetings during the inspection where all team members corroborate their findings, review evidence gathered and approve the draft report.

27. Ann Ford was the CQC Head of Hospital Inspection. She reported to the Deputy Chief Inspector. Ms Ford is a Registered Nurse with a Postgraduate Certificate in Leadership. She has worked in Health and Social Care Regulation for 20 years and has an MBE for services to patient safety. Her role within this inspection was to lead the work of the inspection team throughout the process and be accountable for delivering a robust and rigorous judgement. She also provided support, advice and guidance to the Inspection Chair on CQC regulatory requirements, led the inspection planning stage, ensuring all intelligence available was used in the most effective way and leads development of the areas on which to focus. She coordinated the input of the CQC Analytical Support including document review and manage the CQC Inspection Planner. She oversaw the logging and analysing of evidence and made regulatory judgements based on all evidence presented and determine provisional ratings. She also contributed to briefing and corroboration meetings and deputised for the Inspection Chair where required.

28. Bridget Lees was the CQC Inspection Manager. Her professional qualifications were BSc Clinical Nursing Studies Specialist Practitioner Award Infection Control, MSc Module Management in Infection Control, BSc Nursing, ENB Critical Care Nursing and ENB 988 Teaching and Assessing in Clinical Practice. As part of the inspection, she reported to

the Head of Hospital Inspections and was responsible for operational oversight and delivery of the end-to-end inspection process & report publication.

29. Julie Hughes was a CQC Inspector and part of the Trust-wide inspection team. We do not hold details of Julie's professional qualifications. She reported directly to the Inspection Manager and was responsible for core service inspection, including escalation of any immediate risks identified during on-site inspection, and drafting the inspection report.

30. Daniel Watson was a CQC Assistant Inspector and part of the Trust-wide inspection team. We do not hold details of his professional qualifications. The Assistant Inspector reported to the Inspection Manager and where relevant an Inspector, for a variety of inspection related tasks including administrative tasks and note taking in interviews.

31. Trish Rowson was a Specialist Advisor and part of the Trust-wide inspection team. We do not hold details of her professional qualifications. Specialist Advisors are employed on an ad hoc basis for inspections and are chosen for their current experience. Specialist Advisors reported to the Inspector, and act as a Subject Matter Expert to the Inspector and Inspection Manager for clinical related queries.

32. Phil Shaw was a Pharmacist Specialist Advisor and part of the Trust-wide inspection team. He held the following qualifications: University of Bradford, Bradford, West Yorkshire, MPhil Degree. Research project entitled "An investigation into the relationship between dosage and haematological toxicity of thiotepa, BPharm Honours degree and a BSc Honours degree in Bacteriology. His role involved supporting the Trust wide inspection of the Countess of Chester and specifically looked at medicines optimisation across the Trust. This involved looking at pharmacy services, ward level medicines optimisation and focusing on identified areas of medicines risks.

Urgent & Emergency Care Inspection team

33. Nicola Everitt was a CQC Inspector. Her qualifications included being a Registered Nurse. She reported to the Inspection Manager. She was responsible for this core service inspection, including escalation of any immediate risks identified during on-site inspection, and drafting the inspection report.

34. Peter Quick was a Specialist Advisor. He held the following qualifications; Management in Healthcare, University of Nottingham, Fundamentals of Health and Safety for

managers, British Safety Council, RAF Junior Officer's Command Course, Joint Services Command & Staff College, Pre-Hospital Emergency Care Course, Royal College of Surgeons, RAF Individual Staff Studies Course, Joint Services Command & Staff College, Advanced Life Support, Resuscitation Council UK, Paediatric Advanced Life Support, Resuscitation Council UK, Major Incident Medical Management & Support, ALSG, Generic Instructors Course (MIMMS), ALSG, Contemporary Issues in Defence Nursing (BSc Module), Birmingham City University, Aeromedical Evacuation (Flight Nursing Officer), RAF Aeromedical Evacuation Squadron. He reported to the Inspector and acted as a Subject Matter Expert to the Inspector and Inspection Manager for clinical related queries.

35. Kim Williams was a Specialist Advisor. She held the following qualifications: RGN/RSCN 1983 – Alder Hey School of Nursing, ENB 998 Teaching and Assessing JMU, ENB 199 Accident & Emergency Nursing JMU, MSc in Clinical Nursing Liverpool University, V300 Independent Nursing Prescribing – Liverpool University, Mentorship in practise – Edgehill University, Transforming the NHS leadership course – NHS Leadership academy. She reported to the Inspector and acted as a Subject Matter Expert to the Inspector and Inspection Manager for clinically related queries.

Critical Care Inspection Team

36. Caroline Williams was a CQC Inspector. We do not hold details of her professional qualifications. She reported directly to the Inspection Manager and was responsible for this core service inspection, including escalation of any immediate risks identified during on-site inspection, and drafting the inspection report.

37. Angela McLuckie was a Specialist Advisor. Her qualifications included MBBS – Guy's Hospital, London, FRCA – London, FCICM – Australia and New Zealand, FFICM – United Kingdom. She reported to the Inspector and acted as a subject matter expert to the Inspector and Inspection Manager for clinical related queries.

38. Sheila Reynolds was a Specialist Advisor. Her qualifications included PG Cert in Audit and Clinical Effectiveness (Distinction), BMedSci in Nursing Studies (First Class), ENB Cert 998 Teaching & Assessing in Clinical Practice, ENB Cert 100 Intensive Care Nursing, JBCNS Cert 198 A&E Nursing, State Certified Midwife and State Registered Nurse. She reported to the Inspector and acted as a subject matter expert to the Inspector and Inspection Manager for clinical related queries.

End of Life Inspection Team

39. Julie Hughes was a CQC Inspector. We do not hold details of her professional qualifications. She reported directly to the Inspection Manager and was responsible for this core service inspection, including escalation of any immediate risks identified during on-site inspection, and drafting the inspection report.

40. Howard Evans was a Specialist Advisor. His qualifications included Joint Board of Clinical Nursing Studies 243 Oncology Certificate (Royal Marsden Hospital London), Joint Board of Clinical Nursing Studies 930 Care of the Dying (Royal Marsden Hospital London), Registered General Nurse (Guys Hospital, London), ENB 237 Oncology Certificate (Royal Marsden Hospital London), ENB 998 Teaching and Assessing Certificate (Royal Marsden Hospital London), ENB A18 Diploma in Higher Education in Palliative Care (Royal Marsden Hospital London), BSc (Hons) Palliative Nursing, Smith and Nephew Scholarship (Manchester University/ Royal Marsden Hospital London), V300 Independent Nurse Prescriber (Chester College), Honorary Lecturer in Cancer and Palliative Care (University of Chester), Advanced Communication Skills (National Cancer Action Team). He reported to the Inspector and acted as a subject matter expert to the Inspector and Inspection Manager for clinical related queries.

Maternity Inspection Team

41. Michelle Haller was a CQC Inspector. We do not hold details of her professional qualifications. She reported directly to the Inspection Manager and was responsible for this core service inspection, including escalation of any immediate risks identified during on-site inspection, and drafting the inspection report.

42. Cara Taylor was a CQC Shadow Inspector. She reported to the Inspection Manager and attended the inspection on 16 February 2016 for shadowing purposes. Her qualifications included BSc Enhancing professional Health Care Practice BSc, ENB997/Education Studies, Midwifery Diploma, General Nursing Certificate.

43. Julie Langton was a Specialist Advisor. Her qualifications included MB ChB (Dundee) with commendation, MRCOG, FRCOG, Master of Business Administration (MBA) Open University. She reported to the Inspector and acted as a subject matter expert to the Inspector and Inspection Manager for clinical related queries.

44. Jacqueline Blease was a Specialist Advisor. Her qualifications included Registered Midwife , English National Board- Course 904 Special and Intensive Care of the

Newborn, Foundation Management Course, Supervisor of Midwives, University of Manchester, English National Board- Course 997 Teaching and Assessing in Clinical Practice, English National Board- Course 405 Special and Intensive Care of the Newborn, English National Board- Course 923 Developments in Nursing Care, English National Board- Course A26 Diploma in Midwifery, IV access and cannulation, University of Central Lancashire, Communication, Counselling and Bereavement, Royal College of Nursing, Clinical Leadership Programme. She reported to the Inspector and acted as a subject matter expert to the Inspector and Inspection Manager for clinical related queries.

Medical Inspection Team

45. Joanne McManus was a CQC Inspector. Her qualifications included MSC Pharmacovigilance, Key Skills for Managers / 25 credits at Level HE5, Cardiovascular Disease Risk Assessment (Level 5), Teaching and Assessing in Clinical Practice (ENB 998), Registered General Nursing (level 1), Certificate in Clinical Data Management / Level 1, Cardiovascular Disease Risk Assessment / NQF Level 5. She reported directly to the Inspection Manager and was responsible for this core service inspection, including escalation of any immediate risks identified during on-site inspection, and drafting the inspection report.

46. Laurence Soloman was a Specialist Advisor. We do not hold details of his professional qualifications. He reported to the Inspector and acted as a subject matter expert to the Inspector and Inspection Manager for clinical related queries.

47. Ann-Marie Aziz was a Specialist Advisor. Her qualifications included Registered General Nurse, Diploma in Professional Studies Nursing, Teaching & Assessing Course: Enb 998, Diploma in Higher Education: Cardiothoracic Course: Enb 249, Health Care & Welfare BSc (2:1 Hons), Post Graduate Certificate in Education, Principles of Infection Control Nursing Module Level 3, MSc Practice Development/Health Protection, MSc Leadership & Management. She reported to the Inspector and acted as a subject matter expert to the Inspector and Inspection Manager for clinical related queries.

48. Annie Munson was a Specialist Advisor. Her qualifications included Student Nurse, BSc (Hons) Adult Nursing, Advanced Apprenticeship in Health and Social care, Level 3 NVQ; Health and social care, Coloplast Certified Stoma Care Foundation course, Level 2 Key Skills Maths and English, Level 2 NVQ; Health and social care. She reported to the

Inspector and acted as a subject matter expert to the Inspector and Inspection Manager for clinical related queries.

Outpatients and Diagnostics Inspection Team

49. Deborah Lindley was a CQC Inspector. Her professional qualifications were as a registered general nurse and registered children's nurse, a City & Guilds 7307 Adult Education Teachers certificate, a BSc (Hons) in Applied Psychology, and level two certificates in Counselling Concepts and Counselling Skills. She reported directly to the Inspection Manager and was responsible for this core service inspection, including escalation of any immediate risks identified during on-site inspection, and drafting the inspection report.

50. Michael Rees was a Specialist Advisor. His qualifications included: MRCP Royal College of Physicians of Edinburgh, DMRD Royal College of Surgeons, FRCR Royal College of Radiologists, FRCP Royal College of Physicians of Edinburgh, MILT Institute of Learning and Teaching, FHEA Higher Education Academy, Cert Ed. Bangor University, European Board of Cardiac Radiology, Application PhD by research submitted to University of Ioannina 2004 Doctorate awarded by University of Ioannina 2006 h.c, FICA International College of Angiologists, FACA American College of Angiologists. He reported to the Inspector and acted as a subject matter expert to the Inspector and Inspection Manager for clinical related queries.

51. Wendy Preston was a Specialist Advisor. Her qualifications included Teaching and Assessing, Level 2 ENB 998, Nursing Studies, Diploma, Nursing Studies, BSc (Hons), Health Assessment, Level 3, Non-medical prescribing, master's certificate, Respiratory Care, Masters, PG Cert – Higher Education, Masters Cert. She reported to the Inspector and acted as a subject matter expert to the Inspector and Inspection Manager for clinical related queries.

Children and Young People Inspection Team

52. Helen Cain was a CQC Inspector. She was a Paediatric nurse who was responsible for core service inspection, including escalation of any immediate risks identified during on-site inspection, and drafting the inspection report. She directly reported to the Inspection Manager.

53. Benjamin Egware Odeka was a Specialist Advisor. His qualifications included MBBS Ibadan, DCH Glasgow, FRCP London, FRCPCH London, MA health care Law (Salford). He reported to the Inspector and acted as a subject matter expert to the Inspector and Inspection Manager for clinical related queries.

54. Mary Potter was a Specialist Advisor. Her qualifications included RGN - Register for General Nurses, RSCN- Register for Sick Children's Nurses, DipHRS - Diploma in Healthcare Research Studies (University of Leeds), ENB 870 - An Introduction to the Understanding and Application of Research, ENB 998 - Teaching and Assessing in Clinical Practice. She reported to the Inspector and acted as a subject matter expert to the Inspector and Inspection Manager for clinical related queries.

Surgery Inspection Team

55. Katherine Williams was a CQC Inspector. Her qualifications included Bachelor of Nursing Degree (hons) and a master's degree Health and Social Care Leadership. She directly reported to the Inspection Manager and was responsible for this core service inspection, including escalation of any immediate risks identified during on-site inspection, and drafting the inspection report.

56. Sadasivam Selvakumar was a Specialist Advisor. His qualifications included MBBS, University of Madras, India, MS General Surgery, University of Madras, FRCS (Edin), FRCS Gen, Intercollegiate Board in General Surgery, FRCS (Eng). He reported to the Inspector and acted as a subject matter expert to the Inspector and Inspection Manager for clinical related queries.

57. Lisa Tierney was a Specialist Advisor. Her qualifications included Dip HE specialised Nursing, Registered General Nurse, State Enrolled Nurse. She reported to the Inspector and acted as a subject matter expert to the Inspector and Inspection Manager for clinical related queries.

58. The inspection was also supported by Inspection Planner Steph Addit, who supported with logistical arrangements, travel, accommodation, hospitality and liaison with providers for on-site support, and Lyn Andrews was an Inspection Analyst Team Leader.

59. The 2016 inspection was a routine inspection as part of CQC's scheduled programme of announced inspections. The programme ran from 2013 until 2016 and delivered

comprehensive ratings for NHS acute Trusts. The inspections were to include a mixture of unannounced and announced visits including weekend and evening inspections. The programme formed part of the delivery of our strategy from 2013, and was reflected in CQC business plans, annual reports, press releases and news stories from that point: For example:

- *Chief Inspector of Hospitals announces inspection plans* – Published 18 July 2013. This article relates to changes in the way hospitals were inspected in England. (IT/108 [INQ0017326])
- *CQC's new hospital inspection to start tomorrow* – Published 16 September 2013.This article was published in the week that the new programme of hospital inspections began. (IT/109 [INQ0017344])
- *Our priorities and plans for the next two years* – Published 8 May 2014. (IT/110 [INQ0017416]) We published our business plan for 2014/15 to 2015/16, which set out how we would make sure health and social care services provide people with safe, effective, compassionate and high-quality care, and encourage them to improve. (IT/111 [INQ0017343])

60. The 2016 Inspection team briefing pack for CQC Inspectors stated that the following eight core services were to be inspected, plus any additional services based on risk triggers derived from our intelligent monitoring: (IT/112 [INQ0017286])

- Urgent and emergency services.
- Medical care (including older people's care;)
- Surgery.
- Critical Care.
- Maternity and gynaecology.
- Services for Children and Young People (CYP); (*At the time of the February 2016 inspection, the core service of children and young people included neonatal services. From 2018, CQC's methodology introduced a policy on additional services. Neonatal care was considered an additional service and there is a framework for inspecting neonatal care).* (IT/14 [INQ0010484]; IT/15 [INQ0010502])
- End of life care.
- Outpatients and diagnostic imaging

61. The evidence relied upon for this inspection is detailed within the inspection notes exhibited (IT/103 [INQ0017339]; IT/104 [INQ0017333]; IT/105 [INQ0017340]; IT/106 [INQ0017288]; IT/107 [INQ0017290]). Our guidance document '*Inspection Framework: NHS Trusts and Foundation Trusts'* provides further information on the sources of evidence inspectors may use to reach their conclusions on the leadership and management of a Trust. (IT/29 [INQ0010535]) This is not intended to be an exhaustive list and the evidence obtained will vary between inspections.

62. When reaching conclusions on staffing during any inspection, Inspectors use a range of methods. This includes speaking with patients and staff for their views on staffing levels, observations on wards, and obtaining records such as staffing dependency tools and staff rotas. The exact evidence Inspectors obtained varies between Inspectors and additional evidence may be obtained depending on what people told us and our observations during the visit.

63. As part of our evidence gathering for this inspection, we spoke with patients and/ or carers, as well as observing care and inspecting records. We spoke with 44 members of staff at different grades, including: nurses, doctors, consultants, medical students, ward managers, specialist nurses, and play specialists. We also received comments from people who contacted us to tell us about their experiences.

64. We have collated a list of names and job titles of those spoken with and exhibited as (IT/113 [INQ0017322]).

65. As part of the inspection of the Children and Young People's service, Inspectors spoke to a range of staff, including two healthcare assistants, a play specialist, a shift leader, an NNU (neonatal unit) assistant nursery nurse, a specialist children's community nurse with lead for oncology, a diabetes specialist nurse, an ENP (Emergency Nurse Practitioner), neonates manager and deputy manager, two consultants, three staff nurses (band not specified), two band five staff nurses, five doctors, practice development nurse, a specialist nurse for children with asthma, a lead nurse for children's services, the practice development lead for NNU, the NNU manager, the lead nurse for children's services, manager for CYP complex care team and a neonatal unit manager. A full list of staff we spoke to as part of this visit is in (IT/103 [INQ0017339]).

66. On the neonatal unit, we spoke with six parents. These conversations were held by CQC Specialist Advisors Dr Odeka and Mary Potter. One parent told us that staff were very clear about management plans and found them clear and helpful. They told us doctors

and nurses were accessible. Another parent felt that Liverpool Women's hospital had more staff. A third parent gave positive feedback of their neonatal experience and told Inspectors of positive support for parents from the whole team. They did feel however that space was limited. A record of the discussions is available in (IT/103 [INQ0017339]).

67. As part of the inspection, on the afternoon of 17 February, the inspection team held a focus group attended by a number of consultants working at the Trust. This was one of a number of planned focus groups carried out as a routine part of our inspection process. These consultants worked across a number of the Trust's services, including the neonatal unit. (IT/114 [INQ0017287]; IT/115 [INQ0017289; IT/116 [INQ0017292]; IT/117 [INQ0017324]; IT/118 [INQ0017398]; IT/119 [INQ0017427]; IT/120 [INQ0017431])

68. During the focus group, concerns were raised with us by attendees. The concerns raised were in relation to staffing, and a bullying culture – there was a feeling that there was a lack of support from management. These were not specific to the neonatal unit, but applied to a number of services whose staff attended the focus group. We have not yet located the notes from this focus group but have images of contemporaneous notes completed by a member of the inspection team. (IT/121 [INQ0017319]) From reviewing the available notes from the focus groups, and from recollections of members of the inspection team, concerns were not raised with us regarding either LL or neonatal deaths.

69. Later that same afternoon a meeting was held between the inspection team and the Medical Director of the Trust, Ian Harvey. Available records of this meeting, alongside recollections from members of the inspection team, inform us the meeting included a discussion of the concerns raised by consultees in the focus group. (IT/121 [INQ0017319])

70. The information above fed into the evidence underlying our inspection report. The level of staffing and skill mix of staff on the neonatal unit and on paediatric wards– in particular that this did not meet British Association of Perinatal Medicine (BAPM) standards - had been identified on the inspection site visit as an area of concern, and we made clear to the Trust that action was needed to ensure sufficient numbers of staff - including those trained in advanced paediatric life support. Why the BAPM standards were not being met was later addressed within the inspection report. (IT/102 [INQ0017433])

71. We later followed up on actions taken in response to our concerns through post-inspection engagement with the Trust. The draft inspection report was shared with the Trust on 6 June, and on 27 June we held a Quality Summit to consider the support

required in response to the report and regulatory breaches. This was attended by representatives of CQC; the Trust; NHS Improvement; the Quality Surveillance Group; the local authority; the Overview and Scrutiny Committee; the NHSE area team; the General Medical Council; and the University of Chester. The attendee list is at (IT/122 [INQ0017293]), but we have not been able to locate any minutes from this meeting.

72. Following publication of the report on 29 June 2016, the Trust was given 28 days to submit an action plan setting out the steps both underway and planned to address all areas of concern raised with them during the inspection process. This was submitted to us on 20 July to review, sign off, and continue to monitor through ongoing engagement with the Trust. (IT/123 [INQ0017341])

73. We first became aware of concerns regarding deaths on the Neonatal Unit on 29 June 2016, the day our inspection report was published. CQC Inspector Deborah Lindley received a call from Alison Kelly, Director of Nursing and Quality at Countess of Chester NHS Foundation Trust, informing her the Trust had identified an increase in the number of deaths of newborn babies (differing levels of prematurity) on the Neonatal Unit in 2015-16 and now in 2016 -17 compared to previous years. We were also advised about two neonatal deaths that weekend. Concerns regarding staffing at the neonatal unit were identified during the inspection process (see paragraph 71 above).

74. On 30 June 2016, Alison Kelly emailed CQC Head of Inspection Ann Ford, detailing the actions the Trust were taking following the concerns raised on 29 June 2016. This included a proposal to 'close' the unit, only accepting Level 1 babies, a terms of reference to support the Royal College of Paediatrics and Child Health (RCPCH) review, a review of incident reporting data, a deep dive into staff rotas (of all disciplines) clinical and non-clinical regarding staff on duty at time of neonatal deaths, a review of environmental issues, microbiology review and equipment and a detailed review of security and access to the Unit. The email also confirmed that reviews would be undertaken of staff performance, complaints data and Coroners referrals. (IT/124 [INQ0017411])

75. Clinicians had been tasked with developing a clinical plan by 1 July 2016 of what the model of care would be if the unit closed. Once this plan had been confirmed, liaison was to be undertaken with the Neonatal network regarding operationalising the plan and requesting support. (IT/124 [INQ0017411])

76. Ruth Millward, Head of Risk and Patient safety at the hospital provided further detail via email on 07 July 2016, and advised that three intensive care cots would be closing on

the neonatal unit whilst an independent review of the neonatal service was being undertaken. (IT/125 [INQ0017328])

77. On 28 July 2016 Inspectors attended a Mersey and Cheshire wide Quality Surveillance Group meeting which included NHSE/I and system partners (See Statement Part 1, PP 87-97 re QSGs).

78. On 24 August 2016 an Inspector and Inspection Manager attended an engagement meeting with the CoCH. Maternity and neonatal services was identified as a key risk area in the strategic update provided by the Trust. The meeting agenda shows that an external review was planned for the following week. (IT/126 [INQ0017296])

79. It is our understanding that the RCPCH reviewed the neonatal service at the CoCH on 01 to 02 September 2016.

80. On 22 December 2016 an Inspector attended a further engagement meeting with the CoCH. The neonatal review was an area for discussion, and maternity and neonatal services continued to be identified as a key risk area under the strategic update provided to us by the Trust. We were informed that the RCPCH report was at the draft factual accuracy stage, and we requested a copy of the final report. (IT/127 [INQ0017298])

81. On 17 January 2017, Ruth Millward shared with Inspector Deborah Lindley a letter addressed to NHS England from the Trust advising that the neonatal review had recommended that a further independent case review was required of relevant cases. As a result of this, a final report was not ready for sharing. The letter notes that the Trust had been assured by the review team that there were no immediate actions or concerns. (IT/128 [INQ0017397])

82. On 30 January 2017 we requested and received a copy of the RCPCH review preparation checklist that had been issued to the CoCH for the 01 to 02 September visit. (IT/129 [INQ0017281])

83. On 3 February 2017 the Trust Communication Manager contacted CQC to inform us about a media query from The Sunday Times regarding the RCPCH Report and provide some background information. (IT/130 [INQ0017392])

84. The RCPCH Report was published on the CoCH website on 08 February 2017. CQC had not been involved in this review or had any interaction with RCPCH about their review. Our non-involvement was usual in these circumstances as we did not commission the report and would not have had access to it until it was completed. Our

Inspectors would have read and considered the report prior to discussing this with the Trust at a meeting on 17 February 2017.

85. On 17 February 2017 an Inspector and Inspection Manager met with the CoCH to discuss the findings of the report. The engagement meeting was attended by Tony Chambers, Chief Executive of the Trust at the time. Records we have available suggest this is the first contact CQC had with the Trust board, individual or governor following the report's publication. CQC had met with the Trust board prior to this in relation to our inspection activity. Neonatal services were a key risk area in the agenda for this meeting. (IT/131 [INQ0017299]) We captured minutes for this meeting that took place on 17 February 2017, and shared these minutes with the CoCH via email on 06 March 2017. Ian Harvey, Medical Director at the CoCH provided us with the following strategic update regarding neonatal services and the RCPCH review:

> '*IH explained that following the publication of the external review by the Royal College of Paediatrics and Child Health (RCPCH), this month, the parents of children, that were contactable, were informed and the report has been shared with them and key stakeholders. The coroner has been involved and there are plans to discuss the report further with the paediatricians. Plans for staff include attending Alder Hey to help maintain their competencies. The impact on neighbouring units has been less than expected. There are lessons to be learned around transport processes and in the incident reporting system. The action plan has been requested – due for completion in March 2017.*' (IT/132 [INQ0017300])

86. On 22 February 2017, we wrote to Tony Chambers and asked for a copy of the action plan developed to implement the recommendations of the neonatal service review. (IT/133 [INQ0017301]) This information was shared with us on 22 March 2017. (IT/134 [INQ0017410]) We later received updated neonatal action plans on 13 September 2017 and 17 October 2017. (IT/135 [INQ0017413]; IT/136 [INQ0017412])

87. On 28 February 2017, we attended a Quality Risk Profile (QRP) meeting with the Trust. The QRP was a standardised tool for NHS providers used at that time as an oversight mechanism to rate risks and potentially escalate to a 'risk Summit'. The meeting was attended by an Inspector and Inspection Manager. Records available from this meeting suggest that the main areas discussed were the responsiveness of the Trust for requests for information/assurance, which had deteriorated over the past 6 – 9 months, the number of surgical related Never Events and the Trust's ability to evidence learning and

partnership working specifically within NHSE's Specialised Commissioning services such as Vascular and neonates. (IT/137 [INQ0017337])

88. On 06 March 2017, the CoCH notified us about an incident that occurred on 11 February 2017. The notification related to the intubation and subsequent cooling of a neonate who had attended the hospital's A&E via paramedics. The baby in this incident was referred to the neonatal unit for cooling and later transferred to Liverpool Women's Hospital. In response to this information, an Inspector requested further information on initial learning as well as the root cause analysis. The information was reviewed, and the incident assessed as 'low harm' by the Inspector reviewing the information. (IT/138 [INQ0017372])

89. On 13 April 2017, the neonatal action plan sent to CQC on 22 March 2017 was discussed at an engagement meeting with an Inspector and Inspection Manager. We were provided with an update on the progress of this plan. (IT/139 [INQ0017302])

90. We were not involved in any decisions on re-designating the neonatal unit from a level 2 to a level 1 unit in Summer 2016. We were kept informed of discussions around the unit's designation in our engagement meetings with the Trust. We understand the RCPCH made three recommendations regarding the Level designation of the unit following their review in November 2016:

- Two additional Consultant appointments must be in place before any consideration can be given to possible re-designation as a Level 2 unit.
- Ensure maintenance of skills of neonatal nursing and medical team to ensure that a return to Level 2 can be safely managed. Rotation of staff to Level 3 units should be explored.
- Develop a strategic plan for sustainable recruitment to the Tier 2 rotas through development of nurse practitioner or other roles and review the protocol for locum assessment.

91. These recommendations were captured in the *Neonatal External Review Action Plan February 2017* document that was first shared with us on 22 March 2017. The required actions identified by the Trust to meet these recommendations and progress to completion are captured in the action plans. (IT/134 [INQ0017410])

92. At our engagement meeting with the CoCH on 13 April 2017, they provided us with the following update regarding the level designation of the neonatal service; '*Level 1 remains in place with 98% staffing compliance. The updated review has been requested to be sent once completed. There is a plan in place if a decision is made to move to level two, however, no decisions as yet. Concerns that BAPM standards are difficult to achieve*.' (IT/139 [INQ0017302])

93. We understand that the neonatal unit delivered a model of care which sits between the models of a Level 1 special care unit (SCU) and a Level 2 local neonatal unit (LNU). At our inspection of the hospital in October to November 2023, the staffing requirements for the neonatal service were assessed using the Level 1 standard as a baseline. The service met and exceeded the standards for Level 1, however the model of care provided by the service meant it was not possible to fully assess whether the service had enough staff with the right skills to provide this level of care. Further detail is available at (IT/140 [INQ0017434])

94. Review of available records indicate that CQC first became aware of a criminal investigation on 15 May 2017, following an engagement call with the Trust. The details of the call were logged in an email to then Deputy Chief Inspector of Hospitals Ellen Armistead, by Lorraine Bolam, Acting Head of Hospitals Inspections. The log states:

> *'The baby deaths occurred in 2014/15 and the first half of 2015/16. There had been around 3 baby deaths per year prior to this but they experienced 8 in 2014/15 and a further 5 in the first half of 2015/16. There have been no further baby deaths since June last year when they reduced the unit to Level 1 only, this excludes all deliveries under 32 weeks gestation and all level 2 dependency babies are transferred to level 2 units. The Trust is confident that the unit is safe at the current time.*
> *However, the neonatologists were still concerned and this led to a report to the Child Death Overview Panel which requested the Trust seek assurance from the police regarding any un-natural causes for the deaths. The CEO wrote to the police a few weeks ago requesting that they explore whether a police criminal investigation was warranted. Police have reviewed information supplied by the Trust and spoken with medical staff and deemed further investigation is warranted. The police have indicated that a further review of the deaths may be undertaken by a relevant specialist.*
> *The family of the child whose inquest was adjourned have been to the Trust to speak with the executives. 10 of the families of the 13 children have been contacted by the police family liaison and the others will be shortly. The Trust is liaising with staff and is*

setting up a help line for families and staff. GP's have not currently been informed as the police do not want the identity of the families released at this time.' (IT/141 [INQ0017303])

95. On 16 May 2017, the Trust shared with us their briefing on neonatal services confirming police involvement in neonatal services following the external RCPCH review published in February 2017. (IT/142 [INQ0017359]) Further briefs were received on 18 May 2017. (IT/143 [INQ0017393]; IT/144 [INQ0017428])

96. Also on 16 May 2017, our National Contact Service Centre (NCSC) received a call from Claire Raggett inviting the Inspection Manager for CoCH to a conference call regarding the neonatal death review. We are currently unable to determine if this was attended by CQC. (IT/145 [INQ0017373])

97. On 31 May 2017, Inspectors were told that the current action plan remained in place with twice daily 'safety huddles' now established. These included lead representatives from the labour ward and neonatal. (IT/146 [INQ0017304])

98. On 9 June 2017, an MRM was held. This was attended by an Inspector and two Inspection Managers and was set up to discuss CQC's response to the news that a police investigation was underway. The outcome of this meeting was that the team would wait for the outcome of the police investigation as assurances had been received that processes were in place to monitor safe care and treatment. (IT/147 [INQ0017407])

99. On 12 July 2017, Inspectors were informed that the police investigation was ongoing and neonatal services continued to have daily monitoring. (IT/148 [INQ0017306])

100. On 25 August 2017, Inspectors were again advised that the police investigation was ongoing and that an updated action plan would be forwarded when completed. (IT/149 [INQ0017307])

101. On 12 October 2017 meeting, Inspectors were informed that the police investigation was entering its second phase and that 100 staff were due to be interviewed. (IT/150 [INQ0017308])

102. On 7 November 2017, an MRM was held to review the information on the neonatal police investigation. The meeting was attended by two Inspectors, two Inspection Managers and a Head of Hospital Inspections. Records show that the outcome of this meeting was

that a focussed inspection would not be carried out at this time. It was also agreed that we would not contact the police as the previous agreement with stakeholders was that NHSE would co-ordinate this. It was agreed that the inspection team would continue our monitoring of the Trust at engagement meetings. The Head of Hospital Inspection would contact NHSE for an update and that the team would consider including neonatal services at next inspection when this was presented. Review of our available records show that this update was requested on the same day. (IT/147 [INQ0017407]; IT/151 [INQ0017371])

103. Although not specific to neonatal care, on 22 November 2017, we received information directly from CoCH that following an unexpected emergency delivery a baby was born in a poor condition and required ventilation and transfer to a nearby tertiary unit. In response, an Inspector requested the root cause analysis, and this was shared with us. The analysis showed poor situational awareness and repeated multidisciplinary failures to recognise the need for urgent delivery, leading to delays. (IT/152 [INQ0017375])

104. On the same day, the CoCH also alerted us to a patient who had experienced I&S I&S The Trust confirmed they were investigating this and later shared that the root cause of the incident had been identified I&S I&S We reviewed this information and recorded that no further regulatory action was required. (IT/153 [INQ0017374])

105. In November 2017, Inspectors requested neonatal mortality figures for 2014 – 2016. These were shared with us on the same day. (IT/154 [INQ0017399]; IT/155 [INQ0017401]; IT/156 [INQ0017400]) The mortality figures showed that the (stabilised and adjusted) mortality rates in 2015 were 10% higher when compared with other similar NHS Trusts. The causes of neonatal deaths were summarised as infection, neonatal and congenital abnormality. Inspectors may use the headline data in these reports as part of the inspection process. This this can form part of discussions with clinical staff, depending on any other areas of concern or risks which may have been identified otherwise.

106. An engagement meeting was attended by Inspectors on 11 December 2017. (IT/157 [INQ0017309]) The agenda for this meeting included the standard items and attendees as well as a discussion of the progress against the neonatal action plan. All internal actions were reported as complete. Staff were involved in the ongoing police investigation and were receiving support from the Trust. There were no reported themes or trends emerging from incidents.

107. An engagement meeting took place on 25 January 2018. Inspectors were told by the Trust Medical Director that the police investigation was continuing and that the Trust remained in contact with NHSE. Staff interviews with the police were continuing. No issues or interim actions had been highlighted and the unit was reported to be safe since changes were put into place. There was a discussion around returning to a level 2 unit, however the decision was deferred until April and until staff had been recruited to ensure BAPM standards could be met. (IT/158 [INQ0017310])

108. On 07 March 2018, CQC received an email from Dr Stephen Brearey, Consultant Paediatrician and Neonatal lead at CoCH. The email states that Dr Brearey had been advised to write to the Trust chairman with some serious concerns and to copy Ted Baker (CQC's Chief Inspector of Hospitals) into the email. Dr Brearey requested Ted Baker's details. (IT/159 [INQ0017376]) This email was responded to on 9 March 2018, and Ted Baker's email address was provided. (IT/160 [INQ0017330]) Review of available records show CQC did not receive any further correspondence from Dr Brearey following this email.

109. On 11 July 2018, Julie Fogerty from CoCH telephoned CQC to inform us of the delivery of 21-week-old twins who had sadly passed away. CoCH would not normally report this directly to CQC however, in light of the ongoing concerns and media scrutiny, they wanted to make CQC aware. Julie advised that a multiagency conference call had been held earlier in the week with police taking primacy. Julie told us that Associate Directors were completing walk-arounds regularly to Maternity, Neonatal and other non-clinical areas. This information was discussed by an Inspector and Inspection Manager, and it was agreed that no further regulatory action was required. (IT/161 [INQ0017377])

110. On 18 October 2018, an engagement meeting was held. There was an update on neonatal care provided as well as a discussion on the impact on services. (IT/162 [INQ0017378])

111. Throughout 2018 and 2019, CQC attended a number of meetings with an Incident Coordination Group set up in response to the police investigation. The Incident Coordination Group was chaired by NHS England to monitor the progress of investigations and its impact on the running of services at CoCH. The group included representatives from CQC, the CoCH, NHS England, NHS Improvement, Cheshire Police, Liverpool Women's NHS Foundation Trust, Cheshire and Wirral Partnership NHS Foundation Trust, Cheshire West Council, and West Chester Clinical Commissioning

Group. These meetings took place on 4 June 2018, 10 July 2018, 22 October 2018, 28 January 2019 and 5 April 2019. (IT/163 [INQ0017334]; IT/164 [INQ0017335]; IT/165 [INQ0017332]; IT/166 [INQ0017414]; IT/167 [INQ0017402])

112. On 13 November – 13 December 2018, we carried out a routine inspection. The report of the inspection was published on 17 May 2019. (IT/168 INQ0017418) We did not inspect services for children and young people during this inspection. It is outlined in the 'Inspection Proposal and Regulatory Plan' that services for children and young people would not be inspected. The concerns highlighted in the PIR and by analysts related to surgical site infections and staff turnover, both of which could be investigated within the surgery core service and through interviews with Trust executive and senior leaders. (IT/169 [INQ0017311]) Judith Connor, Head of Hospital Inspections led this inspection. An executive reviewer, Jackie Bird, who was an NHS Chief Nurse and Executive Director of Quality, supported our inspection of the well-led Key Question for the Trust overall. The team included a CQC Inspection Manager, six Inspectors and ten Specialist Advisors. Executive reviewers are senior healthcare managers who support our inspections of the leadership of Trusts. Specialist Advisors are experts in their field who we do not directly employ.

113. In November and December 2018, two MRMs were held to discuss the inspection and decide if any enforcement action was needed. (IT/170 [INQ0017408]) In the inspection report we noted breaches of regulation and issued requirement notices under Regulations 10, 12,17 and 18.

114. On 2 July 2019, we received a telephone call from a member of the public I&S at our contact centre (NCSC). I&S I&S I&S I&S had complained directly to the Trust but was not satisfied with their response. I&S was signposted to the Parliamentary and Health Service Ombudsman. The record states no immediate follow up from CQC was required. This outcome would have been determined based on the Inspector's analysis of the information provided. (IT/171 [INQ0017379])

115. On 9 September 2019, CQC received a concern via our online webform from I&S I&S advised that their family were one of the families involved in the police investigation but wanted to share concerns about their most recent experience of CoCH. They noted poor co-ordination between diabetic and obstetric care but explained their neonatal care had

improved from their previous experience. The information was reviewed by an Inspector who recorded they would raise the concerns with the Trust; no further records in relation this enquiry has been identified and CQC is unable to confirm if this was done. (IT/172 [INQ0017380]).

116. We then received an anonymous concern via our online webform on 28 January 2020. The concern stated:

> *'There has been poor neonatal care in a significant number of Hospitals in England and Wales re Shropshire and Telford, Kent, Morecombe Bay and? Cwm Taf in Wales.*
>
> *This has also occurred in Countess of Chester Hospital.*
>
> *Unless proved otherwise in a court of Law County of Chester Hospital has scapegoated a member of its own staff in order not to face full investigation like the other hospitals.*
>
> *The maternity and neonatal failings have been system failures rather than individual failures but in a complete blame game process County of Chester Hospital has heaped all blame on 1 individual. Hence perhaps County of Chester Hospital itself as a Hospital should face criminal charge of corporate manslaughter.'* (IT/173 [INQ0017381])

117. No specific action was taken once we became aware of the arrest of LL. However, we were kept informed of updates on the investigation via our engagement with the Trust and other stakeholders.

118. On 26 May 2020, we received a concern via our online webform from I&S. I&S explained I&S. They had sent a list of questions to the Trust about their care but had not had a response. I&S's concern was around the lack of communication and any help or support for the family. The Inspector to whom the concern was allocated, recorded that this would be discussed at the next engagement meeting on 30 June, and that CQC would wait for the Health Services Safety Investigations Body (HSSIB) and Trust investigation to be complete. (IT/174 [INQ0017383]; IT/175 [INQ0017802])

119. An engagement meeting took place on 30 June 2020. As this was during COVID, and because of the pressures NHS Trusts were facing at the time, engagement meetings

were shorter than usual and focused on Infection Protection and Control (IPC), staffing pressures, emerging risks and emergency department pressures. (IT/176 [INQ0017382])

120. On the 28 July 2020, we completed an IPC assessment of the Trust. This was held remotely as part of our COVID-19 response. (IT/177 [INQ0017325])

121. Following LL being charged on 11 November 2020, an MRM was held on 17 November 2020 to discuss if any regulatory action was required. In attendance at this meeting were an Inspector, Inspection Manager, Head of Inspection and Deputy Chief Inspector for Hospitals. It was agreed at this meeting that no responsive inspection was required as the charging of LL had not produced any new risks that were unknown to CQC previously. It was determined that there were no immediate clinical risks. It was agreed that neonatal services would remain on the engagement meeting agenda with the Trust to ensure data remained within normal parameters. (IT/178 [INQ0017409]) As our data at the time of this MRM did not indicate safety or clinical risk, we would not normally consider civil enforcement action in response to this information, and the applicable time period for criminal enforcement had likely passed in accordance with section 90 of the Health and Social Care Act 2008.

122. A patient at CoCH raised a concern about maternity care on 22 February 2021. The person told us they felt things were not explained to them during the labour. The information was reviewed, and it was recorded that the information would be noted for ongoing engagement and future inspection activity. (IT/179 [INQ0017360])

123. On 21 March 2021 we received positive feedback from a member of the public about the Maternity and Neonatal Intensive Care Unit (NICU) services. (IT/180 [INQ0017361])

124. On 23 September 2021, an MRM was held to decide whether an inspection of the CoCH was needed. It was decided that an inspection would take place to include the following four core services, based on highest risks: urgent and emergency care, maternity, surgery and medical care. A record of this decision was made in the Inspection Proposal and Regulatory Plan. (IT/ 181 [INQ0017404]; IT/182 [INQ0017403])

125. On 11 November 2021, an engagement call was held with the Trust in relation to the Maternity Core Service. (IT/183 [INQ0017364]) The outcome of this call was that no further action was required. The evidence provided to us by the Trust for the purposes of this call can be found in the following exhibits (IT/184 [INQ0017342]; IT/185

[INQ0017430]; IT/186 [INQ0017327]; IT/187 [INQ0017439]; IT/188 [INQ0017432]; IT/189 [INQ0017415]; IT/190 [INQ0017419]; IT/191 [INQ0017437]).

126. An anonymous whistleblower contacted us on 22 November 2021 raising concerns about maternity staff and the quality of care being provided. The concerns were shared with the Trust who provided an initial investigation report for the incident raised by the whistleblower. A trend review and action plan had been put in place to address the concerns. (IT/192 [INQ0017363]; IT/193 [INQ0017362]; IT/194 [INQ0017803])

127. On 15 February 2022 – 17 March 2022 we carried out an inspection. The report was published on 15 June 2022. (IT/195 [INQ0017435]) We did not inspect neonatal services during this inspection. The inspection team was made up of one Deputy Chief Inspector (who did not attend the site visit), one Head of Hospital Inspections, one Inspection Manager, ten Inspectors, one Assistant Inspector, one Inspection Planner, and nine Specialist Advisors. (IT/196 [INQ0017313])

128. In February and March 2022, six MRMs were held with the inspection team to discuss the inspection findings and agree if any regulatory enforcement action was required. (IT/197 [INQ0017405]) We issued two Section 29a Warning Notices, one in relation to maternity services, and one Trust-wide. (IT/198 [INQ0017314]; IT/199 [INQ0017315])

129. On 1 July 2022, we were made aware via a whistleblower of concerns about a governance report allegedly provided to the Trust in 2020. This suggested that there had been an issue with an agency midwife who had conditions on their registration and that there were currently 5 ongoing police investigations that CQC may not have been aware of. It is recorded that the Inspector would monitor this and follow up at engagement regarding the potential investigations. (IT/200 [INQ0017365])

130. On 27 July 2022 we carried out a routine focussed inspection to follow up on the two warning notices issued previously in relation to maternity services and the Trust more generally. The report was published on 30 September 2022. (IT/201 [INQ0017436]) We did not inspect neonatal services during this inspection. The inspection team consisted of two Inspection Managers, three Inspectors, and was overseen by a Head of Hospital Inspections.

131. In August 2022, three MRMs were held with an Inspector, Inspection Manager and Head of Inspection to discuss the Trust's progress against a warning notice issued for maternity units. It was agreed that sufficient progress had been made. (IT/202 [INQ0017406])

132. We received a concern on 9 September 2022 from a member of the public claiming their I&S I&S. Actions taken by Inspectors included review of the details and the incident would be included in the list for future monitoring/engagement. (IT/203 [INQ0017366])

133. On 17 October 2022, we received a concern from a member of the public that a staff member working in the NICU had I&S I&S. An Inspector discussed the concern with their line manager and agreed that as information was based on third hand information, we could not take this further. (IT/204 [INQ0017367])

134. On 3 November 2022 an enquiry was raised to notify that the Trust had an alarm level outlier for Deferred cord clamping in the National Neonatal Audit Programme (NNAP). An update was provided to CQC by the Trust who advised action had been taken in response to this outlier notification. (IT/205 [INQ0017368])

135. An engagement meeting took place on 15 December 2022. The Trust told us that the CoCH remained of media interest due to the ongoing reporting of the LL trial. There was a programme of support in place for staff required to attend court. (IT/206 [INQ0017336]).

136. The next engagement meeting took place on 31 March 2023. The LL trial was continuing, and the Trust advised that they continued to support staff throughout. (IT/207 [INQ0017317]).

137. On 09 May 2023, we received an anonymous handwritten letter from a midwife at the CoCH. It raised concerns around staffing numbers and the management of the Trust. In response to this information, an Inspector liaised with the Trust, shared the concerns and received a response about the actions the Trust would take in response. (IT/208 [INQ0017369]; IT/209 [INQ0017370])

138. An engagement meeting took place on 10 July 2023. The trial of LL was discussed, and it was recorded that the Trust was working closely with the Police and NHS England throughout but would not be commenting on the trial so as not to affect the judicial process. Support was reported to be in place for staff affected by the trial and those families who currently have babies on the NNU. (IT/210 [INQ0017318])

139. On 5 October 2023 an engagement meeting was held. In relation to LL, it was recorded that after the verdicts were announced, the Trust had continued to be under intense media scrutiny. The Trust worked closely with NHS England in preparing responses. (IT/211 [INQ0017320])

140. We undertook an inspection of Countess of Chester Hospital on the 17 – 19 October 2023 and the 14-16 November 2023. We inspected the Trust's services for children and young people at this inspection and this included the neonatal unit. This inspection team consisted of a CQC Deputy Director, Operations Manager and was supported by ten CQC Inspectors, one CQC Regulatory Coordinator, a CQC Inspection Planner and nine Specialist Advisors. The Trust was rated as 'Requires Improvement'. (IT/140 [INQ0017434])

141. Review of our records indicate that we did not directly liaise with RCPCH, NHS England, Healthwatch, the Health Ombudsman or other regulators in response to each individual concern raised in the above time period. In each case, our inspection teams liaised directly with the Trust to seek assurances on actions taken in response to incidents. In some cases, we signposted people to other agencies to progress their concerns. This is because our primary relationship is with the providers that we regulate. Depending on the timing of concerns, we may raise them in engagement meetings, incident coordination meetings, system improvement board meetings, emerging concerns protocol meetings, or NHSE engagement calls. We liaised with the police throughout this time period via the Incident co-ordination meetings (See Paragraphs 111). We also maintained a dialogue with Healthwatch about maternity services, although this would not have been specific to this Trust.

142. Throughout this time, we monitored risk at the hospital using our regular engagement meetings with the Trust. This was part of our usual process for engagement with an NHS Trust following an inspection as set out in paragraphs 12-13.

143. We also continued to monitor the Trust via data insight. This included the use of CQC Insight reports. CQC Insight brings together in one place the information we hold about a service, and analyses it to monitor a service at provider, location, or core service level. This provides analysis to support the evidence in our inspection reports. Review of these reports did not provide any flags in relation to the neonatal unit that the inspection team would have needed to explore further.

144. In our first statement, CQC's duties in relation to the Duty of Candour and Regulation 20 of the Health and Social Care Act (Regulated Activities) Regulations 2014, was explained at paragraphs 41-47 and 150-156. Our guidance document 'Regulation 20: Duty of Candour' provides additional information on how we monitor a Trust's compliance with Duty of Candour. (IT/212 [INQ0017316]) Our review of available records does not assist with whether compliance with Regulation 20 was considered in relation to any concerns raised with us by parents.

Reflections on the 2016 Inspection

145. All inspections, including the 2016 inspection of Countess of Chester Hospital, go through a quality assurance and factual accuracy process prior to publication. These processes are detailed at pages 44-48 of our guidance. (IT/213 [INQ0017394])

146. Before publishing any inspection report, the quality and consistency of each report would be checked to quality assure our findings and check that our judgements are consistent nationally. The report internal quality assurance process included a peer review of the draft inspection report followed by an Inspection Manager review, and then the report was reviewed by the Head of Inspection. The final stage of the internal quality assurance process was managed by the Deputy Chief Inspector, at which point the draft ratings were confirmed. At the time of the 2016 inspection, this was a National Quality Assurance Group meeting. (IT/214 [INQ0017295])

147. When we have checked the quality of any draft inspection report, we will send the provider the draft documents. We request that providers check the factual accuracy and completeness of the information that we have used to reach our judgements and ratings.

148. The factual accuracy process gives Inspectors and providers the opportunity to ensure that they see and consider relevant information that will form the basis of CQC's judgements.

149. The process encourages providers and the inspection team to consider all relevant information that contributes to our judgements and provides opportunities for providers to tell us where information is not accurate or is incomplete.

150. Where providers do make comments in relation to the factual accuracy of a report, we will decide whether to amend the draft report. To ensure any decisions made are fair and

impartial, all factual accuracy responses will be reviewed by another member of CQC's staff from the relevant Inspection Directorate, who is authorised to sign off the related inspection report. This member of staff will be independent of the original site visit. If a provider supplies additional evidence that the inspection team consider supports a change in rating, the draft report and final ratings will be confirmed by the Network Director (previously known as Deputy Chief Inspector) prior to publication.

151. Where a provider feels we have not followed this process, they are able to request a review of ratings. The only grounds for requesting a rating review after the completion of the factual accuracy process and publication are that we have failed to follow our process for making ratings decisions. A Trust cannot ask for a review of their ratings on the basis that they disagree with our judgements. We will first consider whether the request meets the grounds for review. If it does not meet these grounds, then we will refuse the request and write to the Trust to explain why. If it does meet the grounds, CQC staff not involved in the original inspection will review the aspects of the process that were not followed correctly. As well as our own staff, we may use independent reviewers if their expertise is relevant to the request. All ratings can go down as well as up as a result of a review.

152. The quality assurance and factual accuracy process is designed to ensure that all published reports are reflective of the inspection team's findings during the wider inspection process, including the site visit, but also from evidence such as the Trust's PIR submission, data requests made by CQC, and national audits. CQC were not aware of any concerns about deaths on the neonatal unit at the time of the site visit in 2016. Any recommendations identified at the time of the inspection were reflected in the report of that inspection.

153. Considering the above processes which were used at the time of the 2016 inspection, I consider that CQC's conclusions, on the basis of the evidence available to it at the time, were reasonable and accurate.

154. In relation to the governance of the neonatal unit at the time of the inspection, the Health and Social Care Act does not set any requirements for providers in relation to their governance structures across neonatal settings or the wider Trust. As such, CQC do not provide any guidance or policy on how NHS Trusts should structure their governance and management systems. NHSE does provide code of governance guidance for NHS Trusts. The Trust's structure will be determined by each Trust individually. Section 25 of the National Health Service Act 2006 ("2006 NHS Act") outlines that the Secretary of State may by order establish NHS Trusts to provide goods and services for the purposes

of the health service. Section 27b of the 2006 NHS Act sets out that NHSE may give directions to an NHS Trust established under section 25 about its exercise of any functions. NHSE may make recommendations to NHS Trusts in relation to restructuring (section 27c).

155. We cannot comment specifically on whether the management structure and governance of CoCH was typical for neonatal settings in other hospitals. CQC does not routinely assess the management structure and governance of individual departments within a broader core service as part of the inspection process. In this instance, neonatal services are one service within the wider children and young people's core service.

156. The 2016 report highlights that wider Children and Young people's services were rated 'Good' under the domain of well led at this inspection. The report indicates that the service had governance systems and processes in place at the time. We obtained governance structure charts as part of this inspection, and these described the structure of Paediatric units at the time of our inspection. (IT/80 [INQ0017346])

157. As per CQC's methodology at the time of the 2016 inspection of the CoCH, we completed a Trust level well led inspection. The inspection team reported that at the Trust level, there was a well-developed approach to governance. The published report highlights a divisional governance structure that was well embedded and understood.

158. It is not possible for CQC to say whether these structures and governance processes contributed to a failure to protect babies on the neonatal unit. Our inspection findings from the 2016 inspection reflected our judgements on the structures in place at the time. Any areas for improvement identified in relation to the governance structures and processes were reported on at the time of the inspection. (IT/102 [INQ0017433])

Changes to Hospital Inspections since 2016

159. We have made three sets of changes which have substantially impacted our approach to hospital inspections since the inspection of the CoCH in February 2016. These have been set out below under the following headings: Next Phase Approach and Well-Led Inspection Framework from 2016; Service Framework updates since 2016; and Transition to the Single Assessment Framework from late 2023.

Next Phase Approach and Well-Led Inspection Framework (WLF) from 2016

160. Our strategy for 2016 to 2021, published in May 2016, set out our vision for a more targeted, responsive and collaborative approach to regulation, so that more people recieve high-quality care. (IT/216 [INQ0017294]) These changes were designed to enable us to be more responsive to risk and improvement, as well as to be more efficient and effective – by working closer with our partners to increase alignment and reduce duplication. They had a stronger focus on the importance of leadership to drive improvement.

161. Under the Next Phase approach, for NHS Trusts and Foundation Trusts we aimed to carry out an annual inspection which, as a minimum, would be an inspection of how well-led they were and of one core service. We could also carry out an inspection to follow up on a concern and to review ratings, where appropriate, including where care has improved.

162. In addition to the selected core services at a Trust, we started to assess the overall leadership of a Trust based on our learning of the importance of leadership for the delivery of safe, high-quality care. This included an assessment of how well Trusts assured themselves that basic systems underpinning safe care were in place, for example: learning from incidents. These changes were designed to enable CQC to continue to make sure services provided people with safe, effective, compassionate, high-quality care and to encourage improvement by introducing:

- A more responsive, intelligence-driven approach to regulation, with improved monitoring and inspection activity focused where risk was greatest, or quality was improving.

- An increased focus on leadership, based on the evidence that effective leadership and a positive, open culture are important drivers for improvement and the delivery of safe, high-quality care.

- Closer working with NHS England / Improvement to increase alignment and reduce duplication and support Trusts to meet the dual challenges of quality and efficiency.

163. The Trust-level inspection of the well-led domain was an evolution of our approach to assessing and reporting on key questions at the overall provider level. In strengthening our assessment of the well-led domain, we were clear that there is a demonstrable link

between leadership, culture and the delivery of safe, high-quality care and our focus on well-led was intended to support this link.

164. Following consultation, the Next Phase approach was introduced from June 2017. The first inspections took place between September and November 2017, and the first Next Phase ratings and inspection reports were published in early 2018. (IT/217 [INQ0017297]; IT/218 [INQ0017305]) In September 2020 the Alliance Manchester Business School at the University of Manchester, in association with Deloitte, published their evaluation of the implementation and impact of the healthcare services well-led framework. (IT/219 [INQ0017312]) The NHS National Improvement and Leadership Development Board, representing the collective leadership of the national bodies which governed the NHS in England commissioned this independent evaluation in the autumn of 2018.

165. The report identified a number of positive findings in relation to the Well-led Framework, as well as areas for improvement going forwards. The Framework was intrinsically valuable, providing clarity on what a well-led organisation looks like and enabling leaders to reflect on and change leadership practices. It was a powerful tool which mattered to organisations and individuals, with the rating hugely impacting them. The use of the WLF led to improvements in leadership and governance. They also noted that: there was a need to pay close attention to the balance between culture, leadership, and governance; and to have regard for system context; and that there was scope to broaden its application.

166. This evaluation has informed the subsequent development of the Trust-Level Well-Led assessment in CQC's 2023 Single Assessment Framework.

Service Framework updates since 2016

167. We developed Service Frameworks for inspecting specific core services within Acute healthcare services [See First Witness Statement DATE PP: 61-72]. Below we describe these and the changes they have undergone since that time.

Children and Young People's services

168. The Children and Young People's services inspection framework was a core service framework and was first published in 2015. Updates since 2016 have related to changes in professional standards, good practice, and statutory guidance relevant to the five key questions. We have exhibited the most recent version from 2023. (IT/14 [INQ0010484])

169. Between 2017 and 2023 there have been 8 further iterations developed, each building on the previous version. Version 2 in early 2017 included updates around sepsis, female genital mutilation, records management, the Accessible information standard, National Institute for Health and Care Excellence (NICE) guidance on transition between care settings, and NICE guidance on end of life care. Version 3 in June 2017 included updates to reflect the new assessment framework and for consistency across the different frameworks. Version 4 in September 2017 included updates around sepsis management and outcomes. Version 5 in October 2018 included updates on assessing mental health in acute settings.

170. Version 6 in January 2019 included updates for the environment and equipment section with MHRA guidance on managing medical devices, and the complaints process for private/independent patients. Version 7 in March 2022 included cancer care prompts being added throughout, as well as updates for: safeguarding, mandatory core skills training, assessment and management of fevers in under 5s, Health and Safety Executive (HSE) guidance, pressure ulcer prevention and management, national clinical audits, and NHS seven day service clinical standards. Version 8 in January 2023 included updated COVID guidance, and Version 9 in July 2023 included updated links and COVID guidance.

Neonatal services

171. Since 2018 neonatal services are an additional services framework. Under our additional services policy this framework would not have applied to the CoCH at the time of the 2016 inspection as neonatal services would at that stage be assessed under the Children and Young People framework. (IT/220 [INQ0017323])

172. Version 1 of this framework was published in 2019, there has been no further update to this document since then.

Trust-wide Well-led Framework

173. The Trust-wide Well-led framework was first published in September 2017, with updated versions released up until 2020.

174. Version 2 was published in late 2017 and added good practice references for safe staffing. Version 3 was published in early 2018 and made house style changes. Version 4 was published in March 2018 and added references to equality, diversity and human rights to all key lines of enquiry, included chair of staff equality networks to interviews,

added links to the social partnership forum, the CQC *Equally outstanding report*, the *Safe Data Safe Care report*, and the Health Foundation QI guidance.

175. Version 5 was published in September 2018 and updated guidance on freedom to speak up, added *A just culture*, replaced the whistleblowing term with freedom to speak up, added a link to the *NHS health and wellbeing framework*, added winter/seasonal plans to key evidence, added guidance on the national data opt-out programme, the ICO *guide to GDPR*, the NHS GDPR guidance, the updated Data Security Protection toolkit, and the guidance on embedding QI skills. The Director of Improvement was added to the list of 'must do' interviews.

176. Version 6 was published in April 2019 and included updated links to include NHSE guidance on managing conflicts of interest, NHSE guidance on evidence-based interventions, NICE cost saving guidance, NHSE guidance on Never events, NHSI quality, service improvement and redesign resources, and National Quality Board guidance on learning from deaths. It also made amendments reflecting the cancer assessment framework throughout where appropriate. Version 7 published in January 2020 made typographical amendments.

Transition to the Single Assessment Framework from late 2023

177. As part of my earlier Witness Statement submitted to the Inquiry on 10 January 2024 I have provided information on the underlying rationale for, and changes to our processes made as part of, the development and implementation of the Single Assessment Framework. This is referenced throughout the statement, and with a general overview contained in paragraphs 73-77.

178. It should be noted that this will not begin to apply to CoCH until this year. (IT/221 [INQ0017396]; IT/08 [INQ0010518])

Covid-19 Pandemic

179. In addition to these three sets of significant changes, we also took a number of steps to adapt our approach to the wider prevailing circumstances during the Covid-19 Pandemic.

180. During the pandemic we recognised that we had an important role to play in offering assurance to the public (and Government) around the safety and quality of services, but that doing so wholly through on-site inspections was practically difficult during lockdowns. Our intent was always to balance the value to be gained from a full physical inspection with the risk posed by Inspectors moving between services, alongside the recognition

that every provider was operating an exceptional service. At the start of the pandemic, we moved to an increasingly risk-based approach to our work.

181. During the early stages of the pandemic, prior to suspending routine inspections, we cancelled a number of routine inspections and directed our activity at areas which we considered to have the most risk. The cancellations of inspections were based on daily assessments of risk within the relevant sector and were personally overseen by the three Chief Inspectors.

182. In consultation with relevant stakeholders and with the approval of the Secretary of State, we paused routine inspections from 16 March 2020. Whilst we continued to inspect providers as part of a risk-based approach we rapidly developed new assurance approaches which deliberately limited on-site activity. These approaches were, in the main, not designed to change the rating of the provider, but did examine specific aspects of the safety of services.

183. Following the suspension of routine inspection activity we shifted our emphasis from on-site inspections to a broader regulatory approach. In addition to our ongoing monitoring of services through intelligence gathered from previous regulatory engagement, as well as engagement with providers and stakeholders, we developed and utilised new tools to support our work. We continued to inspect in response to risk and concerns raised, with services remaining the subject of close monitoring, using a range of intelligence sources.

184. Over the course of the pandemic, we developed a number of tools to support this approach, including: the Emergency Support Framework (summer 2020), the Transitional Regulatory Approach and Transitional Monitoring Activity and Application (autumn 2020), and the Direct Monitoring Activity (summer 2021). These were structured approaches and tools for gathering and recording intelligence and using this to assess risk, as part of our risk-based approach to inspections.

Access to drugs in neonatal units

185. Current national guidance focuses on an overarching approach to the safe and secure handling of medicines, with the caveat that services need to make appropriate assessments around specific service and location risks. This includes guidance issued by both NHS England and the Royal Pharmaceutical Society.

186. For example, NHS England's Health Building Note 14-02 – Medicines storage in clinical areas states:

"The guidance is largely related to acute hospitals but may also be applicable to other healthcare settings (for example, community health services, care homes and mental health settings). Storage requirements for medicines will differ depending on local risk assessments, ward/ area type and medicines usage profile." (IT/51 [INQ0010497]))

187. Similarly, the Department of Health's Health Building Note 09-03: Neonatal units, provides best practice guidance. (IT/53 [INQ0010499]) Our regulations require us to refer to both legislation and relevant guidance, such as this when assessing the safe handling of medicines.

188. Whilst CQC had not had a specific role in relation to enhanced monitoring and drug security systems being introduced in neonatal units since June 2016, when we assess providers, we would seek assurances that they have the relevant policies and procedures in place (including audits). These should be underpinned by relevant guidance. Where this is not the case, we would expect the service to provide justification, including assessment of risks and mitigations.

189. It is not possible for CQC to define precisely what impact different systems relating to the monitoring of access to medicines and babies in neonatal units would have in the prevention of deliberate harm.

190. The effectiveness of any system, digital or otherwise would be dependent on a range of factors, that include, but are not limited to:

- What it identifies (for example who is accessing what medicines, when, where and for what purpose)
- How it identifies an issue as needing investigating
- How quickly the issue is identified
- How quickly this issue is investigated
- Who follows the issue up: Note: Our general learning from controlled drugs records systems is that one or more people seeking to circumvent a valid system that can identify them as having diverted controlled drugs (i.e. a CD register and audit) often offer to undertake the audits or follow up on discrepancies personally.
- Auditing of the incidents and system
- Whether the system has an over-ride and/or the ability to wipe records, and if this is auditable
- How well staff are able to use, or adhere to the system.

Processes for raising concerns

191. When considering if concerns were raised appropriately through existing processes, we are limited to commenting on what was shared with us directly throughout this period. It is worth noting that the processes we would engage in now to encourage and support speaking up were newly established during the time of LL's offending. We understand the National Guardian's office and Freedom to Speak Up guardians were set up in April 2016, towards the end of LL's known offending period. The processes used to raise concerns with CQC have been detailed above.

192. I outlined in my first statement (at paragraphs 208 – 220) the systems we have for people to raise concerns with CQC. These apply to Registered Providers, staff working within a service, people who use services or members of the public.

193. In addition to sharing concerns with us, we would have expected that in this time any registered professionals with concerns would have raised these in line with the codes of conduct of their professional body (for example, the General Medical Council). We are not aware if these routes for sharing concerns were used by any professionals at CoCH.

194. We are unable to comment on whether concerns could have been raised with us sooner without knowledge of what other parties knew at various points in time. However, the timeline of our work at paragraphs 15-140 shows that as concerns were raised with us, we captured these, triaged the information and took action as was deemed necessary. This included sharing those concerns with the Trust directly, and participating in meetings with other stakeholders, set out at paragraphs 141. Had the Trust received any concerns about the neonatal unit in between our planned engagement meetings, then they were able to liaise with their CQC relationship owner at any point, who would have facilitated further meetings to discuss any specific concerns. Staff and professional groups can also share concerns with CQC either individually or collectively and are capable of being shared with CQC on an anonymous basis or as a protected disclosure. Where concerns were shared with us about the trust throughout the time period of January 2015 – October 2023, these were considered, and a regulatory response determined.

195. In the context of what was raised with us during this time period, processes for reporting concerns appeared sufficient at the time with all key parties aware of the issues that were apparent as they arose.

Statement of Truth

I believe that the facts stated in this witness statement are true. I 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: 4/4/24