0Witness Name: Jane Tomkinson
Statement No.: 1
Exhibits: JT/01 – JT/32
Dated: 27 March 2024

THIRLWALL INQUIRY

WITNESS STATEMENT 1 OF JANE TOMKINSON

I, Jane Tomkinson, of the Countess of Chester Hospital NHS Foundation Trust, Countess of Chester Health Park, Liverpool Road, Chester CH2 1UL, will say as follows: -

1. I am the Chief Executive of the Countess of Chester Hospital NHS Foundation Trust ("the Trust"). I provide this statement on behalf of the Trust in response to a request dated 27 October 2023 under Rule 9 of the Inquiry Rules 2006 ("the Rule 9 Request"). This statement is based on information available to the Trust at the current time and the knowledge and recollections of a number of current members of staff.

2. To assist the Inquiry to the best of my ability, I have addressed each question set out in the Rule 9 Request insofar as I am able to at this stage of the process.

Introduction

3. My full name is Jane Tomkinson. I was appointed as Acting Chief Executive Officer of the Trust in December 2022. At that time, I held the post concurrently with my role as Chief Executive Officer of the Liverpool Heart and Chest Hospital NHS Foundation Trust, which is a post I held between 2013 and 31 January 2024. I have been appointed as the substantive Chief Executive Officer of the Trust from 1 February 2024. My professional qualifications are MBA, Keele University, Chartered Accountant.

4. My career started in Durham County Council as a trainee accountant. I joined the NHS in 1990, starting as an accountant for Sunderland Royal and Eyes Infirmaries. I have since

held a number of executive positions within the NHS including Director of Finance at the Trust between 2004 and 2011. I then moved to work as Director of Finance, Capital, and Informatics for NHS Northwest from 2011 – 2012. Subsequently, I moved to work as a Finance Director at the North of England Strategic Health Authority and, as set out above, I became Chief Executive Officer of the Liverpool Heart and Chest Hospital NHS Foundation Trust in 2013. I was awarded an OBE for services to NHS finance in the Queen's New Year's Honours in 2016.

The Trust

5. The Trust provides a range of services to the population of Chester and West Cheshire. The Trust's annual report issued in 2022/2023 estimated that the population of this area is approximately 357,000 residents, with this having increased year upon year. The Trust also provides services to Welsh patients covered by Betsi Cadwaladr University Health Board. This includes the Deeside area of Flintshire which the most recent annual report estimated added 50,000 residents who could potentially require the services of the Trust. For reference, in the 2015/2016 annual report, the Trust estimated the population of Cheshire West and Chester as being 260,000, with the population of Deeside being approximately 152,000.

6. The vast majority of services provided by the Trust are delivered at the Countess of Chester Hospital ('CoCH') site situated on Liverpool Road, Chester, CH2 1UL. Although bed capacity can fluctuate on a weekly basis, the latest annual report of the Trust in 2022/2023 reported 438 beds available at this site. The Countess of Chester Hospital is divided into five clinical divisions: Urgent and Emergency Care, Planned Care, Women & Children's, Diagnostics & Clinical Support Services, and Therapies and Integrated Community Care. The wider Trust infrastructure also includes a range of corporate services such as estates, facilities, human resources, finance, and information technology.

7. The Trust also operates Ellesmere Port Hospital, a rehabilitation, intermediate and outpatient facility. In January 2022, the Trust agreed to take a lease on Tarporley War Memorial Hospital in partnership with the Tarporley War Memorial Hospital Trust. This is a facility located 12 miles outside of Chester, partially operated by the Trust as a base for community-based services to serve the local rural population.

June 2015 to June 2016

8. Between June 2015 and June 2016 ("the relevant period"), the Trust operated three divisions: Urgent Care, Planned Care and Diagnostics & Pharmacy, Estates & Facilities. Neonatal care services were originally part of the Urgent Care division, with paediatrics and maternity services sitting within the Planned Care division.

9. The total number of hospital beds during the relevant period was 550, with this including 46 maternity beds.

10. Figures from December 2023 indicate that the most recent total of full-time employees employed by the Trust was in the region of 4,368 members of staff. When accounting for other staff members, for example agency or bank staff, this figure increased to 4,945. In June 2015, the number of full-time employees was 3,348 (3,906 including agency/bank staff), with this having increased to 3,388 (3,945) by July 2016. Within the relevant period, the lowest number of full-time employees was 3,321 (3,876) in August 2015, with the highest number of full-time employees being in May 2016, with 3,394 (3,951).

Commissioners

11. During the relevant period, the Trust had three direct contracts with commissioners. These were with West Cheshire Clinical Commissioning Group ('CCG'), Betsi Cadwaladr University Health Board and NHS England. The contract with NHS England concerning specialised commissioning, whereby NHS England is responsible for the commissioning of certain specialist services on a national or regional level, included the neonatal service at the Trust.

12. Insofar as West Cheshire CCG is concerned, there were monthly quality and contract meetings between the Trust and the CCG. These meetings were attended by the majority of the executive team, with the exception of the Chief Executive. The agenda was set by the CCG, but the Trust could make suggestions as to agenda items. These meetings provided the opportunity for a high-level review of the delivery of services by the Trust, which was responsible for discharging the CCG's statutory functions for providing health services within their geographical area. Following discussion at these meetings, where relevant, the organisations could agree action plans that could be monitored and reviewed at future meetings.

13. Following a structural change affecting the Trust's commissioners, on 1 April 2020 the four Cheshire CCGs (West Cheshire CCG, East Cheshire CCG, South Cheshire CCG and Vale Royal CCG) became a single Cheshire CCG. The process for the Trust reporting and liaison with the new Cheshire CCG remained the same as it had been under West Cheshire CCG, although the identified personnel within West Cheshire CCG who had been constant for some time had now changed. Although Cheshire CCG was responsible for a bigger geographical area than West Cheshire CCG had been, the services that the Trust provided, and therefore the contents of the monthly contract and quality meeting, remained the same.

14. From 1 July 2022, CCGs were replaced by Integrated Care Boards (ICBs). At this time, Cheshire CCG was subsumed into Cheshire & Merseyside ICB ('the ICB'). As ICBs cover a much wider area than individual CCGs, ICBs have created a number of geographical "place" leads within each ICB, often correlating to an area formerly represented by a CCG. Within Cheshire & Merseyside ICB, the locations of the preceding CCGs have resulted in there being a "place" lead within that ICB for Cheshire East, Cheshire West, Wirral, St Helens, South Sefton, Halton, Warrington, Knowsley and Liverpool.

15. As such, although the Trust now liaises with the ICB as the relevant commissioning body, all communication still flows through the Cheshire "place" within the ICB. Monthly quality and contract meetings are held whereby either the Trust or the ICB can raise any specific issues of note, within a wider discussion of the Trust's performance and compliance with the commissioning contract. There is also continuous discussion and liaison between Trust executives and their ICB counterparts outside of these formal meetings.

Neonatal services

16. There are traditionally three levels of neonatal care. These are as follows[1]:
    16.1. Level One - Special Care Baby Unit (SCBU / low dependency). This is for babies who do not need intensive care and who have often been born after 32 weeks' gestation, but require continuous monitoring. This care might include, among other

[1] BLISS website - How does neonatal care work? | Bliss

things, monitoring of breathing/heart rate, additional oxygen support, treating low temperature, tube feeding and matters of a similar nature.

16.2. Level Two – Local Neonatal Unit (LNU). This care is for babies requiring a higher level of medical and nursing support. If a baby is born between 27 and 31 weeks' gestation, and is at least 800g birth weight, they may require treatment in an LNU. Care on an LNU might include short-term intensive care (usually up to 48 hours), short-term ventilation, continuous positive airway pressure (CPAP) or high flow therapy for breathing support, those experiencing apnoeic attacks or those requiring parenteral nutrition.

16.3. Level Three – Neonatal intensive care unit (NICU). This is for babies requiring the highest level of neonatal support. Typically, babies requiring NICU support will have been born before 28 weeks' gestation, and/or be less than 800g birth weight, or be very unwell after birth, in circumstances where support is likely to be required for longer than 48 hours.

17. The North-West Operational Delivery Network (NW ODN) encompasses 3 neonatal networks: Cheshire & Merseyside, Greater Manchester and Lancashire & South Cumbria. The overall purpose of this regional network is to:

- Ensure effective clinical flows through the provider system;
- Facilitate system-wide collaboration;
- Improve multi-professional, cross-organisational engagement;
- Develop consistent guidance and service standards to ensure a consistent patient and family experience;
- Focus on quality assurance;
- Capacity planning; and
- Activity and quality monitoring.[2]

18. The North-West Neonatal Operational Delivery Network involves a number of network meetings, including its Clinical Effectiveness Group, which meets in each locality on alternate months. Although clinical governance and accountability for care remains with each individual Trust within the network, these Clinical Effectiveness Groups allow the Trusts in each locality to share lessons and outcomes for the benefit of all Trusts within the wider network and to assist in reporting to specialist commissioners[3].

[2] What we do – North West Neonatal Operational Delivery Network (neonatalnetwork.co.uk)
[3] Governance – North West Neonatal Operational Delivery Network (neonatalnetwork.co.uk)

19. The neonatal unit at the Trust is part of the Cheshire & Merseyside Neonatal Network. This incorporated:

19.1. 2 Neonatal Intensive Care Units (NICU/level 3 in the aforementioned categories of neonatal care). The 2 NICU facilities were operated by Liverpool Women's Hospital and Arrowe Park Hospital. These units would care for babies down to 23 weeks gestation, babies with complex diagnoses prior to surgery or other specialist treatments, requiring intensive care for greater than 48 hours.

19.2. 5 Local Neonatal Units (LNU/level 2).

19.2.1. The 5 units were situated in the Countess of Chester Hospital, as well as in hospitals in Leighton, Ormskirk, Warrington and Whiston.

19.2.2. The CoCH neonatal unit was one of the larger LNUs in the network, whereas two of the other LNUs did not have intensive care cots.

19.2.3. The admission criteria for treatment at the CoCH neonatal unit and other LNUs required babies to be born from 27 weeks' gestation and / or have a birth weight of 800 grams or above. Multiple pregnancies (for example twins and triplets) were admitted to one of these LNUs if they were born from 28 weeks' gestation or above.

19.2.4. Although LNUs are not 'Level 3' facilities, they are equipped with the means of providing intensive care support to any babies for up to 48 hours. For longer term intensive care beyond 48 hours – or where it was likely that a baby would soon require complex care - babies would be transferred to a NICU, ideally within the region.

19.2.5. Pregnant mothers who are given antenatal diagnoses for their babies from the fetal medicine unit in Chester or Liverpool would typically have a discussion with their clinical team regarding the best place for the birth. For mothers and / or babies with more complex diagnoses, particularly babies who will require time-critical or complex surgery, the birth will be recommended to be in a hospital with a NICU or the closest NICU to the surgical centre. For example, babies might be transferred to Alder Hey Children's Hospital in Liverpool, being the closest surgical unit to Liverpool Women's Hospital. Should a baby have been transferred from the Trust to Alder Hey Children's Hospital, following birth the clinical teams may request a transfer back to the Trust for babies whose mothers booked their pregnancy in Chester when the teams feel it is appropriate and safe to do so.

Inter hospital transfers

20. Prior to 2017 any transfer of babies between hospitals was undertaken by the Cheshire and Merseyside Neonatal Network Transport Service. This was a service linked with the "Cot Bureau", also operated by the Network.

21. The Cot Bureau had responsibility for telephoning each unit in the network twice a day to obtain updates on capacity and acuity, in order to ascertain where there were any available beds or where transfers may be required.

22. Where transfers were required, the Cot Bureau would notify the Neonatal Network Transport Service who would then liaise with the relevant units to arrange and undertake said transfers.

23. In order to streamline services, in 2017 the three neonatal transport services across the North-West Operational Delivery Network were merged. As a result, the Cheshire and Merseyside Neonatal Network Transport Service, as well as its counterparts in Greater Manchester and Lancashire & South Cumbria became "Connect North-West". Connect North-West continue to undertake the functions of transfers between different neonatal units.

24. Between June 2015 – 2016, if a baby admitted to an LNU was deemed to need or potentially need transfer to a NICU or surgical centre (such as Alder Hey Children's Hospital), the doctors within the Trust and other LNUs would phone the transport service to request a team to be deployed to undertake the transfer. The doctors from the referring and receiving units would also be expected to liaise closely prior to and during the proposed transfer to ensure a seamless transfer of care.

25. The same system was used when transferring a baby from a NICU or surgical centre back to an LNU. The clinical staff who undertook the transfers in the network were a combination of tier 2 doctors and advanced nurse practitioners from Liverpool Women's Hospital and consultants from Arrowe Park Hospital, being the two NICU facilities in Cheshire & Merseyside.

Changes since June 2016

26. The Trust was inspected by the Care Quality Commission in February 2016. The resulting report returned an overall rating of "Good" for the Trust, with no concerns raised in relation

to the outcomes for babies cared for by the Trust. Specifically, maternity and gynaecology for the Trust was rated as "good" across all domains.

27. However, the Trust had at that time noted an increase in baby mortality rates in 2015 and 2016, when compared with previous years.

28. Paediatric consultants met with Ian Harvey (Medical Director and Deputy Chief Executive), Tony Chambers, Chief Executive, and Stephen Cross, Director of Corporate and Legal Services, in June 2016. Consultants shared that staff were under extreme stress due to the number of recent deaths on the unit. As such, consultants suggested a temporary reduction in cot capacity and acuity to allow staff to recover from these events and ensure ongoing compliance with national staffing levels.

29. The decision was therefore taken to close three intensive care cots within the neonatal unit. A total of 13 cots remained open to continue to provide specialist and high dependency care for neonates and babies born at 32-weeks and above. Although the CoCH unit no longer operated a Level 2 service, they retained access to 2 high dependency cots, which would not usually be a feature of Level 1 units.

30. A "NNU (neonatal unit) Action Planning Meeting" was convened on Thursday 30 June 2016 (action plan attached as my **Exhibit JT/01 [INQ0014125]**. This meeting was attended by the following individuals: Alison Kelly, Director of Nursing & Quality; Dee Appleton-Cairns, Deputy Director of Human Resources and Organisational Development, Gill Galt, Head of Communication & Engagement; Sue Hodkinson, Executive Director of Human Resources and Organisational Development; Sian Williams, Deputy Director of Nursing & Quality; Ruth Millward, Head of Risk & Patient Safety; Julie Fogarty, Head of Midwifery, Karen Rees, Divisional Lead – Urgent Care.

31. During this meeting, an action was identified for producing a "plan on a page" relating to all babies born prior to 32 weeks' gestation who were being transferred out of the Trust. However, at this date, the group were awaiting confirmation and details from relevant clinical colleagues around their proposed plan to give effect to this action. It was noted that a list of stakeholders had been completed and that executives were to prioritise the cascading of this communication once complete, with further discussion expected on the timing of this correspondence.

32. This plan and the recommended communication lines notifying staff and stakeholders of this change to services were developed over subsequent days through further meetings and email correspondence. The communication lines were developed following liaison with consultants within the neonatal unit, as well as relevant executives within the Trust.

33. On Wednesday 6 July 2016, a meeting of the Executive Team was held. This meeting was attended by Tony Chambers, Ian Harvey, Sue Hodkinson, Alison Kelly as well as other attendees. Communication lines for notifying both Trust staff, as well as wider stakeholders, was noted to have been "ready to go" at this meeting to update stakeholders on the rationale for the Trust taking this proposed action.

34. On 7 July 2016, Tony Chambers issued an "Internal Communications" bulletin to all staff via email, attached as my **Exhibit JT/02 [INQ0014126]**. This updated Trust staff of the changes being made to the services that the neonatal unit would be providing, with immediate effect. This also accompanied the issuing of an external statement attached as my **Exhibit JT/03 [INQ0014127] and [INQ0014128]**. The Trust subsequently commissioned an independent review of neonatal services from the Royal College of Paediatricians and Child Health (RCPCH).

35. Accordingly, in July 2016 the capacity of the unit was reduced to 1 intensive care cot for stabilisation and transfer, 2 high dependency cots and 10 special care cots. Transitional Care was closed. Admission criteria were also temporarily changed to a gestational cut off for planned deliveries of 32 weeks and above.

36. NHS Specialised Commissioning required that any further changes made to the unit to reduce the gestational age of babies accepted or to return to commissioned gestational age or to increase numbers of cots were delayed until after the conclusion of the police investigation and subsequent criminal trial of Letby.

Current provision of neonatal services

37. The North-West Operational Delivery Network made a recommendation for the neonatal unit at the Trust to return to Level 2 / LNU status in October 2023, subject to NHS England approval. Approval has not yet been received.

38. A new neonatal unit was opened in 2021, partly funded by a publicised charitable campaign. It is a larger, modernised space that incorporates family integrated care, which has enhanced the ability of staff and parents to care for babies in a much improved environment. This is currently being used for the provision of neonatal services and has 16 cots. In addition, there is currently construction ongoing to build a new Women & Children's Unit at the Trust. All Women and Children's services will move into the new building to ensure service continuity. At present, construction is expected to be finished in 2025.

Management and governance

39. The overarching structure for the management and governance of Trust in the period between June 2015 and May 2017 was, in descending order:
    - Board
    - Executive Directors Group (a group of all the Trust executive directors)
    - Urgent, Planned Care, Diagnostics & Pharmacy, Estates & Facilities divisions
    - Clinical leadership teams and their parallel risk governance structures.

The Board

40. Within this time period, the Board had overarching responsibility to ensure the operational practices and effectiveness of the organisation. The general duty of the Board of Directors and of each director individually was set out within the NHS Act 2006 and was "to act with a view to promoting the success of the trust so as to maximise the benefits for the members of the trust as a whole and for the public". There were a number of Board committees. These included the Finance and Integrated Governance Committee, the Quality, Safety and Patient Experience Committee, the People and Organisational Development Committee, the Audit Committee, the Charitable Funds Committee and the Remuneration and Nominations Committees. All committees were chaired by a non-executive director. The Board would receive the minutes of each of the committee meetings.

41. As a foundation trust, the Board could delegate any of its powers to a committee of Directors or to an Executive Director. Delegations would be set out in the Scheme of Reservation and Delegation.

42. The main decisions taken by the Board of Directors would include those relating to:

42.1. Strategic direction and policy determination

42.2. The quality agenda

42.3. Actions required to address significant performance issues

42.4. Governance and compliance arrangements

42.5. Major business cases for capital or revenue investment

42.6. The annual plan, financial strategy and annual report

42.7. The acquisition, disposal or change of land or buildings

42.8. Private Finance Initiative proposals

42.9. Major contracts

42.10. Risk, clinical governance standards and policies

42.11. The constitution, terms of authorisation and working arrangements of its committees.

42.12. Approval of standing orders, standing financial instructions and schemes of reservation and delegation

42.13. Arrangements for the Trust's responsibilities as a corporate trustee for its charitable funds.

The Executive Directors Group

43. The Trust executive directors formed the Executive Directors Group. The roles and responsibilities of each of the executive directors were as detailed in my **Exhibit JT/04 [INQ0014129]**.

Divisions

44. Beneath the Board and its committees, and Executive Directors Group, the Trust had a divisional structure. Each department of the Trust was designated to either the Urgent Care, Planned Care or Diagnostics & Pharmacy, Estates & Facilities division, or was designated as a corporate function. This then dictated the management structure beneath this, with the neonatal unit being designated within the urgent care division, and the paediatric, midwifery and obstetric units being within the planned care division.

45. Each division had a lead clinician: the lead for urgent care was Dr Martin Sedgwick, an adult cardiology consultant.

Clinical leadership team and neonatal team

46. Below the lead clinician for the urgent care division sat the clinical leadership team for children's services. During this time period, Dr Ravi Jayaram was the Clinical Lead for Children's Services and Anne Murphy was the lead nurse.

47. Underneath these individuals sat the neonatal team, led by Dr Stephen Brearey. As part of his role, Dr Brearey had oversight of neonatal risk management and development, and maintenance of the Trust's neonatal guidelines and polices; together with liaising with the neonatal unit manager and representing the Trust within the Cheshire & Merseyside Neonatal Network at network meetings and clinical effectiveness group meetings. Eirian Powell was the neonatal unit manager and Yvonne Griffiths was the deputy manager.

48. The clinical leadership team would report into the Women and Children's Governance Board, which would then escalate as necessary to the Quality, Safety and Patient Experience Committee and the minutes from the Women and Children's Governance Board would be received at the respective divisional governance boards for planned and urgent care. Both the planned care and urgent care divisional governance boards could also escalate as appropriate to the Quality, Safety and Patient Experience Committee. The Women and Children's Governance Board was responsible for risk management in the entire area of women and children's services. During the time period specified, the Women and Children's Governance Board chair was Mr Jim McCormack, a senior obstetrician. The Board was made up of a representative from paediatrics or the neonatal unit, an obstetrics risk lead, the risk facilitator, a senior midwife, the neonatal unit manager, the paediatric ward manager and the lead nurse for children's services. It is understood that this Board met monthly.

49. During the relevant period Alison Kelly was the Director of Nursing and Quality. The Head of Risk and Patient Safety within the Trust at that time was Ruth Millward, who reported into Alison Kelly.

50. Each division within the Trust would be allocated a risk facilitator. Risk facilitators would collate information on divisional incidents and risks and consider action and learning

points. Until approximately February 2016, the women and children's risk facilitator was Debbie Peacock. Thereafter, there was a gap and there was no designated women and children's risk facilitator (although Janet McMahon from the risk department provided a short period of support) until Anne-Marie Lawrence started as risk facilitator in approximately April/May 2016.

51. There would be monthly meetings of what was named the Neonatal Incident Review Group (NIRG). These meetings were to review all of the Datix incidents, themes and learning. All neonatal incidents would be reviewed by this group and actions that came out of these discussions would be assigned and taken forward. The attendees of this group would be the unit manager, the risk facilitator, the unit pharmacist, a consultant, usually a junior doctor and sometimes a senior midwife would also be asked to attend. The risk facilitator would then minute the actions. Any identified learning was shared with the neonatal team via a neonatal incident newsletter. Regular neonatal simulations and skills training sessions were influenced by themes picked up from incidents.

52. Following these meetings, either Dr Brearey, as neonatal risk lead, or the unit manager would speak to staff to communicate outcomes and lessons to be learned, or action a revision of the relevant policy as necessary. Dr Brearey also prepared neonatal incident newsletters. These were disseminated to the neonatal unit staff for lesson learning.

53. All learning and summaries from these group meetings were reported to the Women and Children's Governance Board.

54. Further and additional to this, all neonatal deaths were discussed in the perinatal morbidity and mortality meetings, which were held 4 to 6 times per year, with extra meetings arranged due to the increase in deaths during the relevant period.. Perinatal mortality and morbidity meetings provided an open forum for the discussion of babies' care and lessons that could be learned. These were attended by medical, nursing and midwifery staff that were able to attend and on shift at that time. There were fixed slots for attendance at perinatal meetings via the Trust's rolling half day policy in line with which elective clinical work was often cancelled for the meetings to take place. Cases would be discussed within the meeting with learning discussed and any action to be taken.

55. There were also monthly paediatric speciality meetings held by all the managers and consultants within neonatal and paediatrics which was a place to discuss any concerns.

This was a forum where concerns about a particular doctor or nurse could be brought up as well as any issues about staffing.

56. There were no internal changes to the overarching management and governance structure of the neonatal unit during the relevant period.

57. I cannot say with any degree of certainty whether the management structure and governance of the Trust and the neonatal unit at that time was typical of other hospitals of comparable size and range of specialisms. In general, NHS Trusts and Foundation Trusts have flexibility to develop their management and governance structure as they see fit (as long as adhering to the basic statutory structures that are set out in legislation, such as the existence of a Board of Directors and, in the case of Foundation Trusts, a Council of Governors). I understand that other Trusts had a similar division of urgent and planned care structures at the time; however, I am not aware of the detail of those structures. It is likely that the former Trust executive directors in post at that time have more direct knowledge about this.

The Board – composition and operation

58. The composition of the Board of Directors during the 2015 to 2016 period, with relevant qualifications as detailed in their personnel files, is as set out in the table attached as my **Exhibit JT/05 [INQ0014130]**. The Trust directors were:

Non-Executive Directors (Independent)
Chairman – Sir Duncan Nichol CBE
Andrew Higgins – Senior Independent Director
Rachel Hopwood
James Wilkie
Dr Elaine McMahon
Ed Oliver
Ros Fallon

Executive Directors
Tony Chambers – Chief Executive
Ian Harvey – Medical Director
Alison Kelly – Director of Nursing & Quality

Debbie O'Neill – Chief Finance Officer
Simon Holden – Interim Chief Finance Officer (from January 2016)
David Jago – Interim Chief Finance Officer (October 2015-November 2015) (on secondment from Liverpool Heart and Chest NHS Foundation Trust)
Mark Brandreth – Deputy Chief Executive / Director of Operations and Planning
Sue Hodkinson – Director of People and Organisational Development
Lorraine Burnett – Interim Director of Operations (from 1st September 2015)

59. In accordance with the NHS Act 2006 requirements and the Trust's constitution, the Non-Executive Directors including the Chair were appointed by the Council of Governors, usually for an initial term of 3 years, and were eligible for re-appointment thereafter at intervals of no more than three years. The Chief Executive was appointed by the Non-Executive Directors, with the approval of the Council of Governors, and the other Executive Directors were appointed by a committee of the Chair, Chief Executive and the other Non-Executive Directors.

60. The role and responsibilities of the Chief Executive of an NHS Trust are set out in the Accounting Officer Memorandum. The expected role and responsibilities of all directors of an NHS Trust were set out in the NHS Foundation Trust Code of Governance (from 2014), which has recently been replaced in April 2023 with a Code of Governance for all NHS provider trusts. Roles and responsibilities would also have been set out in appointment letters (for Non-Executive Directors) and contracts of employment/job descriptions (for Executive Directors).

61. The risk governance structure in respect of the neonatal unit is set out earlier in this statement. Incidents and risks in the neonatal unit would have been reported to the Women and Children's Governance Board, via the NIRG, which would then escalate as necessary to the Quality, Safety and Patient Experience Committee of the Board. If a risk was deemed high risk and could not be fully mitigated, the risk would be added to the Trust risk register and Board Assurance Framework. Incidents classified as serious incidents in accordance with the NHS England Serious incident Framework applicable at the time would also have been escalated to the Trust's Serious Incident Panel.

62. I attach as my **Exhibit JT/06 [INQ0014131]** the Risk and Patient Safety Annual Report for April 2015 to March 2016 which was provided to the Trust's Board to give an update on

key clinical risk management issues and patient safety progress, including management of risk, incident reporting and analysis of incidents, complaints and claims.

Nurses on the neonatal unit

63. The following nurses worked on the neonatal unit during the period June 2015 to June 2016:

Name	Title/Band	Degree	QIS	R23
E Powell	Neonatal Unit Manager Band 7			
Y Farmer	Practice Development Nurse Band 7 / Senior Neonatal Nurse Band 6 (shared role)	Degree		
Y Griffiths	Deputy Neonatal Unit Manager / Senior Neonatal Nurse Band 6 (shared role)	Degree		
M Lappalainen	Senior Neonatal Nurse Band 6	Diploma	x	x
C Bennion	Senior Neonatal Nurse Band 6	Degree	x	x
C Oakley	Senior Neonatal Nurse Band 6		x	x
L Eagles	Senior Neonatal Nurse Band 6	Degree	x	x
K Ward	Senior Neonatal Nurse Band 6		x	x
Nurse T	Senior Neonatal Nurse Band 6	Degree	x	x

Nurse Y	Senior Neonatal Nurse Band 6		x	x
J Williams	Senior Neonatal Nurse Band 6	Degree	x	x
Nurse W	Senior Neonatal Nurse Band 6	Degree	x	x
B Simcock	Senior Neonatal Nurse Band 6	Degree	x	x
Nurse X	Senior Neonatal Nurse Band 6	Degree	x	x
C Booth	Senior Neonatal Nurse Band 6		x	
A Davies	Senior Neonatal Nurse Band 6	Degree	x	
K Bissell	Senior Neonatal Nurse Band 6	Degree	x	
A Simpson	Senior Neonatal Nurse Band 6	Degree	x	
M Taylor	Neonatal Nurse Band 6	Degree	x	
B Butterworth	Neonatal Nurse Band 6		x	
L Letby	Neonatal Nurse Band 6	Degree	x	
K Brammell	Neonatal Nurse Band 6 - on leave from December 2015	Degree		
S Ellis	Band 5 Nurse, foundation training underway	Degree		
A Hudson	Band 5 Nurse, foundation training underway	Degree		

S O'Brien	Band 5 Nurse	Degree		
M Griffith	Band 5 Nurse			
Nurse Z	Band 5 Nurse	Degree		
J Jones	Nursery Nurse Band 4			
J Peers	Nursery Nurse Band 4			
V Blaimire	Nursery Nurse Band 4			
S Evans	Nursery Nurse Band 4			
L Walker	Nursery Nurse Band 4			
J Cox	Nursery Nurse Band 4			
C Cuthberston-Taylor	Nursery Nurse Band 4			
V Thomas	Nursery Nurse Band 4			
L Marshall	Nursery Nurse Band 4			

64. The above list notes which nurses had undergone neonatal Quality in Speciality (QIS) training and R23 training (an advanced neonatal course which provides additional skills of cannulation, intubation and complex ventilation). All registered nurses would be NLS (Newborn Life Support) trained within two years of joining the team and only NLS trained nurses would attend deliveries requiring resuscitation.

65. The Band 6 nurses had undertaken network training consisting of foundation training (6 months to complete with L3 placements) followed by QIS training (two years post foundation training). Band 5 nurses noted to have completed QIS (see above) had undertaken both foundation and QIS training and were able to provide advanced care for intensive therapy unit and high dependency babies but did not take the shift leader role. The Band 5 nurses without QIS were supported by senior staff through competencies and practice development. They would have to undergo an intravenous course before administering intravenous medications.

66. Band 4 nurses are unregistered nurses with a nursery nurse NNEB (National Nursery Examination Board) qualification. They were supervised by registered nurses Competencies would need to be completed and training given to look after intravenous fluids and administer some oral medications.

67. The lead nurse for children's services, Anne Murphy, oversaw the neonatal unit and supported the neonatal unit manager. The neonatal unit manager was supernumerary and ensured safe staffing on the unit and that appropriately skilled nurses were on duty 24 hours a day, 7 days a week.

68. The deputy neonatal unit manager worked clinically and managed the unit when the manager was absent. The deputy manager co-ordinated the nurse staffing rota, ensuring a skill mix for each shift. For each shift there should have been a minimum of two QIS trained nurses, one additional registered nurse and two additional staff who were either a nursery nurse or registered nurse.

69. The practice development nurse supported new starters and existing nurses to maintain practical skills and supported student nurses. They addressed any learning needs and introduced new equipment, ensuring competencies were updated and renewed.

70. A shift leader with a patient workload (i.e. not supernumerary) was allocated to each shift. Workload was allocated by the shift leader responsible for the shift and could be adapted throughout the shift dependent on acuity and admissions. The shift leader was responsible for checking staffing, arranging breaks and supporting staff on shift. They would also liaise with the delivery suite regarding potential admissions and neonatal acuity.

71. The nursing reporting structure in place at that time was that staff reported to the shift leader. The shift leader reported to the deputy/neonatal unit manager and the consultant on call out of hours.

Doctors on the neonatal unit

72. The following Consultants worked on the neonatal unit during the period June 2015 to June 2016 (it has been detailed if a doctor did not work on the unit for the entire period). The Trust has compiled and provided to the Inquiry a list of the names of all staff who are

believed to have worked on the neonatal unit during the relevant period, which includes junior doctors and locums.

- Dr R Jayaram, Consultant Paediatrician (Paediatric Clinical Lead)
- Dr SP Brearey, Consultant Paediatrician (Neonatal Clinical Lead)
- Dr J Gibbs, Consultant Paediatrician
- Dr Doctor ZA, Consultant Paediatrician
- Dr M Saladi, Consultant Paediatrician
- Dr E Newby, Consultant Paediatrician (up to January 2016)
- Dr Doctor V, Consultant Paediatrician
- Dr S Holt, Consultant Paediatrician (from February 2016)

73. All consultants had a medical degree, membership of the Royal College of Paediatricians and Child Health (RCPCH), Certificate of Completion of Training (CCT), Advanced Paediatric Life Support (APLS) and Neonatal Life Support (NLS) as a minimum. Most consultant were and are APLS and/or NLS instructors.

74. There were 7 Consultant paediatricians, as set out above, 7 middle grade (tier 2) paediatricians (specialist trainee ST3, so in their third year of specialist training, or above) and 8 tier 1 doctors (either paediatric ST1-2 or GP trainee).

75. Every tier 1 and tier 2 doctor was allocated a paediatric consultant educational supervisor while working within the paediatric team. Tier 1 doctors would be allocated to either the neonatal unit, newborn examinations on the post-natal ward or the paediatric ward from a master rota. Tier 2 doctors would be allocated to either the neonatal unit or paediatric ward. Two tier 1 doctors would be allocated a 'long day' from 08:30 to 21:00, one of whom would be on the neonatal unit. One tier 2 doctor would be allocated to the neonatal unit from 08:30 to 16:30 every week day. One "long day" tier 2 doctor would be allocated to cover both the neonatal unit and the paediatric ward after 16:30. A night team of one tier 1 and one tier 2 doctor would cover both the neonatal unit and paediatric ward from 20:30 to 08:30. During weekends, one tier 1 doctor would cover the neonatal unit and perform newborn examinations between 08:30 and 20:30. One tier 2 doctor would cover the neonatal unit and paediatric ward from 08:30 to 20:30. One tier 1 and one tier 2 doctor would cover both the paediatric ward and neonatal unit on a night shift from 20:30 to 08:30.

76. Consultants operated a 'consultant of the week' system. There were 7 consultants available to each cover one week in seven as the 'paediatrician of the week', covering the

children's ward and the neonatal unit for that week from Monday through to Sunday. An on-call consultant, who was not the paediatrician of the week, would cover overnight (from 16:30 to 08:30 Monday to Thursday). The on-call consultant would undertake any urgent work and clinical reviews of new patients on the children's ward and neonatal unit followed by on call from home for the rest of the night. From July 2015, the Friday and Sunday night on-call was covered by the paediatrician of the week and the Saturday cover was shared between the other consultants. Before July 2015, the paediatrician of the week would cover the whole Friday to Sunday period.

77. The junior doctors working on the neonatal unit would be managed by and report to the consultant paediatrician of the week, or whoever was the on-call consultant overnight for any urgent issues. The paediatrician of the week would have overall responsibility for all the babies on the neonatal unit during that week.

Other staff on the neonatal unit

78. The staff other than doctors or nurses allocated to work on the neonatal unit during the period June 2015 to June 2016 are detailed below:
    - Gemma Webster, Paediatric Pharmacist
    - Debbie Peacock, Risk and patient safety lead (until February 2016)
    - Janet McMahon, Risk and patient safety lead (from March 2016 to April 2016)
    - Anne-marie Lawrence, Risk Midwife (from April 2016)
    - V Parkes, Ward Clerk
    - P Steele, Housekeeper
    - S Beech, Housekeeper

79. John Kingsley, Hospital chaplain, and Sharon Dodd, Safeguarding and health visitor liaison, would also have had access to the unit during this time period, but were not specifically allocated to work in the unit.

80. Other staff such as physiotherapists and speech and language therapists would be requested to see babies on an as required basis.

Changes to the management and governance of the neonatal unit

81. In 2015/16 the neonatal unit sat within the Urgent Care division and paediatric and maternity services sat within the Planned Care division. Therefore, perinatal services were separated into two different divisions. From January 2023, the Trust established a distinct 'Women & Children's' division. This brought neonatal services and maternity services into one division with a single leadership team who are directly line managed by the executive team. The maternity and perinatal services can be referred to as "perinatal" services, covering pregnancy and the year following birth. However, prior to this, from January 2022 the Trust Board received regular reports from women and children's services.

82. The Women & Children's Governance Board monitored all quality and risk related issues across women and children's services. The Women and Children's Governance Board fed into QSPEC (the Quality, Safety & Patient Experience Committee) and it was through this mechanism that there was indirect reporting to the Trust Board.

83. There were regular perinatal morbidity and mortality meetings held on rolling half days (pre-arranged half days when elective activity in the Trust was cancelled to allow for multidisciplinary meetings) to discuss clinical cases which were predominantly attended by paediatric and obstetric doctors, with it often being difficult for midwives to fit the meetings into their shift patterns (attendance was not paid if staff were not on shift). A pathologist from Alder Hey Children's Hospital NHS Foundation Trust also presented at the perinatal morbidity and mortality meetings.

84. In 2015/16 all staff had mandatory training on incident reporting. Staff involved in clinical incidents were advised to produce reflective writing and learning which was then discussed with a supervisor or colleague.

85. Currently women and children's services are within one division. This new divisional structure was approved at Trust Board in September 2022 and became operational in January 2023 after successful recruitment of a Divisional Director for Women and Children's services. The division reports directly to the Trust Board on perinatal quality, performance and safety metrics. The reason for this change was to ensure better senior executive and board level oversight of the Trust's women and children's services. The divisional leadership for both the neonatal unit and midwifery services includes the Director of Midwifery, the Divisional Director and the Associate Medical Director who are line managed directly by members of the Executive Directors Group. These individuals are

also members of the Operational Management Board. The Operational Management Board was established by the Trust Board of Directors in January 2023 and has responsibility for the oversight of implementation of the Trust's operational strategies and objectives. It provides assurance to the Board of Directors that effective performance management is being discharged through the Operational Management Board, ensuring delivery of the Trust's plans and operational targets.

86. There is also a clinical lead for neonatal risk in post, with dedicated time in their job plan to oversee risk management.

87. There is now clear divisional reporting to the Board including the reporting of nationally required KPIs and metrics including neonatal deaths. There is Board oversight for perinatal services with any neonatal death reported formally to the Board.

88. Further measures which have been introduced since 2016 with the aim of providing assurance of quality of services and reducing risk in neonatal services include:

    a. Introduction of the Freedom to Speak Up Guardian (Trust-wide), and strengthening of the freedom to speak up policy and process (previously referred to as Speak Up Safely) launched in August 2023.

    b. Perinatal services are now formally reviewed monthly within the perinatal assurance and improvement board, which was formed in March 2023 and chaired by the director of midwifery (DOM). Other attendees include: Divisional Director, Associate Medical Director, Clinical Leads Obstetric and Neonates, Head of Midwifery, Head of Paediatrics, Consultant obstetrician labour ward lead, Divisional Clinical Governance Lead, Risk Midwife, Inpatient matron, Outpatient matron, Neonatal unit manager, Practice development Midwife/Neonates, Professional Midwifery Advocate, Digital Midwife, Labour Ward Manager, SBL Lead and Postnatal Ward Manager. The perinatal assurance and improvement board provides a dedicated assurance meeting for perinatal services where assurance against the nationally required standards (CNST, Ockenden, Maternity three year plan) are reviewed. The terms of reference and its work plan are attached as my **Exhibit JT/07 [INQ0014132]** and **Exhibit JT/08 [INQ0014133]**. This meeting reports into the Women & Children's Governance Board through a Chair's report, where risks, incidents, workforce planning, and audit data and performance is reviewed. This means the Trust now has a dedicated perinatal services assurance

board providing additional assurance, scrutiny and oversight of the perinatal services. Minutes of the meetings and Chair's reports are being provided to the Inquiry.

c. Introduction of an executive led daily Trust wide review in December 2022 of all moderate and above harm incidents with the senior clinical and nursing leads.

d. The introduction of daily safety huddles on the neonatal unit and in maternity - neonatal huddles are meetings of nursing and medical staff to discuss issues such as capacity, workload, expected transfers, staffing, any patient safety concerns, risks, escalations and any significant events arising during the previous shift.

e. Patient Advice and Liaison Service contact details are now clearly displayed on the unit - all staff can signpost parents to this service.

f. The Maternity Neonatal Voices Partnership (MNVP) is now working with neonatal families since May 2023 to collect independent feedback and arrange formal visits to speak to parents and encourage parents to complete a feedback survey through their maternity/neonatal journey.

g. The introduction in 2018 of an allocated executive and non-executive safety champion for the neonatal unit and maternity services – one is the Director of Nursing & Quality (and Deputy Chief Executive) and the other is a Non-Executive Director. This ensures another route for concerns to be escalated if needed.

89. The Trust perinatal service has recently undergone the national SCORE survey which measures different dimensions of culture within the service. The survey was open to all perinatal staff from 31st March – 14th May 2023. Questions focussed on safety, teamwork, local leadership and learning systems. The results were available in August 2023 and demonstrated an improvement within the service, but the current leadership team was also commended on their commitment and dedication to continuously improve the service. Feedback highlighted that staff recognised the sense of teamwork, collaboration and support within the service with specific reference to huge improvements in the culture and leadership over the last 5 years, including listening and communications.

The neonatal unit between June 2015 and June 2016

90. A plan of the neonatal unit prepared by Cheshire Police is exhibited as my **Exhibit JT/09 [INQ0014134]** which sets out the layout of the unit. Photographs of various locations in the unit are contained in a risk assessment document which is exhibited as my **Exhibit JT/10 [INQ0014135]**.

91. The neonatal unit was made up of nurseries, staff rooms, offices, storage and parent accommodation.

92. The number of neonatal cots in each nursery room in the neonatal unit are set out below.
    - Room 1: 4 intensive care cots (ITU) (3 designated plus 1 extra for emergency use/transfer out if needed)
    - Room 2: 3 high dependency (HD) cots
    - Room 3: 4 special care (SC) cots
    - Room 4: 4 special care (SC) cots

93. There were also 4 transitional care cots located on the postnatal ward. These were for babies who required assistance with feeding, but did not need continual monitoring. Babies could stay with their parents. Neonatal unit nurses and postnatal ward midwives would look after mothers and babies utilising the 4 transitional care cots.

94. Intensive care babies required 1:1 nursing care and were always allocated to an experienced Band 5 or Band 6 nurse who were QIS qualified. Where a baby had a central line, the nurse allocated to care for the baby would also have completed R23 training so as to enable them to sample blood from the line.

95. In relation to the high dependency babies, a registered nurse who was QIS qualified would ideally provide care, but if the nurse was not QIS qualified, care should have been overseen by a Senior Neonatal Nurse who was QIS qualified. The target would be a nurse to baby ratio of 1:2. Babies on the special care unit would be looked after by a registered or unregistered nurse and supervised by the shift leader with a nurse to baby ratio of 1:4.

Staffing levels

96. The British Association for Perinatal Medicine Framework for Practice Service Standards for Hospitals providing Neonatal Care (3rd Edition) 2010 (BAPM) sets out the

recommended nursing staffing ratios. These are the same as those set out in the NICE Quality Standards and the DHSC Neonatal Toolkit:

- babies in intensive care should have a ratio of QIS trained neonatal nurses to baby of 1 nurse: 1 baby. This nurse should have no other managerial responsibilities during the time of clinical care but may be involved in the support of a less experienced nurse working alongside her in caring for the same baby.
- babies in high dependency care should have a ratio of QIS trained neonatal nurses to baby of 1 nurse: 2 babies. The more stable and less dependent babies may be cared for by registered nurses not QIS trained, but who are under the direct supervision and responsibility of a QIS trained neonatal nurse.
- babies in special care should have a nurse to baby ratio of 1 nurse: 4 babies. Registered nurses and non-registered clinical staff may care for these babies under the direct supervision and responsibility of a QIS trained neonatal nurse.

97. The DHSC Neonatal Toolkit also sets out that:
    - a minimum of 70% (special care) and 80% (high dependence and intensive care) of the workforce establishment should hold a current NMC registration
    - a minimum of 70% of the registered nursing and midwifery workforce establishment should hold an accredited post-registration qualification in specialised neonatal care (QIS)
    - units should have a minimum of two registered nurses/midwives on duty at all times, of which at least one is QIS
    - there is a nursing co-ordinator on every shift in addition to those providing direct clinical care.

98. Between January 2015 and June 2016, 65% of shifts within the neonatal unit at CoCH were staffed to BAPM recommendations. The national average for neonatal units in the UK in the same period was 58%. It is understood that the staffing levels at that time were comparable to other neonatal units in Cheshire and Merseyside and nationally. This information is recorded on the Badgernet system. Daily BAPM levels were recorded on Badger and this information could be viewed by the Cheshire and Merseyside Neonatal Network and staff members.

99. It is understood from the information available to me that staffing ratios were not always fulfilled according to the BAPM recommendations, but, as noted above, it is understood that the CoCH neonatal nursing staffing levels were comparable to other units across the

country at the time. I understand that the manager of the neonatal unit at the time complied several workforce plans in an attempt to bring the staffing levels closer to the BAPM standards, but ultimately the Trust did not or could not implement the plans. If a baby suddenly deteriorates unexpectedly during a shift, then that baby may go from special care to intensive care requiring 1:1 nursing. That is likely to mean the ratio of nursing staff for that shift not meeting BAPM standards. I understand that staff did their best to manage this, sometimes coming in at short notice, but that the problem in staffing levels was often created by an unexpected deterioration. I further understand that all nursing staff were provided with the opportunity to enroll on Foundation and QIS training courses facilitated by the Cheshire and Merseyside Neonatal Network to enhance skills. Additionally, I understand that senior nursing staff were supported to attend R23 training to ensure sufficient staff were equipped with advanced clinical skills. Workforce business cases were completed and reports were logged on Datix if staff felt staffing numbers were unsafe.

100. The Trust used the Neonatal Clinical Reference Group Workforce Calculator (Dinning) Tool (2013) to support neonatal nurse managers and their colleagues in calculating nursing establishment requirements to meet the national standards. The Cheshire and Merseyside Neonatal Network would send the analysis tool to the Trusts in the region to establish compliance against the BAPM standards. The Trust would receive the analysis tool once per annum.

101. In relation to nursing, it is not believed that bank staff were used often and only during periods of high acuity. It is not felt that the use of bank staff affected the quality of care given as it is understood that the bank staff who worked on the unit during the relevant period would have been familiar with the neonatal unit. A list was maintained within the unit of bank staff who could be asked to work on the unit – in essence, the unit had its own list of bank staff who were given a local induction prior to undertaking any shifts.

102. Junior doctors are not employed by the Trust. Health Education England was the body responsible for allocating junior doctors to the Trust on a 6 monthly (paediatric trainees) or 4 monthly basis (for GP trainees). There would invariably be insufficient numbers of allocated doctors and so the Health Education England programme director would attempt to even out their distribution between Trusts so that every Trust would be limited to 1 or 2 vacancies. These vacancies would be managed by the Trust. If the Trust were given warning of a gap, ideally they would get a locum for a period but this was sometimes not possible so the gap would have to be covered by existing doctors on the rota. The Trust would, for example, use short term locums for on-call slots. As noted above, the Trust has

shared with the Inquiry a list of the names of all staff who are believed to have worked on the neonatal unit during the relevant period, which includes junior doctors and locums.

Staffing rotas

103. Nursing staff rotas were completed monthly and shared with the team. The team for the day and night consisted of two Band 6 nurses (this was a minimum requirement). Additional staff consisted of 3 members of staff - at least one at Band 5 level and the other two at Band 5 or Band 4. Skill mix was a very important factor and staffing levels were adjusted depending on the acuity. Bank and agency staff were sometimes used.

104. In relation to domestic staff, between June 2015 and June 2016 there was a dedicated cleaner, Kath Dunn, on the neonatal unit between 7:30 and 13:00 and a domestic assistant between 13:00 and 17:00, 7 days a week. If the dedicated staff member was absent, they would be covered by the bank staff team. The paper rotas were generated by the domestic supervisor. There were two members of staff who worked weekends only. There was no dedicated staff member overnight. Porters would be bleeped to attend the unit at the request of staff.

Medication

105. Between June 2015 and June 2016 controlled medications were stored in the controlled drug cupboard, which was made of steel, double locked and alarmed. There was a unit with two locked compartments within nursery one for the storage of non-controlled drugs - one compartment held intravenous medication and the other held oral medication. There was also storage for intravenous fluids in a locked cupboard. All medication items required to be refrigerated were stored in a lockable medication fridge which was located in the treatment room. There have been no changes made to how medication is stored since this time. There were no electronic medication records in use at that time which would have recorded access to medication.

CCTV

106. During the relevant period the main entrance and exit of the neonatal unit was covered by CCTV recording 24 hours a day, 7 days a week (see my **Exhibit JT/10 [INQ0014135]**).

CCTV was also situated on the rear stairwell from Cestrian ward (the postnatal ward) and within the parent accommodation block (outside the parent lounge located to view the parent accommodation corridor outside the two bedrooms). My **Exhibit JT/09 [INQ0014134]** provides the location of the CCTV on the unit. There is currently no CCTV within the neonatal or maternity unit. CCTV is located only on the entrance corridor to the neonatal unit and in the parent accommodation.

107. A review of security within the neonatal unit was completed in 2016 making recommendations in relation to increasing the level of CCTV in the unit, but it is my understanding that no changes were made to the CCTV system at that time.

Reporting systems and inspections

108. The Trust uses the Datix incident reporting system, which staff should use to report incidents including a death or patient safety event. Neonatal incidents are reviewed by a neonatal incident review group (NIRG), as referred to earlier in this statement. Learning is shared with those involved in the provision of neonatal care via a newsletter and the incidents are reported to the Women & Children's Governance Board. Incidents are also reviewed at the executive led daily Trust wide review of all moderate and above harm incidents, which takes place with the senior clinical and nursing leads.

109. The Trust is part of the Clinical Negligence Scheme for Trusts ("CNST") administered by NHS Resolution, which also includes a Maternity Incentive Scheme. This incentive scheme is part of the Department of Health and Social Care's Maternity Safety Strategy, which seeks to reward those organisations that have taken action to improve maternity safety. From 2018, under the scheme, 10 maternity safety actions from the previous year are incentivised and where Trusts can demonstrate that they have achieved all 10 maternity safety actions, they can recover an element of their contribution to the CNST Maternity Incentive Fund and receive a share of any unallocated funds. If a Trust is not able to complete all safety actions, they may still receive a discretionary payment from the fund to help them progress any actions not yet complete. Further information on the scheme is available at https://resolution.nhs.uk/services/claims-management/clinical-schemes/clinical-negligence-scheme-for-trusts/maternity-incentive-scheme/

110. The Trust does not have an internal inspection programme. However, as a registered provider of health services, the Trust is subject to regulation by the Care Quality

Commission ("CQC") including inspections in line with the CQC's inspection and enforcement policies.

111. Prior to January 2023, the Trust utilised the NHS England Quality Surveillance Information System ("QSIS") which is a web-based portal that records and reports information to support a Quality Surveillance Programme. This scheme also includes a peer review inspection process. An inspection of the neonatal unit took place in late 2017 and I attach the report as my **Exhibit JT/11 [INQ0014136]** and a further peer review inspection process of the unit took place in 2019 when the Trust was seeking approval for the neonatal unit to return to Level 2 status as described above. Since January 2023, this scheme has been replaced and all provider data is now submitted via the Data Collection Framework.

112. As referred to earlier in this statement, data relating to neonatal care is recorded on the BadgerNet system that then feeds into the National Neonatal Audit Programme ("NNAP"), a national clinical audit commissioned by the Healthcare Quality Improvement Partnership ("HQIP") and run by the RCPCH on behalf of the NHS.

113. During the relevant period, there was no formal reporting process in place to report concerns to the police, although there was a local arrangement with the police for the Head of Security. This arrangement enabled the Head of Security to raise any issues where it was felt that the police could support the security team, such as thefts from site, anti-social behaviour and protocols for when the police would need to bring individuals to A&E who were under arrest.

114. Other reporting/inspection systems relating to the Trust's neonatal services include:

114.1. A perinatal mortality review tool, introduced nationally in 2017. It introduced a template which standardised review of all babies that die within their first 28 days. This process provides for a meeting to take place to include input from an external obstetrician, midwife or neonatologist depending on the type of death. The output of this meeting is reported to the Women and Children's Governance Board and shared with the Operational Delivery Network.

114.2. The Healthcare Safety Investigation Branch's ("HSIB") programme of investigations into maternity and newborn safety incidents which commenced in 2018 as part of a national initiative to improve safety in maternity care. That programme is now hosted by the CQC and known as the Maternity and Newborn Safety

Investigations Programme[4]. It enables reviews of specific cases of babies that have died (e.g. term babies that died in the first few days of life; the deaths of pre-term babies are not reviewed) and term babies with severe brain damage.

114.3. The reporting of all serious incidents to the Strategic Executive Information system (StEIS). Serious incidents are reported and managed in accordance with NHS England's Serious Incident Framework.

114.4. The Child Death Overview Panel (and SUDIC and PRUDIC (in Wales) processes) referred to further below.

114.5. MBRRACE-UK (Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK) is a national system of looking at perinatal mortality in every Trust and region, looking at stillbirths, miscarriages and neonatal deaths, taking into account factors like population and deprivation levels. The system involved a lengthy (approx. 2 year time lag) which meant that MBRRACE data for 2015/2016 was not available in that calendar year, although real time reporting has now been developed. Although issues remain with the system, such as definitions of reporting not matching up to definitions of internal reporting, the Trust is able to access the MBRRACE data.

Raising concerns

115. At the relevant time staff were able to approach their manager, shift leader or matron as applicable if they had a concern, such as a concern about a patient's care or staff member. A staff member could also raise concerns in their appraisals and one to one meetings with their manager. There was no allocated "Speak out safely" champion in the Trust at the time.

116. Today, the Trust promotes an 'open door' policy, there is a new perinatal nurse advocate (who can signpost where to direct a complaint as well as provide confidential support) and Freedom to Speak Up champions on each unit (in addition to the Trust wide Freedom to Speak Up Guardian and executive and non-executive leads for freedom to speak up). Safety champion walkarounds are also conducted monthly and there is an improved exit interview process which provides another option for staff to raise concerns.

[4] Maternity and Newborn Safety Investigation programme now hosted by CQC - Care Quality Commission

117. The GMC annual surveys of consultants and trainee doctors consider the level of training that has been provided and that has been given, and also considers how those surveyed feel about being able to speak out.

118. Investigations into concerns raised are carried out including actively speaking to those involved with assistance from Human Resources as appropriate. Any discussions between managers and staff would be recorded as required on personnel records and actions/help provided as needed e.g. performance management or practice development for training issues. All matters are managed on an individual level by managers in the first instance.

119. The Trust had at the relevant time Speak out Safely and whistleblowing policies. The current policy is now known as Freedom to Speak Up.

120. There are no restrictions on how people may raise concerns. Concerns may also be raised by members of the public, patients, the police, NMC or GMC or others. DATIX can be used to flag concerns.

121. The Trust's Patient Advice & Liaison Service (PALS) and Maternity Neonatal Voices Partnership (MNVP) also provide useful forums for parents and patients to make reports and raise concerns.

122. In addition, it is and has always been open to staff to raise concerns with the GMC, NMC, CQC or to the North-West Neonatal Operational Delivery Network. There is no specific policy within the Trust for this. It is of course the decision of the NMC, GMC and CQC as to whether and how it progresses any report that it receives.

123. The Trust's medical director and GMC's liaison officer meet regularly to discuss what is happening at any given time in ongoing conduct or capability cases and the GMC's liaison officer offers advice about any referrals that should be formally made by the Trust. The Trust also considers if a referral is appropriate or necessary at the conclusion of any internal disciplinary policy, and it is often covered in any outcome letter issued to a member of staff that a referral to a professional regulator may occur.

124. The duty of candour was communicated to staff via the intranet and via emails as shown by my **Exhibit JT/12 [INQ0014137], [INQ0014138], [INQ0014139], [INQ0014140],**

[INQ0014141], [INQ0014142], [INQ0014143], [INQ0014144], [INQ0014145] and [INQ0014146], but the Trust does not have a record of the exact date when these communications were sent. The Trust does not have a record of any formal training being given. The duty of candour leaflet was also shared via email with all new starters at the point of induction.

Disciplinary matters

125. The same bullying and harassment policies and disciplinary policies are in place at the Trust as were used in 2015/2016 although they are under review currently. Where applicable, national frameworks/guidance e.g. Maintaining High Professional Standards in the NHS would be followed.

Complaints

126. Patient complaints in 2015/2016 were managed through the complaints office, with responses invited from the department in writing to enable a response to the complaint to be prepared for the Chief Executive to approve. Patient concerns were managed through the PALS team (as well as complaints officers) who aimed to respond promptly via email or verbally depending on the nature of the concern. Some concerns would escalate to complaints. A report on complaints and concerns was prepared monthly and sent to divisional directors. It would refer to all contacts that month i.e. concerns/complaints and how each was handled, together with the top five themes.

127. Now all complainants are designated a nominated complaints handler. The service identifies a lead investigating officer (normally a service manager or head of nursing) who carries out an investigation which is provided to the complaints handler to provide a response.

128. The Trust's current policy on patient complaints and the policies from June 2015 to June 2016 is attached as my **Exhibit JT/13 [INQ0014147], [INQ0014148], [INQ0014149], [INQ0014150], [INQ0014151], [INQ0014152] and [INQ0014153]**.

Neonatal unit governance meetings

129. Governance meetings in respect of neonatal care took place during the relevant period in the form of meetings of the Women & Children's Governance Board, meetings of the NIRG (discussed above), Perinatal Morbidity and Mortality meetings (also discussed above) and monthly paediatric speciality meetings held by all the managers and consultants within neonatal and paediatrics (referred to above). Other ad-hoc meetings would take place on the neonatal unit such as rapid reviews after the death of a baby or after significant incidents.

130. During the December 2015 Women & Children's Governance Board meeting a Stillbirth and Early Neonatal Death review of 18 cases (including external representation) and an action plan was discussed. It was noted that no themes were identified and that each case was to continue to be reviewed at multidisciplinary meetings. Minutes are attached as my **Exhibit JT/14 [INQ0014154]**.

131. In the April 2016 meeting, staffing levels in the neonatal unit had been escalated and were noted to be on the risk register with it being stated that a business case had been prepared and presented to the Executive Team. Minutes are attached as my **Exhibit JT/15 [INQ0014155]**.

132. During the June 2016 meeting, the thematic review of the neonatal unit in February 2016 was discussed with it noted that there was a higher than expected mortality rate on the NNU and that the cases had been reviewed at perinatal mortality review meetings and that action plans had been developed. Minutes are attached as my **Exhibit JT/16 [INQ0014156].**

Clinical Commissioning Group Monthly Contract Meetings

133. The monthly contract meetings the Trust had with the CCG are referred to earlier in this statement. The meetings were often attended by various people including the medical director, director of operations, chief financial officer and director of quality and safeguarding at the CCG and colleagues from the Trust including the medical director, head of contracts, chief finance officer and director/deputy director of nursing and others dependent on the meeting. In relation to quality and performance, the Trust had quality requirements to report on and reviews of serious incidents, performance and inquests took place during the meetings.

134. Within the relevant period there were meetings on 18 June 2015, 18 July 2015, 20 August 2015, 17 September 2015, 15 October 2015, 19 November 2015, 17 December 2015, 28 January 2016, 25 February 2016, 24 March 2016, 28 April 2016, 26 May 2016 and 23 June 2016.

135. During the CCG monthly contract meetings in the relevant period, there were reviews of compliance with children safeguarding training and a review of an increase in neonatal birth related injuries and facial injuries, which appeared to be as a result of a change in coding. During the meetings, the Trust also shared their narrative response (agenda and papers attached as my **Exhibit JT/17 [INQ0014157] and [INQ0014158]** to the Morecambe Bay Independent Investigation and a comprehensive action plan was provided which noted that a piece of work was being undertaken to review how the governance structure within the Trust may be aligned more effectively across the maternity and neonatal services. In the August 2015 meeting minutes, it was raised that there had been a significant increase in babies born who needed a neonatal diagnosis and the CCG asked for a detailed explanation of the increase, raising concerns that if the increase in activity and complexities was real and not as a result in changes in practice, then the West Cheshire health economy faced a number of significant quality issues. It is noted that there was a detailed discussion about the possible causes of the rise in unplanned admissions and the CCG asked the Trust to undertake an urgent review of the increase in activity.

136. The CCG monthly contract meeting minutes note that the CCG was provided with the minutes of the Trust QSPEC meetings.

Reporting and reviewing neonatal deaths

137. In 2015/16 following the death of a baby, the relevant consultant paediatrician would discuss the case with the coroner to decide or confirm whether a coroner's post mortem examination was required. A "hot debrief" would take place for staff involved at the time with the dual purpose of reviewing any immediate concerns any staff member might have regarding the care and for staff support. The consultant would also be expected to speak to the family and support them as much as possible after the death of their baby. Nursing staff and Trust bereavement staff would support the family in the immediate period after death. The consultant would usually write to the parents shortly afterwards and offer to meet them to discuss any aspects of their baby's care that parents had concerns about. A rapid review would normally take place about 3 days after the death: this would normally include the neonatal unit manager, neonatal clinical lead, the risk and patient safety lead

and other staff such as a trainee doctor or other senior nurse or midwife. There was no standardised format for these reviews at the time, but the risk and patient safety lead would draft a timeline of events and team members would review case notes and investigations to discuss if there were any aspects of care that could be improved. If there were any significant deficiencies in care identified, then these would be escalated to the Women and Children's Governance Board for consideration of a higher level review. These reviews were undertaken to look at the standard of care provided and would take place without definite knowledge of the cause of death – this was determined by the post-mortem and subsequent inquest if planned.

138. In addition, babies would be discussed at the regular perinatal morbidity and mortality meetings (as described above). Minutes of these meetings would be shared with the whole clinical team for wider learning. A process for sharing mortality cases and learning was being developed by the Cheshire and Merseyside Neonatal Network during this time period.

139. The Trust now reports all deaths to the CEG (Clinical Effectiveness Group) of the Cheshire & Merseyside Neonatal Network and through the nationalised perinatal mortality review tool (PMRT) (introduced in late 2016) which supports[5] systematic, multidisciplinary, high-quality reviews, active communication with parents and production of a report. Reports are also made through the CDOP, SUDIC and/or PRUDIC processes. I attach as my **Exhibit JT/18 [INQ0014159], [INQ0014160] and [INQ0014161]** the Sudden Unexpected Death in Infants and Children Protocol 22.11.2013, the Pan Cheshire SUDIC Proforma and Guidance April 2023 and the Trust Guidelines in the Event of a Child Death 29.11.2023. Perinatal deaths are also reported quarterly to Trust Board and to the LMNS (local maternity system) through the perinatal quality surveillance tool.

140. The bereavement team within the Trust liaises with the family and the baby's consultant is also involved. This happens in parallel to the coronial process.

Data

141. All data in relation to each baby is collated on BadgerNet. This is an online platform for maternity, child or neonatal care notes that is accessible by both patients and the Trust.

[5] Perinatal Mortality Review Tool | PMRT | NPEU (ox.ac.uk)

All neonatal Units in the North-West use BadgerNet for collecting and storing patient data, so there is a single database and care record across all localities and units.

142. The Trust use this platform to capture the sex of each baby, the baby's race, gestation, type of birth, diagnoses, levels of care, any cooling Hypoxic Ischaemic Encephalopathy ("HIE") cases, pneumothorax cases, any interventions required, clinical outcomes and method of feeding at birth and at discharge. It will also be used by the Trust to record how many days a baby has spent on ITU, HDU and/or the special care baby unit ("SCBU"), details of blood cultures and sepsis, any invasive interventions and any resuscitation used. The same data is captured in respect of morbidity/mortality cases, where, in addition, the timing of death and whether it was a live birth or not will also be captured.

143. Data entered on to BadgerNet is collated and fed into the National Data Analysis Unit (NDAU). This data is used by the National Neonatal Audit Programme ("NNAP"). This is a national clinical audit run by the Royal College of Paediatrics and Child Health ("RCPCH") commissioned by the Healthcare Quality Improvement Partnership ("HQIP") and run on behalf of the NHS. As explained on its website, the NNAP aims to help neonatal units improve care for babies and their families by identifying areas for improvement in relation to the delivery of and outcomes from care. It can be used as a reporting tool to consider individual neonatal units or networks and access audit results. Viewers can:

143.1. Access an overall annual summary report of NNAP results for a chosen neonatal unit or network for 2014 to 2022;

143.2. View and compare the results for specific NNAP audit measures for different units, unit designations or networks;

143.3. View, via the outlier analysis section, whether a 2022 result for a unit or network is outside the expected range; and

143.4. download a unit-specific poster of NNAP results for display in their unit[6].

144. Data is also used to generate the national MBRRACE report which reports perinatal mortality (this includes maternal mortality, late still births and neonatal deaths of babies born before a viable gestation). During the period 2015/16 there was a 2 year wait before this data was published.

145. The North West Neonatal Operational Delivery Network has a data element, which is further explained on its website at

[6] NNAP Online (rcpch.ac.uk)

https://www.staging2.neonatalnetwork.co.uk/nwnodn/professionals/data/ This enables a quarterly review of issues such as admissions, activity, occupancy, cooling and mortality and is used by locality steering groups to consider changes to services that may be needed.

146. Locally, the Trust considers data collaboratively with maternity services and an optimisation passport is completed. An optimisation passport records matters such as whether antenatal steroids or magnesium sulphate were given prior to birth and is part of a programme to optimise future birth outcomes. Use of the passport is required by the NHS Resolution Clinical Negligence Scheme for Trusts.

Trust policies

147. The Trust has an overarching safeguarding policy in relation to children but not a specific policy for babies. The policies in place between June 2015 and June 2016 and the current policy is exhibited as my **Exhibit JT/19 [INQ0014163], [INQ0014165] and [INQ0014166]**. I also attach the Safeguarding Children Clinical Supervision Policies in effect between June 2015 and June 2016 and today as my **Exhibit JT/20 [INQ0014167] and [INQ0014168]**.

148. The Trust's guidelines in the event of a child death from June 2015 to June 2016 are exhibited as my **Exhibit JT/21 [INQ0014169]**. The current guidelines are exhibited as part of my **Exhibit JT/18 [INQ0014161]**. The policy was revised due to the introduction of PMRT (perinatal mortality review tool) nationally to support standardised mortality reviews across NHS maternity and neonatal units.

149. The Trust's freedom to speak up and whistleblowing policies from June 2015 to June 2016 and the current policy are exhibited as my **Exhibit JT/22 [INQ0014170], [INQ0014171] and [INQ0014172]**. The current policy is in line with national guidance. The Trust sent the policy to the National Guardians Office for feedback and they advised that they were happy with the policy and that it was in line with the national guidance. The policy is available to staff via the Trust intranet. It is understood that the previous policies were in line with national guidance at the time, but a Freedom to Speak Up Guardian was not appointed in the Trust until around 2019.

150. The Trust's current policy on patient complaints and the policies from June 2015 to June 2016 are exhibited as my **Exhibit JT/13 [INQ0014147], [INQ0014148], [INQ0014149], [INQ0014150], [INQ0014151], [INQ0014152] and [INQ0014153]**.

External monitoring and inspections

Child Death Overview Panels

151. Child Death Overview Panels ("CDOP") are part of the child death review process in England. Child death review partners have the responsibility for ensuring that child death reviews are carried out in line with statutory and operational guidance - Working Together to Safeguard Children, issued in 2010 and 2013 (and most recently updated in 2023) and Child Death Review Statutory and Operational Guidance (England) (published in October 2018). Child death review partners, in relation to a local authority in England, are defined as the local authority for that area and any ICBs operating in that area. Child death review partners must make arrangements to review the deaths of all children ordinarily resident in their area, and, as indicated and agreed between those partners, the deaths in their area of non-resident children. Such reviews should be conducted by a CDOP.

152. Locally, the pan-Cheshire CDOP was a sub-group of the four Local Safeguarding Children Boards (Cheshire East, Cheshire West and Chester, Halton and Warrington "LSCBs"). The Pan-Cheshire CDOP met quarterly and reported to the North-West CDOP. The responsibility of the CDOP was to review the deaths of all children up to the age of 18 years old (excluding planned terminations of pregnancy and stillbirths) resident within the four Local Authority areas.

153. The child death review system in Wales operates differently. The deaths of children in CoCH who were ordinarily resident in Wales (for example, Flintshire), would not have been reviewed by the pan-Cheshire CDOP during the relevant period.

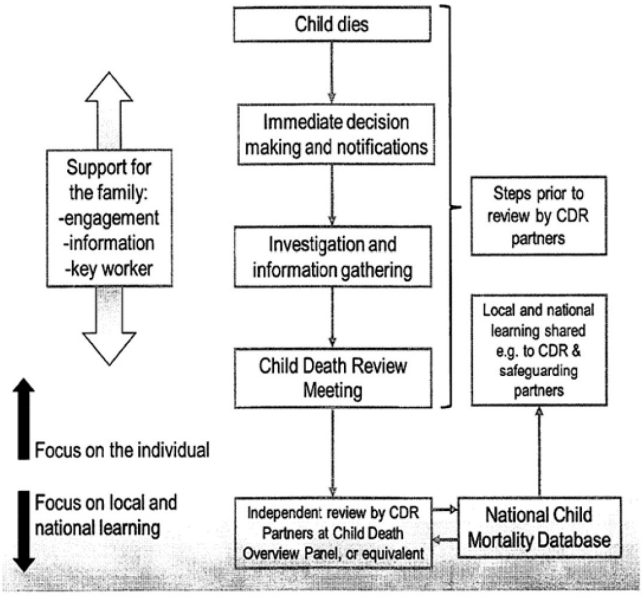
154. The purpose of a CDOP is to bring together relevant partners and agencies to learn lessons and share any findings for the prevention of future deaths. The CDOP ensures independent, multi-agency scrutiny by senior professionals with no named responsibility for the child's care during life.

155. The CDOP is preceded by a Child Death Review Meeting ("CDRM"); a multi-professional meeting including the professionals directly involved in the child's care, where

all matters relating to an individual child's death are discussed. The CDRM is typically the last stage in a child death review process which focuses on the individual. The CDOP is where the focus shifts onto local and national learning. Typically, the CDRM will produce a standardised report which is provided to the CDOP.

156. The child death review process is set out in my **Exhibit JT/23 [INQ0014173]** at page 4 as follows:

Appendix 2F - Child Death Procedures



157. Pan-Cheshire CDOP's core membership is comprised of:

- Independent Chair – this was Mike Leaf.
- CDOP Coordinator
- Designated Nurses x 2 for Safeguarding Children (Warrington and Halton)
- CDOP Nurses x 3 (Cheshire East, Cheshire West and Warrington)
- Specialist Midwife
- Public Health representative
- Coroner's officer
- Designated Doctor for Child Deaths x 3 (Cheshire East, Cheshire West, Warrington/Halton)
- Police Representative from Public Protection Unit Directorate
- Local Authority Service Manager, Safeguarding Unit

- Local Authority Service Manager, Children's Social Care
- Education Representative from Safeguarding in Education Team
- LSCB Business Manager
- Co-opted Advisory Member (Paediatrician/Deputy Coroner)
- North West Ambulance Service (where needed in cases of unexpected deaths)

158. The pan-Cheshire CDOP has permanent representatives drawn from the key professional areas represented on participating LSCBs. Members of the CDOP attend the meetings as representatives of their profession/designation rather than representing their employing organisation. Members have a responsibility to disseminate recommendations and learning. Other members may be co-opted to contribute to the discussion of certain types of death when they occur (see page 13 of **Exhibit JT/23 [INQ0014173]**).

159. The Pan Cheshire CDOP Protocol (ratified by the CDOP in July 2014) is contained within page 29 of **Exhibit JT/23 [INQ0014173]**. This Protocol notes that the "Pan-Cheshire CDOP will meet quarterly beginning in July 2013". It confirms that the "Pan-Cheshire CDOP meets quarterly and is required to receive and analyse information about each child death within the Pan-Cheshire area and consider modifiable factors which may have contributed to the death. These factors can be defined as those which, by means of nationally or locally achievable interventions could be modified to reduce the risk of further child deaths. This will enable the Pan Cheshire CDOP to make recommendations to prevent other deaths in the future. CDOP also has the responsibility for ensuring carers have effective information about bereavement including counselling and other services".

160. The Pan Cheshire CDOP Protocol contains the following section [4.3]:

Referral of Cases to Pan-Cheshire CDOP
The process relates to children resident in the Pan-Cheshire area. There are 3 strands to the child death review processes, depending on the nature of the death:
• Expected deaths: the family receives standard bereavement care, including where appropriate planned palliative care. The doctor issues a medical certificate of the cause of death and the death is registered with the Registrar. Information is collected from all agencies and submitted to the Pan-Cheshire CDOP who will then review the case in depth.

• Where the death is unexpected: the Pan-Cheshire Joint Agency SUDIC Guidelines and Pan Cheshire CDOP Protocol process is followed to gather information and support the family. This process helps inform the Coroner for the Inquest; information is collated through the SUDIC strategy meetings and a report from this case discussion is submitted to the Pan-Cheshire CDOP

• Where, at any stage, a child may have been or likely to be harmed, there will need to be an interagency child protection and / or criminal investigation led by the Police. The nature of the rapid response therefore changes. The subsequent investigation informs the Coroner's inquest.

161. According to the draft Pan-Cheshire CDOP annual report for 2015/16 attached as my **Exhibit JT/24 [INQ0014174], [INQ0014175], [INQ0014176], [INQ0014177] and [INQ0014178]** the Pan-Cheshire CDOP met on five occasions between April 2015 and March 2016. The total number of child deaths notified across the Pan-Cheshire footprint between April 2015 and March 2016 was 64. The total number of child deaths reviewed by the panel between April 2015 and March 2016 was 51.

Child deaths reviewed in 2015-2016 by area by Notification year (year of death)	2012-2013	2013-2014	2014-2015	2015-2016	Total Child Death Reviews
Warrington	1	4	3	1	
Halton	0	2	4	0	
Cheshire East	0	4	10	4	
Cheshire West and Chester	0	3	14	1	
Totals	1	13	31	6	51

162. The annual report notes that between April 2015 and March 2016, there were 39 deaths (75%) where the death was classified as 'expected'. An expected death is defined as a death that could reasonably been foreseen by clinicians for a period of at least 24 hours before it occurred. An unexpected death is then defined as the death of an infant or child which was not anticipated as a significant possibility 24 hours before the death or, where there was an unexpected collapse or incident precipitating the events that led to that death. Of the 39 expected deaths, the final category of death was as follows:

- Acute medical or surgical condition 2;

- Chromosomal, genetic and congenital anomalies 9;
- Chronic medical condition;
- Infection 1;
- Malignancy 1;
- Perinatal/neonatal event 22.

163. Of the 12 unexpected deaths, the final category of death was as follows:
    - Trauma 3;
    - Perinatal/neonatal event 3;
    - Suicide 3;
    - SUDIC 2.

164. The report confirms that "there have been no completed Serious Case Reviews following a child death within Pan Cheshire during 2015/16 and neither has Pan Cheshire CDOP referred a case for consideration of a SCR". A SCR may be required where there is suspicion that neglect or abuse may have been a factor in the death.

165. Rajiv Mattel (an employee of the Trust) is (and was in 2015/16) the designated doctor for the CDOP for Cheshire West and Chester. He confirms in **Exhibit JT/23 [INQ0014173]** that "I (in my designated doctor for CDOP role) and Ms Sharon Dodd (designated nurse for CDOP) receive notifications of all the deaths for children residing in West Cheshire area. Once we get the information, we inform the CDOP. The neonatal deaths were the main focus ever since the investigations started in COCH. As part of the Operation Humming Bird, we also inform the police of any neonatal deaths or unexpected neonatal collapses (ever since these investigations were started in 2017)".

166. The Pan Cheshire CDOP met on 24 March 2017 to discuss Trust's review of neonatal mortality within the neonatal unit during the period January 2015 to June 2016. The meeting minutes in **Exhibit JT/23 [INQ0014173]** record that "children who were included in the review were not all Cheshire children and would be subject to review at other CDOP panels. The systems currently in place for reporting child deaths are not constructed to record the death of a child who resides in another CDOP area. Due to the sixteen month period that was reviewed it would be difficult for the panel to notice a trend as the individual cases would come to panel at different time".

167. A letter from Tony Chambers, Trust CEO, to Chief Constable Byrne of 2 May 2017 attached as my **Exhibit JT/25 [INQ0014179]** records that a meeting took place with members of the Pan Cheshire CDOP on 28 April 2017 and that on the advice of T/Detective Chief Superintendent Nigel Wenham (a member of the CDOP) Mr Chambers was writing to request that Cheshire Police conduct a forensic investigation into the circumstances surrounding the neonatal deaths occurring in the period January 2015 to June 2016.

Quality Surveillance Groups

168. The establishment and role of Quality Surveillance Groups ("QSGs") was set out in national guidance published by the National Quality Board in July 2017 - https://www.england.nhs.uk/wp-content/uploads/2017/07/quality-surveillance-groups-guidance-july-2017.pdf. This noted that QSGs bring together different parts of the health and care system, to share intelligence about risks to quality, with the aim of identifying risks to quality at as early a stage as possible.

169. QSGs operated at two levels: local and regional. The national guidance noted that: 'QSGs should be seen as a network of partners who work together and share information in the interests of patients and service users. This should not be confined to formal meetings. QSGs can act as a virtual network in between meetings, with members interacting with each other in smaller groups where appropriate. Issues should only be brought to the local QSG when they cannot be solved as part of business as usual, and where action is required by more than one organisation. Once a QSG identifies concerns about the quality of care being provided in their area, members can take contractual action, regulatory / enforcement action and / or provide improvement support and performance management in line with their existing responsibilities. It is important to remember that QSGs are not statutory bodies; they have no legislative status, nor formal powers. However, QSG members can take a range of actions as a result of the responsibilities of the statutory members around the table and work to resolve issues at a local level wherever possible'.

170. The national guidance noted that membership of the local QSGs would typically include NHS England, Clinical Commissioning Groups, Care Quality Commission, NHS Improvement, Local Authority, Public Health England, Health Education England and Local Healthwatch The guidance noted that: 'Currently, provider organisations are not generally included in the membership of QSGs for reasons of pragmatism. Local and

Regional QSGs will at any one meeting be discussing a number of providers or groups of providers. To include those providers in the discussion would mean the group becoming very large, and discussions would be impractical. However, it is essential that where a QSG discusses a particular provider and draws conclusions about their quality risks, or where actions are agreed in respect of that provider, that provider is informed'.

171. The Trust was therefore not a member of any QSG during the period June 2015 to June 2016 and is not aware of whether any QSG established during that period discussed the quality of care at the Trust, and specifically within its neonatal unit. I understand that the NHS England Quality Surveillance team made contact with the neonatal unit in September 2016 and arranged two peer review inspections in late 2017 and 2019.

172. In January 2022, national guidance on System Quality Groups published by the National Quality Board replaced the guidance on QSGs - https://www.england.nhs.uk/publication/national-guidance-on-system-quality-groups/.

173. All integrated care systems are now required to have a System Quality Group ("SQG"), focused on enabling quality improvement across the health and care system, identifying risks to quality at as early a stage as possible, ensuring that action is taken to mitigate these risks and driving improvement in quality in an aligned and coordinated way. The guidance sets out the core membership of a SQG, being representatives from the ICB, local authorities, regional NHS England teams, Care Quality Commission, public health, primary care, maternity services, patient safety collaboratives, patient safety specialist(s), provider collaboratives and at least two lay members with lived experience (including Healthwatch). SQGs are expected to escalate any risk or concerns to the ICB, local authority assurance and regional NHS England teams where a response and support is deemed required to address any such quality concerns or risks.

Medical examiner system

174. All acute trusts in England were initially asked by NHS England in 2019/20 to set up medical examiner offices to focus on the certification of all deaths occurring in their own organisation. In June 2021, NHS England sent a system wide letter setting out what local health systems needed to do to extend the role of these offices to include all non-coronial deaths, wherever they occur. It is understood that in December 2023, the Department of Health and Social Care published draft regulations for the statutory medical examiner system planned from 2024.

175. NHS England's website confirms that: "Medical examiners are senior medical doctors who are contracted for a number of sessions a week to provide independent scrutiny of the causes of death, outside their usual clinical duties. They are trained in the legal and clinical elements of death certification processes. The purpose of the medical examiner system is to:

- provide greater safeguards for the public by ensuring independent scrutiny of all non-coronial deaths
- ensure the appropriate direction of deaths to the coroner
- provide a better service for the bereaved and an opportunity for them to raise any concerns to a doctor not involved in the care of the deceased
- improve the quality of death certification
- improve the quality of mortality data".

176. To support medical examiners to ensure consistency in the implementation of medical examiner offices, NHS England has produced good practice guidelines setting out how the National Medical Examiner expects medical examiner offices to operate during the current non-statutory phase of the programme. It is understood that the National Medical Examiner's office agrees a funding envelope with each medical examiner office each year.

177. To the best of my knowledge, the Trust started recruiting to establish its medical examiner office in January/February 2021. 100% of all inpatient deaths were being scrutinised from June 2021. The office is currently funded for 10 sessions a week – a session is a half day so it is funded for 5 days a week. It is understood that from its implementation to December 2023, the office has scrutinised 4 neonatal deaths. Dr Ian Benton currently leads within the Trust on all mortality learning and meets bi-monthly with the medical examiners within the Trust.

178. It is difficult to say at present how effective the system has been, as paediatric and neonatal deaths are also reviewed as part of other local and national perinatal mortality groups (SUDIC, PRUDIC (in Wales), MBRRACE-UK). It does ensure consistency of mortality review and can help in identifying any themes or trends in mortality. However, it is unclear whether medical examiners would necessarily have the specialist knowledge to consider all paediatric/neonatal deaths, as it is understood that a medical examiner is rarely trained in neonatology or obstetrics. It is thought that the system will be more effective once the statutory system is rolled out in 2024. The medical examiner role at

present is not a forensic review of a cause of death. They essentially provide checks and balances to check the cause of death offered by the qualified attending practitioner is appropriate, alongside considering all other aspects of care, including any family concerns.

Care Quality Commission

Report March 2012

179. The CQC inspected the Trust on 20 March 2012 looking specifically at termination of pregnancy services as part of a targeted inspection. The focus of the visit was to assess the use of the forms to certify the grounds on which a termination of pregnancy may lawfully take place. The Trust was found to be compliant with Outcome 21: Records in respect of use of the HSA1 form. I attach the inspection report as my **Exhibit JT/26 [INQ0014180]**.

Report March 2013

180. On 19 and 20 February 2013, the CQC inspected the Trust and found that the hospital met the six standards that were in use at the time (Respecting and involving people who use services, Care and welfare of people who use services, Safeguarding people who use services from abuse, Management of medicines, Staffing, and Records). This was a routine and unannounced inspection. I attach the inspection report as my **Exhibit JT/27 [INQ0014181]**.

181. During the inspection, the CQC spoke with patients, relatives and staff on the paediatric unit as well as two adult surgical wards.

182. Regarding respecting and involving people who use services, the CQC found that people's privacy, dignity and independence were respected. People's views and experiences were taken into account in the way the service was provided and delivered in relation to their care.

183. In respect of care and welfare of people who use services, the CQC found that people experienced care, treatment and support that met their needs and protected their rights. "Five out of six parents we spoke with on the paediatric unit said they were very happy with the care of their child". Play being incorporated into children's care was seen as another positive.

184. In respect of safeguarding, the CQC found that people who used the service were protected from the risk of abuse, because the provider had taken reasonable steps to identify the possibility of abuse and prevent abuse from happening. The CQC found that patients and relatives "commented that they felt comfortable with the service they received and told us that the staff were very helpful and supportive and had put them at ease. One child said "I feel that I would be safe here without my mum". Patients told the CQC that if they did have any concerns, they felt able to raise them with ward staff. Staff were able to give appropriate examples of where safeguarding alerts had been triggered.

185. In respect of management of medicines, the CQC found that people were protected against the risks associated with medicines because the provider had appropriate arrangements in place to manage medicines.

186. In respect of staffing, the CQC found that there were enough qualified, skilled and experienced staff to meet people's needs. "On the paediatric unit all the parents we spoke with told us there were enough staff and that a member of staff checked on their child at least every half an hour. We saw that at least one member of staff was present in the assessment unit at all times".

187. In respect of records, the CQC found that people were protected from the risks of unsafe or inappropriate care and treatment because accurate and appropriate records were maintained.

Report 29 June 2016

188. The CQC carried out an announced inspection of the hospital on 16-19 February 2016, and an unannounced visit to the out-of-hours service on 26 February 2016. The report of the inspection was published on 29 June 2016, which I attach as my **Exhibit JT/28 [INQ0014182]**. Overall, the CQC rated the hospital as 'requires improvement' with the areas of effective, caring and well led being judged to be 'good'. The CQC found overall that services were provided by compassionate, caring staff and that patients were respected and treated with dignity. However, it found that improvements were needed to ensure that services were safe and responsive to people's needs.

189. In respect of services for children and young people, the CQC rated such services as 'good' overall. The areas of effective, caring, responsive, and well-led were found to be

'good' (see page 106 of the report). The domain of 'safe' however was found as 'requires improvement' and there were a number of reasons given for this by the CQC.

190. The CQC noted that nurse staffing levels on the children's unit did not reflect Royal College of Nursing (RCN) standards (August 2013) and had resulted in eight incidents between January 2015 and January 2016, of which two involved a direct impact on patients.

191. The CQC found that nurse staffing levels on the neonatal unit did not meet standards recommended by the British Association of Perinatal Medicine (BAPM). Between January 2015 and January 2016, 11 incidents were recorded that related to the acuity of patients and staffing breaching BAPM standards and on seven occasions in that period the neonatal unit had been closed to admissions.

192. The CQC acknowledged that nurse staffing was recorded as a risk on the divisional risk register for both the children's unit and the neonatal unit; however, the risk to the neonatal unit was first recorded in 2010.

193. The CQC noted that the neonatal unit lacked storage space and resources for the care of patients who required strict infection control measures. There were also concerns held by the CQC around the secure storage of patient's medical records on the children's unit. The CQC found that emergency resuscitation equipment was in place but records indicated that daily checks of the oxygen, suction and the defibrillator were not consistently completed. The CQC stated that controlled medicines were stored correctly; however, were not consistently checked as per the Trust's policy.

194. The CQC found that there was not always a member of nursing staff on duty trained in Advanced Paediatric Life Support (APLS) on the children's unit; however, the unit was funded for four training places per year and plans were in place to train all nurses at band 5 and above. Most registered nursing staff on the neonatal unit were qualified in Newborn Life Support training (NLS) and plans were in place for the remaining staff to attend the course (see page 108 of the report).

Warning Notices

195. There were no Warning Notices issued to the Trust under section 29A of the Health and Social Care Act 2008 during the date range June 2015 to June 2017.

Report 17 May 2019

196. On 13-15 November 2018 and 11-13 December 2018, the CQC undertook a full inspection of surgery, medical care and urgent and emergency care at the Trust. The CQC also inspected the well-led key question for the Trust overall.

197. The CQC rated the Trust overall as 'requires improvement' and the areas of safe, effective, responsive and well led were also rated as 'requires improvement'. Caring was rated as good. I attach the report as my **Exhibit JT/29 [INQ0014183].**

198. The CQC did not specifically review services for children and young people. The rating for services for children and young people therefore remained as 'good' overall.

Report 15 June 2022

199. Between 15 February 2022 to 17 March 2022, the CQC undertook a risk-based inspection visiting urgent and emergency care services, surgical services, maternity and medicines core services as part of the inspection.

200. The CQC rated the Trust as 'requires improvement' overall. It rated the domains of safe, effective, and responsive as 'requires improvement'. Caring was rated as 'good'. The well led provider rating for CoCH was 'inadequate.' I attach the report as my **Exhibit JT/30 [INQ0014184].**

201. In rating the Trust, the CQC did not inspect services for children and young people, so the current ratings remained the same ('good' overall).

202. The inspection of the maternity services raised a number of points both negative and positive, which were connected to neonatal care. There was criticism about the "significant distance" between the main maternity theatre and the Neonatal Unit and the amount of time it might take to travel between the two. The report of the inspection noted the following at page77:

"*Perinatal mortality is defined as any in-hospital death within seven days of birth. It includes both stillbirths and neonatal deaths. Neonatal deaths that occur in any hospital within seven days are included in this indicator. Late neonatal mortality is defined as any in-hospital death between seven and 27 days of birth. The latest national data available shows the observed rate for perinatal mortality at Countess of Chester had been better than expected during the reporting period between September 2020 and March 2021, showing an improvement following a peak during the previous reporting period (June to August 2020). However, due to a lack of overall data reporting in 2022, there is currently no latest data available which establishes the trust's current position. The trust reported following the inspection that internal outcomes data had been benchmarked against the Northwest Coast (NWC) average. Trust data showed the maternity services performed in line or better than the NWC average for neonatal deaths, still births and babies requiring cooling for the period between April 2021 and March 2022*".

203. Leadership in maternity services was deemed to be inadequate. The CQC was (at page 84)"*…told maternity was, at the time of inspection, part of the planned care division within the trust. There were plans to change the divisional structure and create a Women's and children's directorate which included with neonatal services at the trust*"

204. Concerns were found in relation to maternity and trust-wide governance processes, which led to the CQC serving CoCH with two warning notices under Section 29A of the Health and Social Care Act 2008. The warning notices instructed CoCH that they needed to make significant improvements in the quality and safety of governance and safety processes across trust services and significant improvements in governance systems relating to referral to treatment processes, implementation of the electronic patient record system and around the management of incidents, learning from deaths and complaints.

Report 30 September 2022

205. On 26-27 July 2022, the CQC undertook a focused inspection of services provided by CoCH. The only question looked at was that of Well Led and CoCH was inspected but not rated. The CQC inspected maternity services only and I attach the report as my **Exhibit JT/31 [INQ0014185]**.

206. This unannounced focused inspection was made to follow up on the last inspection and the actions taken further to the two warning notices. The CQC did not inspect services

for children and young people on this occasion and so the ratings remained the same ('good' overall).

Inspection October 2023

207. The CQC inspected the Trust on a number of days during the period 17th October 2023 to 16th November 2023. This was an unannounced inspection including an inspection of children's and young people services and maternity services. I attach the report as my **Exhibit JT/32 [INQ0014186]**. As discussed in my third statement, the CQC ratings for the Trust's maternity services and in the well led domain moved up from "inadequate" to "requires improvement" as a result of this inspection. Findings included:

207.1. "The trust had prioritised diagnostic activity and self-assessment since the last inspection to enable it to act to improve care and treatment. The trust welcomed external reviews in several key areas to stress test internal systems, identify weaknesses and formulate improvement plans. Leaders understood the priorities and issues the trust faced and needed to turn plans into action to embed and sustain improvements."

207.2. "Staff in most services and leaders at all levels told us that the trust was a better place to work than it was a year ago. The trust had relaunched Freedom to Speak Up processes with a refreshed policy and new champion roles to ensure all staff felt able to raise concerns. Leaders told us they were committed to acting the concerns raised by staff."

207.3. "Leaders had the skills and abilities to run the service. They understood the priorities and issues the service faced. They were visible and approachable in the service for women, birthing people and staff. They supported staff to develop their skills and take on more senior roles."

Statement of Truth

I believe that the facts stated in this witness statement are true to the best of my knowledge and belief. 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: ____27 March 2024_____