Witness Name: Dr Sara Brigham
Statement No.: 1
Exhibits: SB/01 – SB/03
Dated: 4 July 2024

THIRLWALL INQUIRY

WITNESS STATEMENT OF DR SARA BRIGHAM

I, Dr Sara Brigham, will say as follows: -

1. My full name is Dr Sara Anne Brigham.

2. I qualified as a Doctor in 1994 from the University of Liverpool with an MB ChB degree (Bachelor of Medicine and Bachelor of Surgery) with commendation. Upon qualification, I worked as a House Officer in General Medicine and General Surgery in Warrington Hospital between August 1994 and August 1995. I then worked as a Senior House Officer ("SHO") in Obstetrics and Gynaecology in the Liverpool Women's Hospital from August 1995 to August 1996. Following a move to the Royal Liverpool University Hospital, I worked firstly as an SHO in Accident and Emergency from August 1996 to February 1997 and then Urology from February 1997 to August 1997. I then returned to Liverpool Women's Hospital from August 1997 to August 1998 and worked again as an SHO and then as Locum Registrar between August 1998 and October 1998. As part of the Mersey Deanery Registrar Rotation, between October 1998 - October 2004, I rotated to Leighton Hospital in 1998 - 1999, Arrowe Park Hospital in 1999 - 2000, Liverpool Women's Hospital in 2000 - 2002 and Countess of Chester Hospital in 2003 - 2004. I was a Clinical Research Fellow in the Liverpool Women's Hospital between October 2002 and October 2003 and a Locum Consultant Obstetrician at that hospital between October 2004 and July 2005.

3. Since July 2005, I have worked as a Consultant Obstetrician and Gynaecologist at the Countess of Chester Hospital ("the Hospital"). I have held the role of Associate Medical Director, Women and Children's Division at the Hospital since 5 June 2023. In addition, I was the Clinical Lead for Obstetrics and Gynaecology at the Hospital between 2018 - 2023,

and the Clinical risk lead for Obstetrics between 2013 – 2017. I was also the Training Programme Director for Obstetrics and Gynaecology for the Mersey Deanery between 2011 - 2017.

Neonatal and maternity services

4. The neonatal service and maternity service within the Hospital sat within separate divisions during the period 2015 to 2016. The neonatal service and paediatric service sat within the urgent care division, with a clinical director and divisional medical director providing medical leadership along with senior nursing and operational leadership. Maternity services (which included the obstetric service as well as the midwifery led service) sat within the planned care division, again, with its own medical, nursing and operational leadership.

5. As the two services sat within separate divisions in 2015/2016, they had different line management as explained above. From a clinical risk perspective, the two services were brought together through the Women and Children's Care Governance Board, which was already well embedded by the time I joined the organisation, and which was chaired by Mr McCormack, who was also a Consultant Obstetrician and Gynaecologist. Incidents would be followed up within the respective division (urgent or planned care) from a day-to-day management perspective and then the Women and Children's Care Governance Board would have overall oversight of incidents and reviews from both divisions through its monthly meetings.

6. In 2015/2016, the maternity service would be notified of a death or serious incident through the patient safety leads via the Datix incident reporting system. Any incident reported through the Datix incident reporting system in relation to the neonatal or maternity service would be received by the relevant service's patient safety lead and they would decide the next steps in terms of type of investigation and operationally manage the incident day to day. At that time, maternity and neonatal services would have investigated any incident separately. If the harm from a maternity incident was moderate or severe, it would also go through obstetric secondary review (a Trust initiative to give more in-depth investigation and not a nationally agreed review). I attended these reviews along with the Head of Midwifery and the patient safety lead to look at the incidents and decide jointly what the learning from that review was, if any escalation was needed and how to disseminate learning.

7. In the current system in place, reviews would be planned jointly from the outset. If a death occurred on the neonatal unit, the maternity service would provide a full review of care up to and including delivery.

8. Discussions and reviews of any baby deaths reported through the Datix system would be reviewed by the neonatal service via their incident review group. A death would then have been escalated for a National Patient Safety Agency ("NPSA") review, the report of which would be received at Women and Children's Care Governance Board along with an action plan. In addition, stillbirths and perinatal deaths would be discussed at perinatal mortality and morbidity review meetings (which are joint meetings between maternity and neonatal teams), and any learning discussed.

9. I personally would enter an incident into the Datix management system if I had been involved in an incident or witnessed one. I would, however, occasionally request the midwifery team to input onto Datix as often the medical staff are busy dealing with the clinical incident.

10. I would not have, and do not currently, input an incident on the Strategic Executive Information system ("StEIS") as this was and continues to be the roles of the Trust governance and patient safety leads.

Designation of the neonatal unit

11. In 2015/2016, the neonatal unit was designated as Level 2, which meant it accepted babies above 27 weeks gestation or 28 weeks for multiple pregnancies (twins or triplets). That was changed in 2016 to accept babies greater than or equal to 32 weeks gestation but I do not recall exactly when that was. The fact that the Hospital's neonatal unit was Level 2 meant that any mother who was to deliver her baby below the gestational age of 27 weeks prior to 2016 or below 32 weeks from 2016, would have to have their care transferred out to a hospital that had a neonatal unit that could accept the baby and the mother should it be born at that gestation.

12. Between 6 and 7 July 2016, meetings were held with members of the Hospital relating to the decision to redesignate the Level 2 neonatal unit to a special care baby unit. I remember attending some meetings around this time but cannot remember exactly when they were or what was discussed and did not receive any minutes of these meetings. I have been shown notes of meetings on 8 July 2016 which show that I was present, but I am unsure why my clinical lead for Obstetrics and Gynaecology was not present (Dr Davies) nor the Chair for Women and Children's Governance Board (Mr McCormack). I

understood that the neonatal unit was being downgraded due to the increased numbers of deaths that had occurred. I believe that was a decision that was made between the neonatal team and the executive team, and I was not involved. I am unsure as to whether a meeting took place with the maternity team prior to this decision to discuss - it may have taken place with the clinical lead for Obstetrics and Gynaecology or the Head of Midwifery. I did not question the decision. I did wonder why 32 weeks was chosen as the new limit. However, I am not a neonatologist and I value my neonatologists' views and what they felt was appropriate.

Reviews

13. I have been shown document [INQ0003174] which shows me listed as an attendee at a meeting on 8 July 2016 at 1230 at which it is recorded "*Alison Kelly advised that Clinical Team are continuing with Data analysis. Majority of case reviews now complete which have a generated a list of clinical reviews which are being undertaken by Sarah [sic] Brigham, John Gibbs and June Henderson.*" I do not recall being asked to undertake any reviews. I had previously undertaken a review of the obstetric care given as outlined in the review of stillbirths and neonatal deaths at the Countess of Chester Hospital January 2015 - November 2015 (discussed in more detail later in this statement). I remember some clinical reviews taking place but as an obstetrician I would not lead these reviews.

14. I have been referred to document [INQ0004892], which is an email from Joanne Davies to Stephen Brearey, Alison Kelly and Ian Harvey on 6 July 2016 where Joanne Davies has said: "*Sara Brigham has raised concerns about a case today that has severe perinatal asphyxia following collapse on the NU, (as yet I don't think the neonatal care has been reviewed) I was therefore wondering if there were other babies who have had sudden collapse but have survived that should be included in the investigation.*" I confirm that this collapse would not have been included in my review, which was a review of obstetric care in the period up until November 2015 and focussed on stillbirths and neonatal deaths, not collapses.

Concerns about mortality and Lucy Letby

15. As an Obstetrician, I did not have any dealings with Lucy Letby. The maternity team were aware of the increased mortality rates on the neonatal unit and were obviously concerned about it, but I was not in work between June 2015 and October 2015 as I had had planned surgery. On my return to work in October 2015, my clinical lead for Obstetrics and

Gynaecology advised me that there had been an increased number of baby deaths and so we arranged a thematic review of the obstetric care of those babies (which is discussed later in my statement). I believed that the neonatal team had already looked at the neonatal care and had not found any clinical themes, but I did not have a formal report in relation to this review at that time. No themes were identified in relation to Maternity or Obstetric care on these reviews, some learning was identified which was disseminated.

16. In terms of when concerns were raised about Lucy Letby, I think that that was in the summer of 2016. I remember the neonatal team raising the fact that they had concerns that a member of staff was at the centre of these deaths with the executive team at a meeting that I was present at – but I cannot recall who was there and when it was. I recall the executive team not being able to comprehend that these deaths were due to a particular member of staff.

Child A, Child C and Child D

17. I have been referred to the death of three babies on the neonatal unit and the unexpected collapse of another baby in June 2015. As I have explained above, I was not at work from June 2015 until October 2015 I&S.

18. Child A, Child C and Child D's obstetric care was reviewed within the "review of stillbirths and neonatal deaths at the Countess of Chester Hospital January 2015 - November 2015" discussed elsewhere in my statement. I have also been referred to document [INQ0003191], which is a brief summary of the cases of Child A, Child C and Child D, prepared by Dr Stephen Brearey. I did not see that review at the time. It may have been shared with my other colleagues.

19. I have been referred to a meeting on 2 July 2015 to discuss the cases of Child A, Child C and Child D but I was off work at this time so did not attend and do not know who else attended. I have been informed it was a Speciality Specific Serious Incident Meeting and asked how it was different to a Serious Incident Panel Meeting, but I do not know as I did not attend, and we do not have that type of meeting in obstetrics. I do not know who normally attends these meetings which are specific to the neonatal team. I have been told Julie Fogarty (Head of Midwifery) attended. If so, she would have been considered the maternity unit representative for this meeting.

Review of neonatal deaths and stillbirths at Countess of Chester Hospital – January 2015 – November 2015" (the "November Review") [INQ0003589]

20. As explained above, I was off work from June 2015 until mid October 2015 I&S I&S When I came back from this leave, my colleague, Dr Davies, who was the clinical lead for Obstetrics and Gynaecology, advised me that there had been an increase in the numbers of neonatal deaths and stillbirths and that we should undertake a thematic review of the maternal care. I was asked to set the review up and co-ordinated the review. I did not have any specialist training to chair this review.

21. I was given a list of maternity case note numbers to review, which I believe was generated by the risk team. I did not formulate this list myself as I had been off work for the 4 months preceding and as such did not have any recollection of or clinical involvement in these cases.

22. The report was written in November 2015. It was presented to Women and Children's Governance Board in December 2015 and the Quality Safety and Patient Experience Committee in December 2015. The action plan was completed in February 2016.

23. The 18 stillbirths and neonatal death cases were identified by the risk team utilising the Neonatal Badger system and DATIX reporting systems. 6 of the 18 cases were neonatal deaths.

24. The neonatal team was not involved directly in the review as we were looking at the obstetric and maternity care, but it did involve the patient safety lead Debbie Peacock and Head of Midwifery along with external representation.

25. The key findings of the review were as follows:

    25.1. 18 cases were identified of either stillbirth or neonatal death. 3 of these cases did not need to be included in the review as one was diagnosed with antenatal hydrops, one had antenatal multiple anomalies on ultrasound and the last case underwent termination of pregnancy for early pre-labour premature rupture of membranes. Of the remaining 15 cases, all had been reviewed previously at a multidisciplinary review apart from 3. The three cases that had not been previously reviewed were still birth cases and were due for review at the next Perinatal Mortality and Morbidity meeting.

    25.2. In two cases, issues were identified with the maternity care that it was felt had impacted on outcome. Both of these cases involved misinterpretation of cardiotocograph recordings. The clinical staff involved in these two cases were not

the same staff and had already been through supervision, with individual learning and action plans.

25.3. The external reviewer (Lesley Tomes, retired Head of Midwifery and Supervisor of Midwives) felt that our review process was extremely robust and open and transparent. No new issues were identified from the review.

26. I exhibit the full review including its Annexes and the action plan as my **Exhibit SB/01: INQ0102750**

27. I have been asked specifically to review the neonatal deaths within the report to correlate them with the identity of the babies. The review undertaken was to look at maternal care and not neonatal care and as such did not utilise the identities of the babies. However, I have been able to revisit this report and cross reference with other sources to be able to provide further correlation.

28. The maternal care described in Row 4 of the action plan relates to a baby that I believe is not part of the Inquiry's Terms of Reference. The maternal care in Row 6 relates to Child A, Row 7 relates to Child C, Row 8 relates to Child D and Row 11 relates to Child E. Row 18 relates to a baby that I do not believe is included in the Inquiry's Terms of Reference.

29. In addition, I have been asked specifically about other babies that died and whether they were included in the review. I was asked about a baby who died on 4 September 2015 at 05:16am; this relates to maternal care reviewed in Row 15. I was also asked about a baby who died on 27 September 2015 at 08:52am; this relates to Row 18. I was also asked about Child I who died on 23rd October 2015. I cannot find any reference to this child within my review and so can only conclude that this child was not on the list that I was given to review. I reviewed all maternal cases that were provided to me on a list.

30. I have set out above the committees to whom the final review report was presented. No one discussed the review with me following presentation by the head of midwifery of the review to a 14 December 2015 Quality, Safety and Patient Experience Committee meeting or after it was circulated by an email from Lorraine Milward on 9 February 2016 to Hospital staff.

31. On 14 January 2016, I emailed Stephen Brearey [INQ0005224], noting that, in the review, obstetricians were asking the neonatal team regarding delayed cord clamping in pre-term infants and asked him if I was correct that this is not currently in place at CoCH. Stephen confirmed in his reply that it was not. I also asked him for guidance as the recent NICE preterm labour guidance advised delayed cord clamping in preterm infants. He advised that, currently, the organisation was not in a position to be able to support delayed cord

clamping in preterm infants due to risk of babies becoming hypothermic, so, in the meantime, the advice was to continue with immediate cord clamping for preterm babies.

32. I have been referred to a document titled "Thematic Review of Neonatal Mortality" prepared by Dr Stephen Brearey and which I am told Ian Harvey asked to be merged with the November Review. I did not see this document at the time and I was not asked to merge this. I am not aware that this review was merged with the November Review.

Increased deaths and learning from deaths

33. I do not know the exact numbers of deaths that occurred on the neonatal unit between 2015 and 2016.
34. I was able to access data in a report prepared by MBRRACE-UK. The data for deaths in 2015 was presented in a report in 2017. I am not aware of any other organisations' data about the mortality rate and number of serious adverse events on the neonatal unit other than the regional neonatal network.
35. Lessons were learned about adverse incidents or deaths in the Hospital through dissemination by e-mails/poster presentations/changes in guidance/discussions at rolling half day education sessions and perinatal mortality and morbidity meetings. Individual learning took place on a one-to-one basis depending upon the learning. Discussions took place within the Hospital. I was not involved in any network discussions about adverse incidents and/or deaths of babies.
36. I had been off work from June 2015 until mid October 2015 I&S When I returned to work, I was advised by my clinical lead about the increased neonatal death rate on the unit. This concerned myself and my other Obstetric colleagues. My greatest concern occurred when we delivered the triplets. These were delivered in good condition, with good weights, at a gestation that is considered the appropriate and the best gestation for triplets, so the deaths in June 2016 came as a shock. At this stage, concerns were already being discussed about the deaths and so I did not need to raise my personal concerns regarding the triplets; they were already on the Trust's radar.
37. I was not involved in the investigation of the deaths on the neonatal unit from the neonatal perspective. As is the process now, where there is a need to review care and other specialities are involved, those other specialties would be involved in the investigation from the outset. As to postmortems, the neonatal team would request the postmortem for a neonatal death, not the maternity team. Obstetricians would only request a postmortem for a still birth.
38. I did not attend any discussions or debriefs (formal or otherwise) between doctors on the neonatal unit and/or between doctors and other medical staff in respect of the deaths of

babies on the neonatal unit between 2015 and 2016. As an obstetrician, I would have been involved in more general learning and discussion about the deaths but not the debriefs which would have been for the specific neonatal team.

39. I became aware of the concerns regarding the safety of babies on the neonatal unit in 2015/2016 and suspicions about Letby when the neonatal consultants came to discuss their concerns with us (the obstetric consultants) at a meeting in Conference Room A. I cannot remember exactly what date the meeting was or who attended, either from the neonatal or obstetric teams. I remembered being totally shocked that someone had potentially caused these deaths. However, I also remember feeling that for them to have raised this concern they must have significant evidence to support their concerns as they were senior members of the organisation.
40. I have never raised any issues regarding the neonatal unit and the safety of babies at the Hospital with members of the executive team myself.
41. I have been referred to a meeting held in possibly May 2016 or July 2016 at which Stephen Brearey apparently alluded to Lucy Letby being responsible for the deaths, "Eirian Powell told him not to do so and Jim McCormack pointed to Eirian Powell and said, *"you are harbouring a murderer*."" I have been told Eirian said I was present at this meeting. I do not recall this meeting specifically. It is possible it is the same meeting that I reference above, where the neonatal team came to discuss their concerns with us at a meeting in Conference Room A. I do remember Mr McCormack being particularly upset in the meeting, as were the whole team – but I do not remember a disagreement and do not exactly recall what happened or what was said. As I say above, I cannot remember when that meeting was or who was there, including if Eirian Powell was present.

Culture and atmosphere

42. I was not in work from June 2015 until mid October 2015 I&S However, I was not aware that the culture and atmosphere in 2015/2016 was any different from previous years. I had not really had much involvement with the executive team as I was not in a significant leadership role. I was line managed by my colleague Dr Davies who was my clinical lead and also my colleague Mr McCormack who was Chair of the Women and Children's Governance Board. After my immediate line manager, the clinical lead, there was the Clinical Director (Liz Redmond) in planned care and then the Divisional Medical Director (Mr Semple)
43. My recollection at the time of those that raised concerns is that they felt that their concerns had not been taken seriously enough. This concerned me as I felt that they were senior members of the organisation and the thought that they felt that an individual was at the centre of the increased deaths was very difficult to comprehend. However, to have raised

this concern in the first place needed to have significant evidence to support it and therefore their concerns should have been taken seriously. However, I was only seeing this from the neonatal team's perspective. I was not aware of what exactly was discussed between the neonatal team and the executives.

44. I was not involved in the decision made regarding Letby's presence on the neonatal unit including the decision that she would only be rostered on day shifts and the decision to redeploy Letby to an administrative role. As an obstetrician, it was not a decision for me to make.
45. I had heard unofficially that Letby had raised a grievance.
46. When she was charged in November 2020, I was in total shock that someone could do that and be the cause of the deaths whilst working as a nurse in our unit.

Royal College of Paediatrics and Child Health ("RCPCH") external review

47. I cannot recall when I was informed about this external review. From recall, there was not much time from being asked to attend a meeting with the review team and the actual meeting with them on 2 September 2016. I thought it was appropriate at the time to have the review, to ensure we were looking at the increased deaths from all different angles, but I did not have the review's terms of reference. I was told very little about the review, other than being asked to attend a meeting with them. I was not sent anything via email. When I attended the meeting with the reviewers, I recall that I asked if I could see the terms of reference which they had on the table, but there was no time to read fully. At the meeting, I outlined what was reviewed in the November 2015 review and the outcomes. I cannot remember what else was asked or discussed in the meeting. I was not asked to provide the November 2015 review report prior to our meeting, although they asked for it at the meeting. I therefore provided it via email a few days later, on 6 September 2016 [INQ0010057]. I sent them the full review, including its annexes (which appeared as embedded documents in the review), and which is attached above as Exhibit SB/01.
48. I do not know when the Hospital received the final RCPCH Review, and I never got to see the report.
49. I was not aware that the Hospital commissioned an independent consultant neonatologist to undertake an independent case review and never saw the Advisory Medical Report produced by Dr Jane Hawdon.

Serious Incident Framework

50. I have been referred to e-mails in relation to a revised Serious Incident Framework published in March 2015. I do not recall the detail of how the Hospital managed change in relation to this. Other colleagues may have been involved. I was not in a significant

leadership role at the time and would not have expected to have coordinated or been involved in disseminating this change. I was not aware of how the revised framework operated. I was not aware that the Hospital had decided not to report neonatal deaths on StEIS as a result of this new framework.

51. As a result of the revised framework, there was an email exchange between Ruth Millward and myself (see [INQ0005030]) requesting clarification on the required method of review of all unanticipated admissions to the neonatal unit. This is because the information that had been disseminated to me via our patient safety lead was that the organisation had decided to report all such unanticipated admissions routinely on StEIS. I felt that would be exceedingly time consuming and would take resources away from teams to investigate the serious incidents with little benefit as all term admissions to the neonatal unit were reviewed in any event by a neonatal consultant (currently the process of term admission review is for a joint review by a neonatal and an obstetric consultant with midwifery and neonatal nursing presence). If any concerns were identified in this internal review, they were then taken through the incident management process, but I felt it was unnecessary to report them externally on StEIS as a matter of routine and did not know why the change was made. In my comment "*I was under the impression from NHS England that only those babies who went for cooling were to be STEISd and have a level 1 review*," This was to advise that I was under the impression that babies going for cooling would be automatically reported to StEIS.

Trust's culture, management and governance structures/processes

52. My role in 2015 - 2016 was Consultant Obstetrician and Gynaecologist and Obstetric Clinical Risk lead. This was not recognised as a significant trust leadership role at the time and did not have recognised time within my job for this role. I had my colleague Mr McCormack as overarching Chair of the Women and Children's Governance Board. I also was line managed by Dr Davies who was the clinical lead for the service. We were managed from an operational and a governance perspective within the planned care Division. From this perspective therefore, there were other consultants within the service who were more involved in the operational and leadership perspectives of the Hospital rather than me.

53. The Women & Childrens Care Governance Board in 2015/2016 (subsequently known as the Women and Childrens Governance Board and now, the Women & Childrens Governance Committee) provided the main function of assuring the appropriate management of risk for maternity and neonatal services. It received and reviewed incident data and trends, received and reviewed serious incidents reports and action plans and monitored them until completion. The Women & Childrens Care Governance Board also

reviewed annual training reports, six monthly midwifery staffing reports and clinical care audits reports. It ratified policies and guidelines, Obstetric Secondary Review action plans, risk register updates, audit and infection control updates, Business Continuity Plans, updates from the National Confidential Enquiry into Patient Outcome and Death, from NICE (the National Institute for Health and Care Excellence) and the NPSA. The various incident review groups (Obstetric Primary Review Group, Obstetric Secondary Review Group and Neonatal Incident Review Group) fed into Women and Children's Care Governance Board.

54. When a neonatal serious incident was reported via Datix, the process was for it to be reviewed at Neonatal Incident Review Group and a decision made as to level of investigation/reporting to StEIS. The formal report would then be received at Women and Children's Care Governance Board and the action plan would then be reviewed at that Board until all the actions were completed.
55. The Women and Children's Care Governance Board met on a monthly basis and minutes of this meeting were received at the planned care and urgent care divisional boards as well as by the Director of Nursing. Any items of note were escalated to Patient Safety and Experience Committee. Outside of this structure, medical staff had the ability to escalate concerns up through the medical leadership structure within the planned care and urgent care divisions. For maternity, that would have been through Dr Davies the clinical lead, then the Clinical Director for planned care and then to the Divisional Medical Director and subsequently to the Medical Director or alternatively approach any member of the leadership team directly. The same process would apply for neonatology escalating up through the urgent care division.
56. I have been asked about Alison Kelly's role on the Women and Children's Care Governance Board. I am not sure when she joined the organisation, but I had not had much interaction with her around 2015/2016. I do not know when she attended the Women and Children's Care Governance Board, but she would have received the minutes. She was later the Board level maternity safety champion and so I attended bi-monthly meetings with her and the head of Midwifery.
57. I have been asked to describe any meetings I recall where issues regarding the safety of babies on the neonatal unit during 2015/2016 were raised and these have been covered above in my statement. There may have been more such meetings that more senior leaders in the organisation attended but I am not aware of them.
58. Since 2015/2016, the following changes have been made to the operation of the Women and Children's Care Governance Board

    58.1. The perinatal service now sits within the Women and Children's division, the performance of this service is monitored closely through a monthly performance

meeting chaired by the divisional director of Women and Children's services. Alongside that, the Perinatal Assurance and Improvement Board meets monthly to review in detail any governance, risk and quality issues affecting maternity, obstetrics and neonatology and that then feeds into the Women and Children's Governance Committee which takes a view across the broader Women and Children's Division.

58.2. The Women and Children's Governance committee and Perinatal Assurance and Improvement Board have agreed Terms of Reference and Women and Children's Governance Committee has an annual reporting schedule, clearly articulating the standing agenda items and the frequency of receipt of various reports such as training surveys/ CQC reports and action plan as examples.

58.3. There is a monthly Women and Children's Quality & Safety report presented at the governance meeting, which includes an Incident Management Report (that includes the total number of reported incidents for the whole division including maternity, neonatology and paediatrics and shows the level of harm), an update on the current position regarding management of open StEIS serious incident investigations and the current position regarding non StEIS incident investigations and more recent Patient Safety Incident Review framework investigations ("PSIRF").

58.4. Quality and safety dashboards are also presented monthly for maternity, neonatology and paediatrics. Included in these dashboards are admissions to neonatal unit, neonatal deaths along with stillbirth data and other markers of morbidity.

58.5. Chair's reports are received from the specialties within the division.

58.6. From Women and Children's Governance committee, a chair's report is sent up to the trust's Quality Governance Group highlighting any issues of concern or risks needing escalation.

59. The Hospital has changed significantly since 2015/2016. The biggest change has been within the fact that the perinatal service now sits within Women and Children's division and so the perinatal service (Obstetrics and Neonatology) is operated, led, and governed within this Division, rather than previously sitting within two divisions and managed in silos. In addition, in 2015/2016, the Women and Children's Care Governance Board had no direct reporting to the Trust Board and there was limited formal direct access to the executive team due to reporting structures as the maternity and neonatal services sat as directorates within the two separate divisions. That has now changed. I attach as my Exhibit SB/02: INQ0102751 a governance structure and reporting chart for the Women and Children's division in 2024, together with a structure chart for the Urgent Care and Planned Care divisions in 2015. Other changes include:

59.1. There is now Board oversight for perinatal services, with any neonatal death reported formally and directly to Board. Perinatal services are now formally part of the

Trust Integrated Performance Review (a performance review tool). Bi-monthly maternity updates to board typically include updates on progress for Maternity incentive scheme, progress against national standards and Ockenden. The updates also include information and learning from complaints and incidents and concerns raised from external partners such as CQC. In addition, within this board update is the quarterly perinatal quality surveillance report where any perinatal death is included along with learning. The Board also receive a Bi-Annual Maternity staffing paper. Annually, they also receive the CQC maternity survey. The perinatal service is also included in the Trust wide learning from deaths report. The governance team add into a new integrated quality report triangulating learning for complaints incidents and claims. In addition, we also now provide data that is included the strategic oversight framework (the dashboard).

59.2. As I have described above, Women and Children's services is now within its own division with direct reporting to Board on perinatal service performance, metrics and governance. There is significantly more governance support within the division than previously, including a Band 8b governance partner, two Band 7s and a Band 4 admin support as well as Consultant clinical risk leads within the care groups. We also have an Audit Midwife in post. The Women and Children's Governance committee have a standing monthly agenda item to consider all open incidents, reviewing what has been reported, action plans and learning. A Chair's report including key risks and escalation is then provided from the Women and Children's Governance committee to the trust Quality Governance Group which considers all risks and quality issues across the whole organisation and is accountable to the Quality and Safety Board Committee.

59.3. There is a triumvirate for the Women and Children's division which includes an operational, midwifery and medical lead and I am the medical lead for the Women and Children's triumvirate. The triumvirate are line managed by the executive team and the Women and Children's triumvirate ensure they are fully informed of all events throughout neonatal, paediatric and obstetric services, including weekly reviews of incidents and investigations and learning from them.

59.4. In addition to the weekly triumvirate review of incidents, every Thursday, there is also a Trust wide patient safety learning meeting and the triumvirates from all the divisions across the Trust attend and discuss any incidents that have caused moderate harm or above to give oversight over the whole organisation including any learning.

59.5. There is also now a Trust-wide daily Senior quality, safety and site position briefing meeting. This is attended by the triumvirates of all the divisions, senior nursing

and the executive team. It is chaired by the Chief Operating Officer or their deputy. Any incidents that have occurred in the preceding 24 hrs or over the weekend in the case of a Monday are discussed along with any operational issues. Any actions are then expected to be fed back to the meeting the following morning.

59.6. Within Women and Children's services, there is a daily incident review meeting by the risk team and matrons who consider all incidents and the level of harm caused. Incidents that resulted in moderate harm will have an immediate review, to see if they need to be escalated for StEIS or further patient safety investigation.

59.7. There is an executive buddy for the neonatal unit and maternity services as well as Neonatal and Maternity Executive and Non-Executive safety champions. There are Freedom to Speak Up Guardians and champions and policy/processes in place.

59.8. The divisional reporting floor to board is now clearly articulated which includes reporting of nationally required KPI's and metrics including neonatal deaths. The Nurse/Midwife Divisional leadership team is in place with a Band 9 Director of Midwifery along with Heads of Midwifery and Paediatrics. There are Clinical Directors for Women's and Children's Care Groups and there is a Perinatal Improvement and Assurance Board in place chaired by the Director of Midwifery.

60. Together, in my view, all of these described above improve safety as there is much greater visibility of any patient safety issues across the whole organisation, allowing the Board and management to be much better informed of any issues or concerns within any of the services. Managing Women and Children's services in one Division also prevents the previous silo working.

Communications and monitoring

61. I was not in a senior leadership role in 2015/2016 and I did not have first-hand experience of briefing the Trust Board at that time. Formal and informal communication has always been accepted within the organisation. Formal communication would occur up to Trust Board through the medical leadership and operational leadership structures in place in both planned and urgent care divisions from the divisional boards to the then Quality and Safety, Patient Experience Committee. Formal minutes from Women and Children's Care Governance Board would be received at Quality and Safety, Patient Experience Committee and also by the Director of Nursing. In 2023/2024, there is an open-door policy to the Executive team and all members of the organisation are encouraged to raise any issues with the Executive team. I feel that it is easy to talk to a member of the team should the situation arise. There are now a number of regular meetings with the Executive team, again making it easier to discuss any issues/concerns. The monthly Operational

Management Board is an example of one of these meetings. This is a meeting with all executives where each division, represented by the Triumvirate, provides a presentation on their quality and safety, performance and work force. It is an opportunity to raise any concerns and for the Board to have even more oversight of the governance and risks within each Division along with any concerns.

62. I have been asked if there were any issues with the processes that existed in 2015/2016 for staff to raise concerns about the safety of babies with management that contributed to the failure to protect babies from Letby. I feel that as the perinatal service was split across two divisions, the individual services may not have been as visible and there was no direct Board reporting.
63. In terms of monitoring of neonatal deaths or serious incidents on the neonatal unit during 2015 and 2016, the maternity service had a quality and safety dashboard prior to 2015/2016 which included total deliveries and method of delivery, caesarean section rates and postpartum haemorrhage rates etc. This dashboard was mainly focused on maternal morbidity, but, in April 2015, we included stillbirth rates and unanticipated admissions to the neonatal unit. I am unsure whether the neonatal service had a similar dashboard. It was not a perinatal dashboard. Other than through the governance structures and Datix reporting, I am unsure if neonatal death rates would have been formally captured in any other way.
64. As to external monitoring of such deaths and serious incidents in 2015/2016, deaths were reported to MBRRACE -UK for the national perinatal mortality surveillance report, but the report from 2015 was not published until 2017 and so the data was not real time. This report did include specific data for each unit. "Each baby counts" was a UK-wide quality improvement programme led by the Royal College of Obstetricians and Gynaecologists ("RCOG") and was introduced in 2015. with an aim to reduce by 50% the incidence of stillbirth, neonatal death and severe brain injury as a result of incidents during term labour by 2020. All babies fulfilling these criteria were included from the Trust. The first full report was produced in 2017 (with an interim report in 2016) but mainly covered general themes across UK maternity units rather than specific data for the Countess of Chester Hospital. Apart from these matters, there were no other requirements for external reporting of perinatal service metrics as far as I am aware.
65. The process for reporting deaths within the service was via Datix (from there a further review would take place). Perinatal service metrics were reported externally as described above.
66. If we had had a perinatal dashboard in 2015/2016, the increase in neonatal deaths would have been visualised month by month for all the team to discuss and identify further investigations or actions. A quality and safety dashboard and report is now presented at

Women and Children's Governance committee on a monthly basis, where death rates are included, facilitating any increase in numbers to be discussed by all the team and actions advised. We also now have a standardized Quarterly Perinatal Board report that is reported to Trust Board as well as externally to Cheshire and Merseyside Local Maternity and Neonatal System.

Summary of changes and developments

67. I attach as my **Exhibit SB/03** two PowerPoints related to Neonatal Unit Development dated June 2023, **[INQ0009429]** and **[INQ0009430].** As the current Associate Medical Director for Women and Children's division, myself and my colleagues within the Divisional Triumvirate were asked by our Executive team to provide some assurance that what happened in 2015/2016 could not happen again. The PowerPoint was shared with the Executive Team. The second version was created by the Chief Executive to present externally to the organisation.
68. The PowerPoints list what is different from the 2015/2016 period and what is the position now from a perinatal service and Divisional perspective, trust wide, regional and National perspectives. The issues in the "then" column were from evidence that the Divisional Triumvirate had from working within the maternity service at the time. There is now much more visibility and scrutiny of the perinatal service, with easier and regular access to Board and, regionally, the data is going outside of the organisation, so there is also external scrutiny. In 2015/2016, MBRRACE data was reported two years later, so there was a time lag. National reports do still have a time lag due to their inherent nature but, regionally and within the organisation there is now more local review and scrutiny than in 2015/2016.
69. All the changes that have been described at service, divisional, Trust and national/regional level are as described in the presentation. Some were made as a result of the events that occurred in 2015/2016, but some were also due to changes nationally and regionally.
70. The issues in the way in which the neonatal and maternity services were structured in 2015/2016 meant that there was less visibility of the perinatal service as the maternity and neonatal services sat within two separate divisions and the Women and Childrens Care Governance Board fed into the Quality Safety and Patient Experience Committee with no direct reporting to Board. In addition, the reporting structure created limited direct access to the executive team and the services sat as directorates within Divisions. Changes in place now are outlined in the PowerPoint and elsewhere in my statement but include:
    70.1. Board oversight for perinatal services with any neonatal death reported formally to Board

70.2. Women and Children's services now within its own Division with direct reporting to Board on perinatal service performance and metrics

70.3. Perinatal services now formally part of the Trust Integrated Performance Review

70.4. Daily Trust-wide review of all moderate and above harm incidents

70.5. Women and Children's Triumvirate now members at Operational Management Board

70.6. Triumvirate line managed by executive team members

70.7. Executive buddy for neonatal unit and maternity services

71. The only potential way to further improve reporting and monitoring now would be to have live data, but then there would be data quality issues as all data received from the electronic patient record system is only as good as what is entered. However, as we are now in a Division, any deaths that occur now, do not wait to be reviewed on a dashboard/formal report, we as a Triumvirate are aware of them as soon as they occur and instigate an appropriate investigation. Also, with the Executive led senior quality, safety and site position briefing, any deaths would be discussed on this daily meeting. In addition, there are the weekly trust patient safety learning meetings and patient safety oversight meetings. The Board also receive a quarterly perinatal report that facilitates them to be able to identify any trends, such as increased numbers of deaths.

Current governance and leadership/management within the organisation

72. I have been asked if any changes to the management structure at the Hospital would better ensure that staff members are able to raise concerns regarding the safety of babies at the Hospital. The Executive team are a new team. They have brought in several different processes that facilitate easy access to the Board, both formally and informally. There is a daily executive led senior Quality, Safety and Site Position Briefing at 8 am, followed by Trust wide safety huddles. At the weekly patient safety learning meetings and weekly patient safety oversight meetings, (also discussed above in my statement) the triumvirate along with the Business Governance partners present the incident position for each Division along with the learning from any moderate or above incidents. A discussion then takes place as to whether they can then be closed or whether a further investigation needs to take place along with immediate learning. Perinatal services now sit within Women and Children's Division with its divisional management and leadership structure with direct reporting to Board on perinatal service performance and metrics. The Women and Children's Triumvirate are members of the Operational Management Board. The Triumvirate is line managed by the executive team members. There is an executive buddy

for neonatal unit and maternity services. Freedom to Speak Up Guardian and Champions and policy/processes are now in place. All of these make it easier to raise concerns.

73. I have already discussed elsewhere in my statement the significant enhancements made to the governance of Women and Children's services.
74. The monthly Neonatal Incident Review Group is responsible for the review of neonatal incidents. It provides feedback and lessons learnt to individuals, rolling half day presentations and group feedback via email. They suggest changes in practice to reduce the likelihood of reoccurrence of incidents and, where possible, to minimise the impact of the incident. They will also review all open incidents and ensure appropriate closure and ensure that all investigations are on track for completion. The risk team are part of the group and it is led by the neonatal clinical risk lead and matrons within the service. Outcomes form part of the quality and safety report considered by the Women and Childrens Governance Committee meeting.
75. The last CQC well led inspection was in November 2023 and that has shown, following the implementation of all the changes described above, an improvement from "inadequate" to "requires improvement." It is hoped that all the changes across the organisation will continue to be embedded and that at the next inspection the rating will have improved further to "good."

Reflections

76. All the changes as described above have made a positive impact on the organisation and the safety of all our patients and families. However, I am not sure what further improvements could be made to keep babies in neonatal units safe from the criminal action of a rogue healthcare professional. I still find it very difficult to believe that a healthcare professional has caused these deaths. I am unsure as to how rogue health care professionals can be prevented from working in healthcare
77. The Trust, the region and the NHS as a whole is a very different place today than it was in 2015/2016. There is now so much scrutiny and visibility of perinatal services.
78. I have been asked about CCTV use to prevent some of the crimes. CCTV use would be reliant upon someone constantly monitoring the screen who had significant clinical knowledge to be able to understand what they were seeing and whether it was appropriate or not. If a person was intent on doing harm, they could try and block the view of CCTV. I also am not sure how all the families would feel about dignity and privacy if CCTV was in place.
79. Systems, including security systems relating to the monitoring of access to drugs and babies in neonatal units, would not necessarily have prevented deliberate harm being caused to the babies named on the indictment. Some of the babies were not harmed by

drugs. It is also important to get access to drugs in a timely fashion for medical treatment; too many security precautions could delay treatment. Access to neonatal units is already limited by swipe card access and only families and staff are present so it is difficult to see what else could be done.

80. Perhaps in time there will be a way to carry out character analysis of healthcare professionals before they start work, so a rogue professional is not employed but it is extremely difficult. It is important to trust employees too. The issue is not simply limited to health, and it is relevant to other industries and professions too. Everyone is more vigilant now. No one ever thinks it will happen in your hospital.
81. I do not have any documents or other information which are potentially relevant to the Inquiry's Terms of Reference which have not already been provided to the Inquiry.
82. I would like to offer my sincere condolences to all the families who have been affected.

Statement of Truth

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

Signed: PD

Dated: 04.07.2024 | 23:15:48 BST