Witness Name: Andrew Bibby

Statement No.: 1

Exhibits: AB/01 - AB/46

Dated: **16 July 2024**

THIRLWALL INQUIRY

WITNESS STATEMENT OF ANDREW BIBBY

I, Andrew Bibby, will say as follows: -

Introduction

1. The information that was revealed during LL's criminal trial has had quite a profound impact on both my colleagues working in NHS England's North West Specialised Commissioning and on myself. Whilst we have been deeply affected by the turn of events in this case, the impact it has had on us must pale in comparison to the inconceivably more significant impact that it will have had on the families of LL's victims. Our thoughts have been, and will remain with, those that have been more directly affected by LL's crimes and I would, as part of this evidence submission to the Inquiry, like to offer my heartfelt condolences.

2. It is beyond comprehension that events of this nature could happen in an NHS Hospital. The NHS has a workforce that is motivated to come to work to do a good job, to help others, and to provide a high-quality healthcare and deliver the best possible outcomes for the patients and communities that we serve. We value the trust and respect that patients and communities have in our staff and our services. Whilst the actions of individuals like LL are, fortunately, extremely rare in within our health service, the consequences of these actions will have been felt across the service as a whole.

3. I have been asked to address a number of questions by the Inquiry, and I organise my answers as follows:

   a. My background, career history, and role as Assistant Regional Director of Specialised Commissioning (North)

   b. How specialised commissioning works, our management and governance structures, and how we work collaboratively with others across the NHS

   c. My role in assuring the quality of specialised services, including how we as commissioners identify issues and resolve concerns around the quality of specialised services

   d. My role in addressing specific concerns in respect of the neonatal unit (which I refer to in this statement as **the Unit**) at the Countess of Chester Hospital (which I refer to in this statement as **the Hospital**)

   e. My reflections

4. In summary, I make these key points: -

   a. The primary role of commissioners in the NHS is to secure the greatest health benefit possible for our population within the budget and resources available to us. However, commissioning is much more than simply purchasing services; we also forecast the level of need for services and secure sufficient capacity to meet that need, and play an important role in assuring healthcare services by ensuring that the services we commission are safe, high quality, efficient and economic.

   b. The specialised commissioning team in the North region was, in April 2015, a largely self-sufficient team. We had a contract management team, service specialists for specialised services, our own finance team, and embedded quality staff. We worked collaboratively across disciplines to continuously improve the delivery of specialised services in our region by adopting a matrix approach, and each group of specialists within our specialised commissioning team were plugged into the relevant parts of NHS England's wider infrastructure at appropriate points and levels.

c. The contract management and monitoring undertaken by commissioners like me is one of several levers that are used to ensure quality care, but other processes are required to assure patient safety and quality on the frontline, the governance arrangements of our providers, and effective regulation of healthcare provision. To a large extent, we as commissioners rely upon providers being open and transparent with us about the issues they face, and on other parts of the healthcare system playing their part in the overall assurance picture.

d. I was never fully informed about the concerns at the Hospital, and I felt that my attempts to obtain the information I needed to take informed decisions were repeatedly frustrated. By way of example, I was unaware that clinicians at the Hospital had raised concerns about a possible link between the increased mortality rate on the Unit and a particular individual until the end of March 2017, I did not know that the Trust had removed LL from the Unit, and I did not learn of LL's identity until the day of her arrest. I have reflected on this as I have prepared my statement.

e. The NHS had changed significantly since the events at the Hospital. The integration of health and care through integrated care boards is leading to improvements from a quality perspective, commissioning is now more joined up resulting in improved patient pathways and better outcomes, and we have formalised whistleblowing procedures and provided more effective escalation routes, through Freedom to Speak Up.

f. I have carefully reflected on the lessons that need to be learned from the tragic events that the Inquiry will examine, and in the final section of this statement I offer some personal reflections in the hope that these will aid the Inquiry in its important work.

Approach to my statement

5. In this statement, I have set out my response to the questions that the Inquiry has asked me in the Rule 9 request it sent to me on 1 May 2024 (the **Rule 9 Request**). Before turning to address those issues, I would like to explain the process through which I have drafted this statement and my involvement to date in responding to the Rule 9 requests made to NHS England.

6. This statement has been drafted on my behalf by the external solicitors acting for NHS England in respect of the Inquiry, with my oversight and input. This statement is the product of drafting after communications between me and those external solicitors in writing, by telephone and video conference.

7. Prior to giving this statement, I had contributed to the process through which the NHS England corporate witness statement (which provides an overview of NHS England's role; the applicable statutory frameworks; its knowledge and involvement in events relating to LL; and its views on a range of issues relating to culture, management and governance within the NHS and which I refer to in this statement as **NHSE/1**) was drafted. This included attending several meetings with NHS England's solicitors to assist with responding to the questions relating to the North regional arrangements; the governance of specialised commissioning; and the North region's involvement and knowledge of events involving LL. As part of this process, I also provided relevant documents and other materials to NHS England's solicitors, which were then disclosed as exhibits to NHSE/1. As a result, I have few additional exhibits to disclose with this statement.

8. This statement covers the period from April 2015 to March 2019, which is referred to in this statement as the **Relevant Period**.

Background

9. I have worked in specialised commissioning in the NHS for most of my career.

10. I started my first healthcare commissioning role in November 1998 as a Contracts Manager (HIV/AIDS) for the South West HIV Voluntary Sector Purchasing Consortium. In April 2001, I was promoted to the role of Senior Commissioning Manager for what, by then, had become the South West London HIV and GUM [genitourinary medicine] Commissioning Consortium.

11. In March 2003, I became a Senior Commissioning Manager / Senior Commissioning Analyst for the National Specialised Commissioning Team, based within the Department of Health and then subsequently hosted by the London Strategic Health Authority. In July 2009 I was appointed as an Associate Director (Commissioning) for the South East Coast Specialised Commissioning Group. At that time, and as described in paragraphs 33 and 34 of NHSE/1, Strategic Health Authorities were responsible for overseeing and managing the health service and NHS services (including specialised services) were commissioned

by Primary Care Trusts. In that role I managed a team of Specialised Commissioning Managers who led on a portfolio of contracts with providers in Kent, Surrey and Sussex. I also managed the relationship with the Primary Care Trusts and provider trusts in Surrey and Sussex.

12. I was a member of the NHS Commissioning Board operating model design team for specialised services, which developed the structure for specialised commissioning in preparation for the legal establishment of NHS England on 1 April 2013.

13. In January 2013, I became the Regional Head of Specialised Commissioning, Armed Forces Healthcare and Health in the Justice System (for NHS England North Region) and in January 2015, I moved to the role of Assistant Regional Director of Specialised Commissioning (North) in NHS England as a result of a restructure of the organisation. In May 2019, I became the Regional Director of Health and Justice and Specialised Commissioning (North West), this remains my role now.

14. I hold a first class honours degree in healthcare management from the University of Westminster.

15. I have described my role as Assistant Regional Director of Specialised Commissioning (North) in more detail (at paragraphs 16 to 18 below). I also produce a copy of my career history as **Exhibit AB/01 INQ0103037**, which includes a summary of my responsibilities in this role.

My role

16. During the period from January 2015 to May 2019, I was one of three Assistant Regional Directors of Specialised Commissioning for the North Region. My role was to lead NHS England's specialised commissioning function in, what was at the time, the North West sub-region of NHS England's North region, which comprised Cheshire, Merseyside, Greater Manchester, Lancashire, and the southern portion of what was then the administrative area of the County of Cumbria that included Barrow in Furness and Kendal. For the purposes of this statement, I refer to this team as the **Specialised Commissioning Team (North West)**. The Specialised Commissioning Team (North West) commissioned specialised services for a population of approximately 7 million. The size and composition of the team is discussed further at paragraph 26.

17. We managed the contracting of specialised services from approximately forty providers (the majority were NHS bodies, but some were commercial healthcare providers or third sector organisations) across the sub-region. We were responsible for ensuring that appropriate contractual arrangements were in place with providers of specialised services, that service specifications were adhered to, that quality health services were provided to our population, and that budgets were managed and adhered to. NHSE/1 provides a fuller description of NHS England's commissioning responsibilities at paragraphs 88 to 91, and of specialised services commissioning at paragraphs 477 to 482.

18. As part of my role as an assistant director, I was a member of the Specialised Commissioning Regional Leadership Group, which provided strategic leadership, challenge and support for the planning and delivery of specialising commissioning in the wider North region. I describe the membership and functions of the Specialised Commissioning Regional Leadership Group below at paragraph 39.

Specialised commissioning in the North region

19. The Specialised Commissioning team for the North region oversaw the delivery of all specialised services that were directly commissioned by NHS England within an overarching strategy that was set by NHS England.

20. Specialised services are defined in Section 3B of the National Health Services (2006) Act (as amended). The Secretary of State decides whether a service is classified as a specialised service based on whether the service meets one of several specified factors. During the Relevant Period, the factors that applied were:

    a. the number of individuals who require the provision of the service or facility;

    b. the cost of providing the service or facility;

    c. the number of persons able to provide the service or facility; and

    d. the financial implications for Clinical Commissioning Groups if they were required to arrange for provision of the service or facility themselves. (N.B. This criterion was removed by amendments made to the National Health Service Act 2006 by the Health and Care Act 2022).

21. Services that the Secretary of State determines meet one or more of these criteria are listed in the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012. This includes the commissioning of specialist neonatal services, which is one of approximately 160 specialised services commissioned by NHS England through its regional structures.

22. Specialised commissioning is therefore a specific, statutory function of NHS England that is distinct from, but integrated into, NHS England's wider statutory functions (which are described in NHSE/1 at paragraphs 61 to 77).

23. NHSE/1 explains how NHS England was established on 1 October 2012 and became fully operational from 1 April 2013 (see, in particular, paragraphs 46 to 55 of that statement). From this date, NHS England became responsible for directly commissioning specialised services. During the period 2013 to 2015, the function of commissioning specialised services was performed by a sub-set of the 27 area teams described in paragraph 84 of NHSE/1. By the commencement of the Relevant Period (2016), these area teams had been consolidated into NHS England's regional team structures and the function of specialised services commissioning was discharged through those regional teams. At this time, specialised commissioning had only been a function of NHS England for approximately 2.5 years, and the specialised commissioning teams in the regions were continuing to work with teams across the region to develop and enhance specialised commissioning's place in those regional structures. These arrangements have continued to evolve over time, particularly in the context of preparing for the delegation of some specialised services commissioning to Integrated Care Boards.

24. I consider the primary role of commissioners in the NHS as being to secure the greatest health benefit possible for our population within the budget and resources available to us. As commissioners of specialised services, we gather and use information on historical trends from an activity process perspective, demographic changes, advances in treatments, and new technologies to ensure that we are commissioning the right services in the right quantities at the right time to meet the needs of our population. It is also our role to ensure that the services we have commissioned are delivering properly to meet those needs. I explain how this assurance process worked in paragraphs 47 to 58 below.

25. Commissioning is a bottom-up process, in that we rely on information and data reported into us by others. Much of this information flows into us from providers, but we also receive statistical information and data from a range of other sources. We review a wide range of

information, some service-specific, some provider-specific, and some general, to develop intelligence which in turn informs our commissioning decisions. For example:

a. We use data from the Office of National Statistics to understand demographic trends like changes in the birth rate in our population, and average life expectancy. The Office for National Statistics also produces statistics on key public health indicators, like the proportion of the population that smokes. This helps us to predict future trends in the healthcare needs of our population and the services we need to commission to meet those needs.

b. What was then NHS Digital (which is now part of NHS England) provides us with activity and performance data for the providers in our region.

c. We receive qualitative information on providers' activity and performance from other teams in NHS England (and in what was NHS Improvement during the Relevant Period). This information allows us to benchmark the data we receive directly from our providers, to understand how they are performing relative to other providers of the same specialised services.

d. Clinical registries provide us with information on outcomes and incident rates.

e. We review the reports that are published by the Care Quality Commission following their inspections. If the Care Quality Commission make significant findings that might have implications for services that we commission, then they usually share those findings with us prior to publication so that we can take any necessary action to ensure continuing service delivery, although this was not always the case during the Relevant Period. Care Quality Commission reports can also be discussed at meetings of our local and regional quality surveillance groups (of which the Care Quality Commission is a member), and my team now have a system in place for systemically reviewing all Care Quality Commission reports upon publication.

f. We will also receive information from complaints and whistleblowing disclosures, where those complaints or disclosure raise matters that are relevant to specialised commissioning.

26. The Specialised Commissioning team in the North region was, during the Relevant Period, essentially a self-sufficient team. We had a contract management team, our own service

specialists for specialised services, our own finance team, and embedded quality staff. In many ways, we operated like a clinical commissioning group (described in NHSE/1 at paragraphs 127 to 132), in that we were directly responsible for commissioning services for the populations we served, and we employed all the specialists we need to perform that function effectively. However, we were also part of NHS England's national specialised commissioning infrastructure, and we engaged with NHS England's wider structures through our participation in the North region.

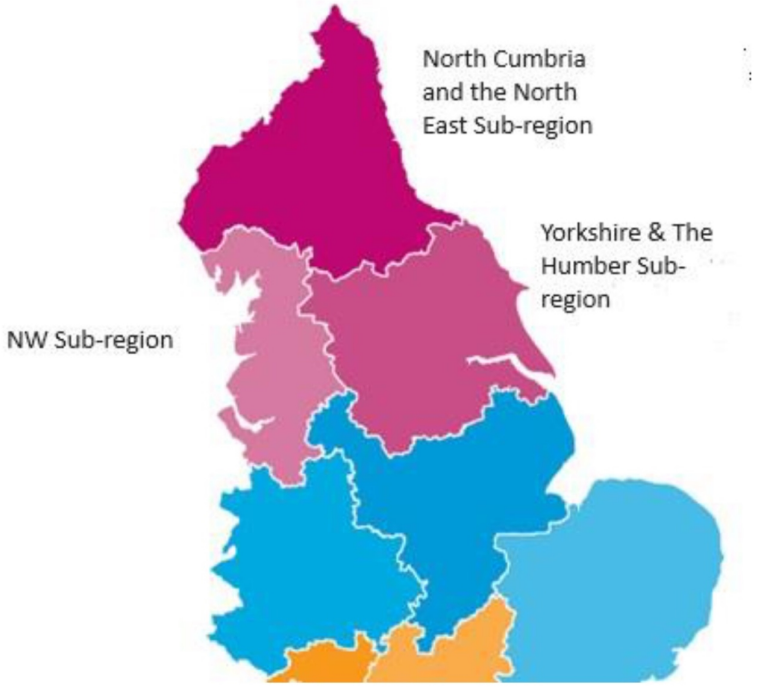
27. Each group of specialists within our Specialised Commissioning team were plugged into NHS England's wider infrastructure at appropriate points and levels. For example, our quality leads were members of the North region's quality surveillance groups (see paragraph 110 below) at regional and sub-regional levels, our finance team fed into the national finance structures for Specialised Commissioning, and our commissioners liaised informally with other commissioners in the region (principally, Clinical Commissioning Groups) to share information and intelligence.

28. We also benefitted from the matrix working approach that is embedded in NHS England's processes and ways of working. Matrix working is a system of working that takes a broader view of functions and services, where horizontal connections and relationships cut across vertical structures and processes. Matrix working allows NHS England to take a broader view of commissioning and helps to mitigate the risk that functional silos emerge which tend to deter collaboration and partnership working. In practice, matrix working meant that we could and would seek advice from and share intelligence with specialists and experts across the North region, national teams, and other NHS bodies such as clinical commissioning groups.

29. While the NHS landscape and infrastructure has changed since the Relevant Period, in my view the function of commissioning has remained largely unchanged.

Management and governance structures

30. During the Relevant Period, the North region comprised three sub-regions, each with their own assistant director. I was the Assistant Director for Specialised Commissioning for the North West. The other assistant directors for the North region covered North Cumbria and the North East, and Yorkshire and the Humber. The map below shows the geography of the North region, and its three sub-regions as it was at that time.



31. Subsequently, as NHS England's internal structures have changed and we moved from having four to seven regions nationally, the North West sub-region has become a region in its own right and the North East and Cumbria and the Yorkshire and Humber sub-regions have become the North East and Yorkshire Region.

32. Each assistant director also acted as the lead for different aspects of specialised commissioning. I led on acute strategy across the region, and the other two assistant directors led on mental health strategy, and commercial and procurement respectively.

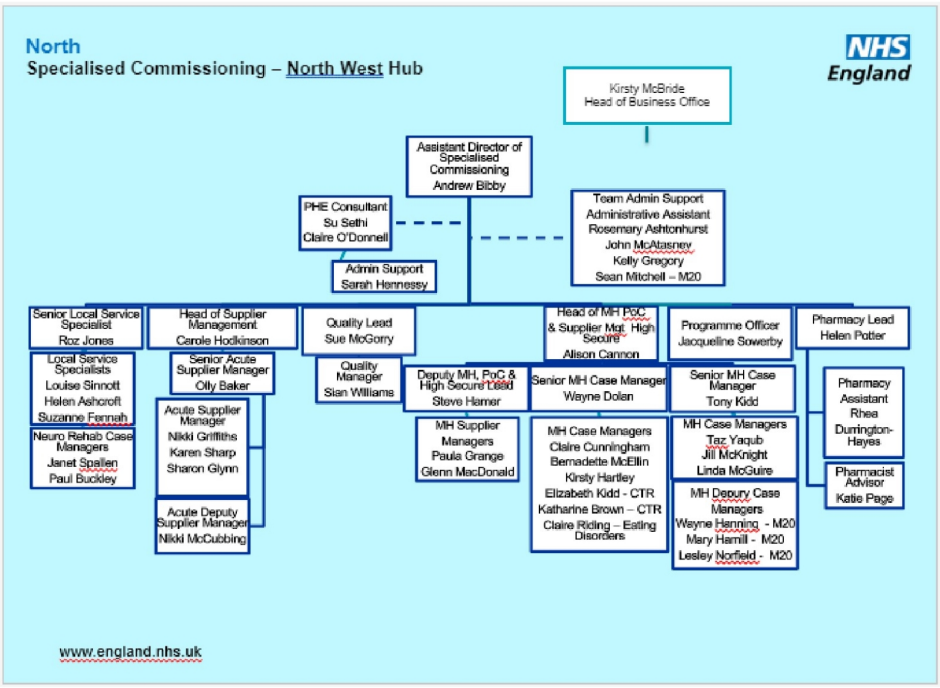
33. Acute care is where patients receive active, short-term care for a condition; it includes treatment for a severe injury, period of illness, urgent medical condition, or to recover from surgery. Our acute strategy included services provided in accident and emergency departments, inpatient and outpatient surgery and medicine. As the lead for acute strategy for the North region, I worked with the service specialists (see paragraph 35 below) across our region to facilitate shared learning across that group, to ensure that best practice from one provider, or in one sub-region, was shared across the region, and to professionally develop those service specialists to ensure that they were effective in their roles.

34. The Hospital fell within my sub-region. The Hospital was one of twenty-one providers of specialist neonatal services in the North West sub-region and one of approximately forty providers of specialist neonatal services across the North region. Specialist neonatal

services are provided exclusively by NHS Foundation Trusts and NHS Trusts and are co-located with consultant-led Obstetric Services. NHS England's contract for specialised services with the Countess of Chester Hospital NHS Foundation Trust (which I shall refer to in this statement as **the Trust**) was one of the smaller ones in the sub-region due to the limited number of specialised services provided by the organisation – during the Relevant Period, NHS England commissioned nine specialised services from the Hospital, with relatively low volumes of activity being undertaken in these service areas.

35. Each of the three assistant directors for specialised commissioning in our region led a team of commissioning staff, who were responsible for commissioning within the sub-region. This Specialised Commissioning Team (North West) comprised largely of two role groups (i) supplier managers – who were responsible for managing our contractual relationship with providers of healthcare; and (ii) service specialists – who worked on service strategy, determining what level of need we should make provision for, and ensuring compliance with national service specifications. I line managed those commissioning staff working in my sub-region and provided strategic oversight of all commissioning across our sub-region.

36. The following organogram shows how the staff in my sub-region were organised. The arrangements are also described in the North Region Specialised Commissioning Team Governance Arrangements document that was published in June 2015 and reviewed in December, and which I produce here as **Exhibit AB/02 INQ0103034.**



37. During the Relevant Period, I would meet with my Senior Leadership Team for specialised commissioning in the North West sub-region on a weekly basis. This group followed NHS England's scheme of delegation, which is described in the North Region Specialised Commissioning Team Governance Arrangements document (see paragraph 36 directly above). My Senior Leadership Team wasn't an executive body, in that it didn't have decision making functions and powers of its own. However, I would exercise those decisions that were delegated to me through NHS England's scheme of delegation through, and in consultation with, this local governance group.

38. The North region specialised commissioning team also included a Clinical Director, a Director of Nursing and a Finance Director, each of whom reached into each of the three sub-regions to support those commissioners.

39. I was line managed by the Regional Director of Specialised Commissioning for the North, who chaired the North Region Specialised Commissioning Leadership Group which included:

    a. the assistant regional directors for specialised commissioning (of whom I was one),

    b. the Clinical Director, Specialised Commissioning (North),

    c. the Nursing Director, Specialised Commissioning (North),

    d. the Finance Director, Specialised Commissioning (North), and

    e. the Head of Financial Management, Specialised Commissioning (North).

40. In preparation for meetings of the North Regional Specialised Commissioning Governance Group, my team would prepare, and I would approve performance reports for the preceding quarter. These meetings assisted with the internal formal process of assuring specialised commissioning activity within the region, and supplemented other routine conversations that would take place between myself and the other senior members of the Specialised Commissioning team on a regular basis. I produce here, the following exhibits:

    a. **Exhibit AB/41 INQ0102987** - the North West Performance Report for July 2016;

    b. **Exhibit AB/42 INQ0102989** - the North West Performance Report for August 2016;

c. **Exhibit AB/43 INQ0103070** - the North West Performance Reports for September 2016;

d. **Exhibit AB/44 INQ0102991** - the North West Performance Reports for October 2016;

e. **Exhibit AB/45 INQ0103000** - the North West Performance Reports for March 2017;

f. **Exhibit AB/46 INQ0103002** - the North West Performance Reports for April 2017;

I have not been able to locate those completed monthly performance reports that were completed during the Relevant Period, but which are not listed above, and I am therefore unable to disclose these to the Inquiry.

41. The Regional Director of Specialised Commissioning for the North reported to the Executive Regional Director for the North, who was the accountable person for NHS England in the North region. The lines of accountability therefore ran from the commissioners, through the assistant directors in each sub-region to the Regional Director for Specialised Commissioning for the North Region, and through them to the Executive Regional Director for the North Region.

42. Work in the North region on specialised commissioning was supported by the national Specialised Commissioning Oversight Group, which provided co-ordination and operational oversight, and was underpinned by national clinical reference groups. These are described in NHSE/1 at paragraphs 101 to 104.

43. Clinical reference groups bring together expert clinicians for a particular specialised service or group of specialised services from across the country. These clinicians are supported by one or more representatives from specialised commissioning, either from the national team or from the regions or both. Clinical reference groups would provide clinical input into the development of national service specification(s) for specialised services, and they would develop the key inputs, standards, and expected outcomes for those specialised services. They would also contribute to the development of clinical policies for their specialisms. The specifications, standards, and guidance they produced would inform our commissioning of those services, as I explain at paragraphs 49 to 51 of this statement.

I have been involved in various clinical reference groups over the years, but I was never involved in the Clinical Reference Group for Specialist Neonatal Services.

44. The Specialised Commissioning Oversight Group provided a forum where specialised commissioners from across the country could come together to learn from one another's experience, to take decisions collectively, and provide collective oversight for specialised commissioning. This was not a top-down structure or about performance management of regional commissioning teams; it provided a forum for peer-review and peer-accountability. The Specialised Commissioning Oversight Group allowed commissioners to take decisions collectively for specialised commissioning across the whole country; it was not a forum for holding individual teams or regions to account for the decisions they took for their area. That accountability for performance within a region flowed through the regional line of accountability, explained in paragraph 41 above. I did not routinely attend meetings of the Specialised Commissioning Oversight Group. My line manager, the Regional Director of Specialised Commissioning for the North, was the representative of our region on this Group. I may have covered for the Regional Director of Specialised Commissioning for the North at meetings of the Specialised Commissioning Oversight Group on one or two occasions, but I do not recall attending any meetings of this Group during the Relevant Period.

45. In mid-2015 a Specialised Services Commissioning Committee, reporting to the NHS England Board, was established. The work of the Specialised Commissioning Oversight Group continued but it now reported to the Specialised Services Commissioning Committee. The role of the Specialised Services Commissioning Committee and its place in NHS England's governance structures is described in NHSE/1 at paragraphs 101, 105 and 106.

Quality assurance

46. Paragraphs 324 to 332 of NHSE/1 explain what is meant by 'quality' in the context of the NHS, and paragraphs 332 to 352 of that statement explain NHS England's role in relation to quality, including patient safety.

47. The Specialised Commissioning Team (North West) was responsible for carrying out quality assurance of the specialised services that we commissioned. This programme of quality assurance covered forty hospitals and 160 different specialised services.

48. Quality assurance, from a commissioning perspective, focusses on compliance with standards, performance against pre-agreed measures, and ensuring that effective processes are in place. These are all set out in the national service specification for each specialised service, or in standards or guidance documents that are incorporated into those service specifications by reference.

49. Specialist neonatal services, like all specialised services, has a national service specification. I produce a copy of the Neonatal Critical Care (Intensive Care, HDU and Special Care) specification that applied throughout the Relevant Period as **Exhibit AB/03 INQ0009232**. These national service specifications are critical to ensuring that providers of specialised services deliver high quality, safe and patient-centred care.

50. The neonatal critical care specification incorporates the service and quality standards produced by the British Association of Perinatal Medicine. The British Association of Perinatal Medicine's service and quality standards describe what a specialist neonatal unit needs to provide to meet the needs of neonates in three prescribed categories of need, which are largely based on the gestational age of neonates at birth and birthweight. This includes, for example, the staffing ratios that need to be achieved on the unit, the minimum permitted distance between cots, the diagnostic and other services (such as rapid access to an MRI scanner) that need to be available to neonatal patients, and other specialists and allied health professionals (such as pharmacists capable of formulating perinatal nutrition) that need to be available to care for and support patients on a neonatal unit. The British Association of Perinatal Medicine's standards for neonatal care particularly emphasise the importance of parental partnership in care, and neonatal units are expected to work towards a model and philosophy of care within which families are enabled to be primary caregivers to their babies in partnership with clinical teams.

51. On an annual basis, we require each provider to self-assess against the national service specification for each specialised service that we commission from them. Providers are required to declare their performance against each required standard and measure in that specification, and to assure us that they had the necessary processes and procedures in place for that service. Any incidences of non-compliance had to be declared to us as part of this annual assurance exercise, and each provider's chief executive officer was required to sign each annual return for each specialised service, to ensure that they were personally accountable for any errors or omissions in their submissions.

52. While this was an annual exercise, the process of verifying, clarifying, and following-up on annual assurance returns formed a substantial part of the work that my team did. If we felt that a return was lacking sufficient detail, we would follow up with providers to request further information. If a provider declared that they were complying with every standard for a particular specialised service, then we would challenge that assertion and seek evidence in support. We would also evaluate each return considering any other intelligence we had on a particular provider, or service, including the outputs from inspections carried out by regulators like the Care Quality Commission, feedback from our Operational Delivery Networks (see paragraphs 128 to 129 below), and reports received through the Strategic Executive Information System (see paragraphs 83 to 84 below). This process often took weeks, or months, of dialogue and information exchanges between the Specialised Commissioning (North West) Team and a provider, and each annual return might be clarified or amended multiple times before we finally accepted the provider's submission.

53. We wouldn't routinely visit providers as part of this annual assurance exercise. However, if we were unable to satisfy ourselves that a provider's annual self-assessment return provided a full and accurate account of their services, then we could arrange a visit by a peer review group (see paragraph 57 below for more detail on the peer review programme).

54. Members of the Specialised Commissioning (North West) Team would occasionally visit hospitals as part of the commissioning, contract monitoring, and quality assurance process. Our supplier managers would hold routine contract review meetings at the providers' premises, although these meetings wouldn't routinely involve visits to particular units unless there was something in particular that the provider wanted to show us. Our quality teams also visited hospitals and units in response to specific concerns. I would visit individual providers on an exception basis, for example if there were concerns about capacity that might impact commissioning, or if we had a particular concern. For example, I recently visited a hospital after a clean and safe inspection by the Care Quality Commission indicated issues with the presence of mould in hospital bathrooms, and I recently visited a spinal unit to discuss concerns around capacity for spinal specialised services in our region.

55. If a provider failed to meet a prescribed standard, they would be required to prepare and submit a service improvement plan. That service improvement plan would be incorporated into their NHS contract, and their delivery against that service improvement plan would then form part of their routine contract monitoring for the coming year. Our supplier

managers (see paragraph 35 of this statement) would meet with each provider of specialised services every month for a formal contract review meeting. During those meetings, providers would be required to demonstrate that they were satisfying the requirements of their NHS contracts. Our supplier managers, who were senior and highly skilled, would review with each provider their previous month's activity data across the whole range of specialised services that we commissioned from them. Those discussions usually took several hours, and the supplier manager would take the provider through any trends or anomalies in that data, work with the provider to understand that data and what was it was telling us, and agree any action that needed to be taken to ensure that they continued to deliver in accordance with their service delivery plan. They would also be challenged to show how they were implementing the actions set out in any service improvement plans that had been agreed as part of the annual assurance exercise, and they would be required to account for any failures to implement any such actions.

56. Our assurance activity was carried out in a proportionate way, and focussed on those areas where we would routinely see problems that presented a risk to the delivery of quality services for our population. However, the process of ongoing contract monitoring, combined with the annual assurance exercise for each specialised service, meant that we had a good understanding of how each of our providers was performing, and how we should target our assurance activity to ensure the highest standards of care across all specialised services in our sub-region.

57. We also had a peer review programme, that was triggered in two ways. First, our rolling peer review programme focussed on different themes within specialised commissioning. To the best of my knowledge, we have never carried out a thematic review of specialist neonatal services. Secondly, we could request a peer review of a particular provider location, or cluster of providers, of a specialised service if we had concerns about the quality of those services in our region or sub-region. These peer review teams comprised subject matter experts from around the country, and they were part of the broader specialised commissioning infrastructure in NHS England.

58. Some aspects of compliance with contractual requirements were assured through routine inspections by regulators like the Care Quality Commission or NHS Improvement (as it was known during the Relevant Period).

59. It is important to understand that concerns like excess deaths, or morbidity rates outside the expected range, would not be picked up through these routine quality assurance

processes because this routine monitoring focussed on structures, processes, and clinical arrangements for the delivery of each specialised service, rather than outcomes (which were subject to separate monitoring arrangements). Concerning trends in outcomes would trigger more reactive quality processes, and these interventions would usually be led by the Clinical Director and the Director of Nursing. However, the Medical Director and/or Director of Nursing would brief me on any interventions they were involved in or aware of that might impact on my team's commissioning work. Typically, this would be done through an in-person briefing or huddle, where we would discuss the concern, the options available to us, and the steps that we would need to take.

60. I have been referred, in the Rule 9 request, to the Direct Commissioning Assurance Framework (**Exhibit AB/04 INQ0009226**) that was published on 28 November 2013. That assurance framework reflected the specialised services commissioning structures that were in place at that time, when we had a national support centre, four regions, and 27 areas teams. That framework assurance document largely served to ensure that the regional teams could hold the area teams to account for the commissioning they undertook, supported by the national support centre. It is described in NHSE/1 at paragraph 92.

61. However, by June 2015 direct commissioning of specialised services was carried out by the regions, and the Direct Commissioning Assurance Framework had been largely overtaken by those structural changes in our infrastructure.

62. The six assurance domains contained in the Direct Commissioning Assurance Framework focus on structural aspects of commissioning. They require us to assure, for example, that providers have effective relationships in place with their partners and stakeholders, that they are engaging in public engagement, and that they are testing their structures and behaviours to ensure that they are effective and resilient. The Framework was not about testing individual decisions and actions but ensuring that the broad structures and processes were in place to ensure that decisions and actions taken within those structures were appropriate. Therefore, I regard the six assurance domains as things I would need to see to satisfy myself that I and my team were good commissioners, rather than something that I would be mindful of in every action and decision that I took.

63. I have been asked in the Rule 9 Request to address the legal duty imposed on NHS England to secure continuous improvement in the effectiveness and safety of services and the quality of the experience undergone by patients by section 13E of the National Health

Service Act 2006. While I am not a lawyer specialising in health policy, I understand that this duty requires NHS England to work to continuously improve the health service of the country. It is not a duty to continuously improve every specific service every single day of the year, it is a general duty that is broader than that.

64. I understand this to be a behaviour, a culture, and a way of working, that underlies all that we do in the way of a thematic concept. In specialised commissioning, everything we do is about ensuring that our providers improve, and the services they provide improve, so that we are able to continually commission more and better healthcare for our populations from the resources available to us. For example, this might mean securing more of the same service for the same budget, it might mean getting slightly better value for money so that resources can be released to meet other needs, or it might mean securing the same service at a higher quality for the same cost, or re-prioritising the services we procure to better meet the changing needs of our population.

65. I am not an expert in safeguarding, and I would therefore defer to more experienced colleagues in NHS England who are specialists in this area and whose help I would seek. However, from a commissioning perspective, part of my role was to ensure that the contractual arrangements we put in place with providers reflected the duties imposed on NHS England and that these flowed down to providers through their contracts. Providers are also subject to various statutory obligations, in their own right, as statutory bodies with their own functions and responsibilities.

66. The NHS standard contract (explained in NHSE/1 at paragraphs 56 to 60) included specific obligations for NHS providers to comply with all relevant legal duties, including the duty imposed on NHS England to make arrangements to ensure its functions are discharged having regard to the need to safeguard and promote the welfare of children (imposed by section 11 of the Children Act 2004), and the specific statutory duties imposed on providers themselves. However, in my experience the contractual obligations imposed on providers through the NHS standard contract are significantly more onerous than the duties imposed by statute. As a commissioner of specialised services, I very rarely if ever felt that I needed to rely on the statutory obligations imposed on providers, as the contractual obligations were stringent and the contract itself provided a robust infrastructure around the commissioner-provider relationship that allowed us to hold providers to account.

67. As commissioners, we ensured that NHS England's statutory duty to have regard to the need to safeguard and promote the welfare of children when providing services to the NHS

was discharged through our commissioning of specialised services. The national service specifications, referred to in paragraph 49 above, would set down national requirements and standards for each service which reflect the duties imposed on NHS England. We would ensure that our contracts with providers for specialised services required providers to deliver those services in accordance with the relevant specifications. Service condition 1.1 of both the 2015/16 and 2016/17 versions of the NHS standard contract that were in place with the Trust during the Relevant Period required providers to "*provide the services in accordance with the fundamental standard conditions of care and the service specifications*".

68. We would also ensure that our contracts reflected the specific duties that applied to each provider as a statutory body and flowed down the duties imposed on NHS England corporately. For example, service condition 32.3 of both the 2015/16 and 2016/17 versions of the NHS standard contract that were in place with the Trust during the Relevant Period required that:

> *"32.3 The Provider must comply with the requirements and principles in relation to the safeguarding of children and adults, including in relation to deprivation of liberty safeguards and child sexual exploitation, set out or referred to in:*
> *32.3.1 the 2014 Act and associated Guidance;*
> *32.3.2 the 2014 Regulations;*
> *32.3.3 the Children Act 1989 and the Children Act 2004 and associated Guidance;*
> *32.3.4 the 2005 Act and associated Guidance;*
> *32.3.5 Safeguarding Guidance; and*
> *32.3.6 Child Sexual Exploitation Guidance."*

69. We required providers to self-assess annually against the relevant service specification and other contractual obligations, and rolling peer review process would provide additional assurance that these duties were being discharged. We also had reporting arrangements in place, through which trusts were required to report serious incidents and we relied, as I have said above, on the inspection regime of the Care Quality Commission to examine the quality of care.

70. The NHS mandate for April 2015 to March 2016 (**Exhibit AB/05 INQ0012901**) sets out the objectives that NHS England is expected to achieve during each financial year. I understand it is an instruction from Government, via the Department for Health and Social Care, to NHS England. It is described in detail in NHSE/1 at paragraphs 72 to 76. While

the NHS Mandate sets the strategic direction, NHS England is required to translate the high-level instructions in the NHS Mandate into action, policy or guidance for the rest of the NHS. The NHS mandate therefore reflects the Government's instructions to NHS England on how NHS England should direct or instruct the NHS.

71. The NHS Mandate for April 2015 to March 2016 instructed that all patients should be able to expect to be treated in a safe and clean environment and to be protected from avoidable harm. While I have not specifically checked NHS mandates for other years, I would be surprised if this requirement was not included in the NHS mandate every year. There is an established infrastructure for both clean and safe care within the NHS, and in so far as it related to specialised services, it would form part of our assurance activity (described at paragraphs 51 to 56 above) because it would be prescribed through the NHS standard contract both in general terms and through incorporation of a detailed specification for each individual specialised service that we commissioned.

72. As described in NHSE/1, for much of the period that the Inquiry is considering there has been a distinction between the regulatory functions carried out by Monitor (later NHS Improvement) and the assurance and direct commissioning performed by NHS England. It is only relatively recently that these various roles have come together under NHS England's overall remit.

73. During the Relevant Period, the provider regulator role was performed by Monitor and latterly by NHS Improvement. This was very different to the relationship that we as direct commissioners of specialised services had with NHS providers. We would hold providers to account for the delivery of individual clinical services, whereas the regulators would hold providers to account for being a good provider of healthcare. This might include meeting the relevant governance standards, or having a financially balanced plan, or complying with corporate governance requirements like holding regular and effective board meetings.

74. Even today, others in our region would primarily be responsible for discharging NHS England's regulatory relationship, for example by carrying out quality reviews, or taking regulatory action where a provider was failing to meet a requirement in relation to its provider licence.

75. The specialised commissioning team, of which I was part, was rather different. We had a contractual relationship with NHS trusts and foundation trusts in our area, and we held

these NHS trusts and foundation trusts to account in relation to their contractual requirements. Our role was to carry out contract monitoring and assurance, as I have explained in paragraphs 51 to 56 above.

76. Since the Relevant Period, NHS England has continued to review and revise its structures to respond to changing needs and priorities and to continually improve the services the NHS provides for patients. Direct commissioning (of which specialised commissioning is part) is even more integrated into the work that wider regional teams in NHS England do. There is a clearer expectation that different teams and services will collaborate and there is a greater emphasis and reliance on matrix working. Our medical teams are much more closely integrated with the Directors of Nursing and Clinical Directors for the North region and their teams, and we have closer relationships with the regional finance team, communications team, and the work of the commissioning operations team. I think things have moved on a lot and specialised commissioning is now more closely stitched into the fabric of the region than we used to be. There's no longer a sense of 'escalating to' the region; they would naturally be part of our discussions and decision making from the start. While I would hope that we never experience an issue like that which occurred at the Hospital again in future, I feel confident that there would be much closer working between the specialising commissioning team and the wider NHS England region, and this would mean, for example, that the regional nursing and clinical teams would be part of our discussions around how to address emerging issues and concerns from the outset.

Policy, guidance, training and support for providers

77. It was not the role of the regional specialised commissioning teams, or my role as Assistant Director for Specialised Commissioning (North), to write guidance or policy for use by hospitals on the safeguarding of babies and children, forensic investigations following unexpected baby deaths in hospital, speaking up and raising concerns, or on the management of grievance procedures. This was done elsewhere in NHS England, usually at a national level, by specialist policy teams.

78. It would not have been consistent with the approach taken to the development and publication of this type of support in the context of specialised commissioning for this to be produced regionally. This is because one of the aims of nationally commissioning specialised services was to ensure appropriate consistency in approach. National policy in relation to a particular specialised service, such as specialist neonatal care, was included in the relevant national service specification for that specialised service. We then

referred to those national service specifications when commissioning specialised services at a regional level.

79. Policy in relation to broader practices, that were not specific to specialised services, were developed by NHS England nationally and then applied across the NHS. To the extent that they needed to be reflected in our commissioning arrangements for specialised services, they would be incorporated through our contractual arrangements with providers.

80. If new or amended policies are needed for the NHS, then it is right that these are prepared nationally by dedicated policy teams. We would want new policies and guidance to be written by subject matter experts who could bring appropriate expertise to the role and develop policies that met the identified need.

81. It was not the role of the Specialised Commissioning (North West) Team to provide training or support to hospitals on the matters described in paragraph 77 above, although I cannot speak to whether this might have been provided by the wider regional team at NHS England.

Investigations

82. I am unable to comment in detail on the processes through which sudden unexpected child deaths in hospital are investigated as this is not within my area of professional knowledge and expertise. However, I am familiar with the Serious Incident Framework and the reporting of incidents through the Strategic Executive Information System (commonly referred to as StEIS).

83. Sudden unexpected child deaths in hospitals should always be reported on the Strategic Executive Information System. The Strategic Executive Information System is described in paragraphs 357 and 358 of NHSE/1, and I do not repeat that general information here, except to say that we, the Specialised Commissioning (North West) Team, had direct access to the Strategic Executive Information System and would rely on providers submitting reports through this system to alert us to serious incidents that might require action on our part.

84. Through the Strategic Executive Information System, we are provided with information on individual cases. I believe that the Strategic Executive Information System allows providers to direct each report to the most appropriate commissioner, so a provider could elect to

direct reports about specialised services to the Specialised Commissioning team and to direct reports about other commissioned services to the relevant clinical commissioning group. However, I understand that the system defaulted to reporting to the relevant clinical commissioning group and most quality nurses would likewise report incidents to their clinical commissioning group in the first instance. However, as clinical commissioning groups participated in our local and regional quality structures with representatives from specialised commissioning (see paragraph 110 on our Quality Surveillance Groups), any concerning reports, or patterns or trends in reporting, would be brought to our attention through these structures.

85. My team would review the outputs from the Strategic Executive Information System, which was basically a very large spreadsheet detailing each reported incident, on a regular basis. This review involved interrogating the data in the Strategic Executive Information System line by line. We would hope and expect to see regular reporting of low-level incidents by providers in our sub-region, as regular reporting would suggest that regular learning from incidents to continually improve services was embedded as a way of working in the culture of the organisation. Infrequent reporting, or frequent reporting of serious (high harm) incidents, were both causes for concern. If we identified concerns of this type, then we would usually raise this with a provider through our routine contract monitoring discussions, to better understand the reasons for this and to agree any action that needed to be taken to either improve reporting, or to address patterns of reporting that indicated a quality issue with the services provided. This might also prompt us to require a peer review, or to refer the provider to the Care Quality Commission.

86. In my experience the quality of reporting through this system was inconsistent across our region. The quality of returns made through this system varied significantly, with some providers submitting detailed reports promptly, while others provided only the minimum information necessary, or delayed submitting their reports through this system. This wasn't necessarily a cause for concern, as there was a range of reporting styles across our network of providers, and even those providers at the less frequent / less detailed end of the reporting spectrum may nevertheless be providing adequate reports for our purposes. I wasn't aware of any concerns around the Hospital's reporting through the Strategic Executive Information System prior to the Relevant Period. As explained in more detail in NHSE/1 at paragraphs 510 to 513, the Care Quality Commission report published on 29 June 2016 recorded that there was a "*positive incident reporting culture*" and that "*staff were confident and competent in raising matters of concern, incidents were subject to investigation and feedback was used to underpin practice changes to avoid reoccurrence*".

As the Hospital was only a small provider of a limited number of specialised services, we would not have received a volume of reports from them in respect of specialised services so we would not have been as aware as other commissioners (principally, the West Cheshire Clinical Commissioning Group) about concerns about the quality or frequency of reporting. If there were concerns, these would be raised through the Quality Surveillance Groups (see paragraph 110 below).

87. The NHS England Serious Incident Framework, which was first published in 2013 and subsequently reviewed and refreshed in 2015, provided guidance to providers on the identification, investigation, and management of serious incidents. I produce here as **Exhibit AB/06 INQ0009236** the NHS England Serious Incident Framework, dated 27 March 2015, that was in place during the Relevant Period. The Serious Incident Framework specifically did not provide a definitive list of events/incidents that constitute a serious incident, because where lists are created there is a tendency to not appropriately investigate things that are not on the list even when they should be investigated, and equally a tendency to undertake full investigations of incidents where that may not be warranted simply because they seem to fit a description of an incident on a list. However, the Serious Incident Framework did set out circumstances in which a serious incident must be declared. This included "*acts and/or omissions occurring as part of NHS-funded healthcare (including in the community) that result in unexpected or avoidable death or one of more people*", "*unexpected or avoidable injury to one or more resulted that has resulted in serious harm*" and "*unexpected or avoidable injury to one or more people that requires further treatment by a healthcare professional in order to prevent the death of the service user or serious harm*". As specialised commissioners, it was our role to support providers to interpret and apply this framework and to comply with their reporting requirements, and to assure that providers were so complying.

88. There is obviously a need to assess each occurrence against these criteria and against the wider definition of serious incident provided in the Serious Incident Framework. The Framework makes clear that any unexpected or avoidable death of a child in hospital should be treated as a serious incident and reported through this system immediately. However, it was generally the case that expected and unavoidable patient deaths, i.e., those for which there was a clear clinical cause and explanation, were not required to be reported in this way. I would not, therefore, expect a provider to report every death of a neonatal patient in hospital through this system.

89. There are several ways in which information about less serious incidents might come to our attention, but we would always inform an NHS trust or foundation trust if the threshold for reporting on the Strategic Executive Information System was met and require them to make a report through this system. However, any unexplained death in hospital should always be reported through this mechanism.

90. We would also have expected to receive 24-hour and 72-hour reviews, as well as root cause analyses, whenever a serious incident occurred. These review procedures are described in the NHS England Serious Incident Framework, which was first published in 2013 and subsequently reviewed and refreshed in 2015. I produce here as **Exhibit AB/06 INQ0009236** the NHS England Serious Incident Framework, dated 27 March 2015, that was in place during the Relevant Period. Serious Incidents must be declared as soon as possible, and immediate action must be taken to establish the facts, ensure the safety of patient(s), other services users and staff, and to secure all relevant evidence to support further investigation. This is commonly referred to as a 24-hour review. Within 72 hours, a provider must complete an initial review to confirm the level of investigation required. A root cause analysis is the recognised system-based method for conducting such investigations. It has three levels of investigation, depending upon the seriousness of the incident that has occurred. Providers are required to report serious incidents that relate to the provision of specialised services to NHS England. The specialised commissioning quality team would then quality assure the robustness of the provider's serious incident investigation and the action plan implementation undertaken by the provider.

91. We wouldn't routinely be informed about matters being referred to, or investigated by, a coroner. In my experience, we only tended to learn about coroner led investigations if and when the coroner asked NHS England to be an interested party in a particular investigation, or post-inquest if the coroner issued NHS England with a Regulation 28 Prevention of Future Deaths report. NHS England's involvement in coronial processes typically only happened if another witness in that process made specific comments about commissioning in their own evidence to the coroner. Some coroners would invite us to participate in their proceedings on a more routine basis, but this was and is very much at the discretion of the individual coroner. Consequently, there is a very variable approach across our region. Occasionally, a coroner may specifically request that the Specialised Commissioning (North West) Team assisted the coroner with their investigation, as an interested party. In those circumstances, I would usually lead NHS England's engagement with the coroner. More typically, a coroner would approach NHS England through the North region, and we would then discuss and agree as a regional team which specific team

or individual would be best placed to assist the coroner with their investigation. Where it was felt that the subject matter of the investigation related specifically to the commissioning of specialised services, then I or another member of the Specialised Commissioning (North West) Team would volunteer to lead for NHS England. I cannot specifically recall the Specialised Commissioning (North West) Team ever being asked to be an interested party in proceedings in the coroner court in Cheshire.

92. The Specialised Commissioning (North West) Team were not routinely involved in Child Death Overview Panel proceedings. I cannot recall ever being personally involved in a Child Death Overview Panel.

93. The Rule 9 Request asks me to consider when I would expect the police to be contacted about a sudden unexpected child death in hospital. I think this is a very difficult question to answer in generalities, and I do not have the expertise to offer an informed view on what NHS England's policy should be. I think the question also implies a level of knowledge about the events at the Hospital, that we simply didn't have at the time. However, as I explain at paragraphs 67 to 68 above, we would have expected providers to have appropriate processes in place, including in relation to safeguarding, and I would expect these processes to result in the reporting of serious incidents that might ultimately lead to police involvement promptly. Local safeguarding arrangements should also prompt contact with the police in appropriate circumstances.

94. If a hospital, or unit, identified an unexpected outcome, or was identified as an outlier in terms of its outcomes over a period through statistical analysis, then you would expect the trust to go through the usual processes to identify a potential cause for those outcomes. You would first expect the trust to rule out mistakes, both in terms of specific medical care and overall clinical practice on the unit, as these are the most common causes of unexpected outcomes. This would typically involve clinicians looking at practices on the unit, and reviewing case notes, with the aim of identifying a common cause that was resulting in poorer outcomes. I think, in the absence of any specific evidence, that you would only suspect that something untoward might be happening that might necessitate police involvement, once you had got a series of data, had carefully scrutinised that series of data, identified a pattern, but been unable to explain that pattern.

95. I think that we reached the conclusion as soon as we reasonably could have done in relation to the events at the Hospital (as I describe further below), but I do feel that the quality of reporting of, and investigations into, serious incidents has improved, and I think

that would lead us to the conclusion that the police should be involved sooner now than it did at that time.

Identifying issues and raising concerns

96. As I explain in paragraphs 51 to 56 above, the Specialised Commissioning (North West) Team was responsible for carrying out quality assurance of the specialised services that we commissioned. This programme of quality assurance covered forty healthcare providers and 160 different specialised services. We carried out routine contract monitoring and assurance activity on an annual basis, and deep dives into specific specialised services were carried out on a rolling basis.

97. In addition to the assurance reports that were submitted to us by NHS trusts and foundation trusts in our sub-region, we also gathered and received intelligence from a range of sources, and we were provided with statistical information about the performance of providers and the specialised services we commissioned from them from a number of national teams in NHS England.

98. We receive mortality statistics annually from MBRRACE-UK, which is hosted by the National Perinatal Epidemiology Unit at the University of Oxford. The process by which these are collated, analysed and reported is described in NHSE/1 at paragraph 459. Paragraphs 509, 522, 528, and 576 of that statement provide detailed evidence on the mortality data reported in respect of the Hospital during the Relevant Period.

99. A significant amount of work goes into analysing mortality data at a national level. MBRRACE-UK's work is disseminated to regional commissioners of neonatal services and neonatal operational delivery networks. In the North West, the North West Neonatal Operational Delivery Network (which I refer to in this statement as the **Neonatal Network**) undertake a detailed appraisal of MBRRACE-UK data and discuss any issues emerging from that data with the Specialised Commissioning (North West) Team. However, the lead in time for this work is quite long, and it takes time for mortality data for our providers to reach us. For example, we are currently looking at last year's mortality data.

100. The data we receive does not compare units on a like for like basis as different neonatal units are set up to provide one of three levels of care based on the categories set out in the neonatal critical care specification. As a result, some units are equipped to look after more complex, clinically unstable patients and, as such, we would anticipate a higher

mortality rate on these units than those providing lower levels of care to less complex and more stable patients. However, the national data we receive does not make 'casemix adjustments' which take account of the different complexity of patients being cared for in each centre in their benchmarking comparisons, so we need to identify these factors and draw conclusions based on the data and our own knowledge of, and intelligence on, the different services we commissioned from different providers.

101. We did not receive information about post-mortems, or referrals to coroners, and we would only be notified of an inquest if the coroner decided that we should be an interested party in those proceedings. However, I do think on reflection there might be a case for us to receive data related to post-mortems or referrals to the coroner as these might act as early warning signs before statistically significant trends would become apparent in the data. This type of mechanism, alongside reporting via the National Medical Examiner processes which are currently being established to review all hospital deaths which do not go through coronial procedures, would give commissioners a more comprehensive picture of mortality in the services we commission.

102. Whistleblowing and Freedom to Speak Up reports are generally dealt with internally within NHS trusts and foundation trusts. While a trust might choose to share these concerns with us, we in the Specialised Commissioning (North West) Team would not routinely receive complete information regarding whistle-blowers or those who have raised concerns through the Freedom to Speak Up arrangements. However, the NHS now has much more robust processes in place for dealing with whistleblowing and Freedom to Speak Up disclosures. While these disclosures would rarely be made to the Specialised Commissioning (North West) Team directly, I am confident that, as a result of i) the improvements in the mechanisms for handling Freedom to Speak Up and whistleblowing consistently, and ii) recent changes to the regional operating model for NHS England whereby different teams work much more closely together, we would be alerted by the relevant Freedom to Speak Up Guardian if we needed to be because a disclosure affected the commissioning of specialised services.

103. Complaints in relation to commissioned health services can be made in two ways, either to the provider (typically an NHS trust or foundation trust) or to the commissioner (which, at the material time would have been the relevant clinical commissioning group for non-specialised services, and now the relevant integrated care board; and NHS England for specialised services).

104. If complaints are made to NHS England about a provider of specialised services (either directly to the Regional Specialised Commissioning Team or via the Complaints Team), then we would be aware of the content of that complaint, but if such a complaint was made directly to the provider we would not be. In my experience, it would be unusual for the Specialised Commissioning (North West) Team to receive complaints about specialised services directly from patients or their family members. Patients typically complain directly to providers, rather than to us. If a patient is dissatisfied with the response that they receive from the trust, then they may direct their complaint to the Parliamentary and Health Services Ombudsman. I have never been contacted by the Parliamentary and Health Services Ombudsman about a complaint concerning the provision of specialised services that we commissioned.

105. Trusts do not share internal committee minutes or the minutes of their private board meetings with my team. They also do not provide us with the minutes of their public board meetings, although these are publicly available. We, the Specialised Commissioning (North West) Team, do not routinely review the minutes of public meetings. We have forty providers in our region, and the document pack for typical meeting of their board might be 250 pages long. We do not have the capacity to review these documents for all trusts on a regular basis, and I do not believe that they would provide us with information that we needed and that wasn't available to us through other means in a more useful format.

The Specialised Commissioning (North West) Teams' role in addressing concerns

106. If the Specialised Commissioning (North West) Team had concerns about a hospital, there were two tracks we could take, one if we were worried about a particular service or unit at a hospital, and one if we were worried about the hospital or the trust's leadership of that hospital. For example, if we felt that serious incidents were not being reported in the way that we would expect, this might be a particular issue on a specific unit, or it might be a more widespread failure that indicated a governance issue at that trust.

<u>Concerns with a specific service or unit at a trust</u>

107. If we identified a concern with a particular service, we would usually speak to the service as a first step, to explain that we were unhappy with how it was performing, to set out our

concerns, to ask the service what they knew and to ascertain what they were doing to improve that service.

108. We might then raise the issue more formally with the trust as a contract performance issue. We might also escalate our concerns to the Medical Director for our region, who might write formally to the relevant operational team setting out our concerns about quality and requiring specific action to be taken to address those concerns.

109. If we were unable to resolve our concerns through dialogue with the trust at a regional level, then there are several parties whom we could mobilise to assist us.

110. Depending on the issue, we might report our concerns into NHS England's quality infrastructure, through the Quality Surveillance Groups (as they were then). Quality Surveillance Groups are explained in more detail in NHSE/1 at paragraphs 378 to 387. This action would usually be taken by the regional Medical Director or the regional Director of Nursing, who led on quality issues. The Quality Surveillance Group could carry out what were then single item reviews (and what are now rapid quality reviews). This provided a means by which we could carry out a deep dive into a particular service.

111. We, or the provider, or both of us jointly, could request the appropriate Royal College to carry out an independent review of the service and to make recommendations for service improvement, or we could instruct an appropriate expert to carry out an independent review.

112. We would not take each of these steps on every occasion, and we would exercise our judgment to decide which might be the most appropriate escalation step for a particular issue. However, one or more of these steps would usually resolve the issue.

Concerns with a hospital or trust as a whole

113. If the Specialised Commissioning (North West) Team had wider concerns with a hospital and/or a trust's leadership of that hospital, such as concerns about under-reporting or delayed reporting across multiple different services at that hospital, of if we were concerned about a particular service but felt that the trust was not responding adequately to our concerns, that might lead to us proceeding along the second 'corporate' track to address concerns around governance and accountability at the trust.

114. Some of the steps that we would take on this track are the same as the steps that we would take for service-specific issues. For example, our first step would usually be to discuss our concerns with the appropriate hospital or trust leaders. We would raise contract performance issues, which could result us in the issuing of a contract performance notice, which is a formal contractual lever which requires the trust to meet with the contracting authority within a specified timeframe and answer any specific service or performance related questions outlined, and/or develop an action plan to resolve a delivery/performance/quality issue. Contract performance notices can be helpful, because they bring our concerns to the attention of both the trust's board, and to the regulator, the Care Quality Commission.

115. If this didn't resolve our concerns, then we would usually feed into NHS England's quality infrastructure, as a hospital's failure to e.g., report serious incidents through the Strategic Executive Information System, or to carry out root cause analyses in a timely way, or to learn and improve, was a red flag for service quality and could have been masking more serious issues.

116. The steps that we would take are therefore similar, but we would focus our interventions and reporting on what the organisation as a whole was doing. However, our focus throughout was on supporting providers to improve.

117. It is important to bear in mind that we were, largely although not exclusively, reliant on quality and performance information flowing up to us, from NHS trusts and foundation trusts, so that we could target our assurance processes effectively. Although the care regulator, the Care Quality Commission, undertook inspections of care. However, I remain of the view that it would be extremely difficult to operate the specialised commissioning system in any other way.

118. Since the Relevant Period there have been structural changes made that have improved the way we work, the system is the same but there are other inputs and a more formalised Freedom to Speak Up process which both feed into our team more routinely. There is also a much more robust process to review each unexpected neonatal death. If we were to see the same circumstances now, we would have a richer picture of the views of people reviewing the deaths and I am confident that we would conclude that something untoward was happening sooner.

119. In theory, staff members or boards of directors could escalate issues directly to the Specialised Commissioning (North West) Team. Staff members do not usually do this, but directors may sometimes pick up the phone to discuss issues with us. This would usually be a supportive conversation, and we would discuss with them the action they were proposing to take, or we might suggest other courses of action that were open to them. However, no one from the Hospital ever pro-actively rang me to discuss neonatal services at the Hospital, or any other issues around hospital management or trust governance during the Relevant Period.

120. It was not the normal route for staff members to contact us about issues with their colleagues, or with concerns about the hospital they worked at. It would be a peculiar mechanism for clinical staff to contact us as the commissioner for specialised services if they had issues with colleagues, or concerns about the hospital they worked at. I would not think that many clinical staff would even know who we are. I cannot recall a time when a clinician or other staff member has ever contacted me directly to discuss concerns about a colleague or the hospital they were working at. Clinicians were more likely to know of other teams and the operational delivery networks.

121. I would not necessarily expect a trust to raise issues that arose between staff members or concerning individual staff members with the Specialised Commissioning (North West) Team directly, unless there was a very serious conduct issue which we needed to know about because it undermined the provider's ability to deliver commissioned services, or, e.g., because it impacted the provider's succession plans.

122. Now, I would expect concerns of this type to be raised through Freedom to Speak Up channels, or as a whistleblowing disclosure. If these sorts of disclosures raised quality concerns, then I would expect those to be channelled through the Director of Nursing, and they would then involve us as commissioners of specialised services if necessary.

123. I have never been contacted by anyone raising concerns about a particular nurse. However, I would not expect these sorts of issues to be raised with the Specialised Commissioning (North West) Team. Individual members of staff would usually raise these concerns within their hospital or trust, and I wouldn't expect a trust to routinely report to us on internal disciplinary or grievance procedures. If a member of staff wished to raise a whistleblowing disclosure, then I would expect them to speak to their Freedom to Speak Up Guardian, or another Freedom to Speak Up Guardian elsewhere in the NHS if they didn't feel able to raise it within their own trust in this way. I would expect those Freedom

to Speak Up Guardians to take concerns of the type being raised within the Hospital during the Relevant Period very seriously, and to escalate these within NHS England and with other external bodies appropriately.

124. The Rule 9 Request asks my opinion on the factors that tend to encourage or inhibit members of staff from raising concerns about patient safety. Whilst there are people more expert than me in dealing with whistleblowing disclosures and responding to concerns around quality and patient safety who would be able to give a more informed opinion on what we can do to encourage members of staff to raise concerns, my personal view is that there are two primary reasons why people might not come forward and ways to encourage them to do so. There should be a safe space for people to raise concerns without fear of reprisal and there should be clear entry points into that process, there should also be confidence that action will be taken as a result of individuals raising their concerns. In my view, the Freedom to Speak Up structures and processes within the NHS have addressed both issues and I would hope that members of staff now feel much more confident to raise concerns about patient safety.

Concerns about the mortality rate on the Unit

125. The Hospital reported two serious incidents through the Strategic Executive Information System on 30 June 2016 in relation to the cases later described as 'Child O' and 'Child P'. These reports were directed to the West Cheshire Clinical Commissioning Group, the local commissioner of non-specialised services and the commissioner of the majority of NHS services provided by the Hospital. My team became aware of these reports in early July 2016, and I was briefed about these cases then, although I did not see the actual submissions made through the Strategic Executive Information System.

126. I was first alerted to the fact that the MBRRACE-UK mortality statistics for the Unit indicated that they had experienced a run of poor outcomes by the Hospital. I cannot recall precisely when this was, but I have been directed by the Rule 9 Request to a timeline that was created by staff members at NHS England North on 4 April 2017 and subsequently updated on 20 May 2018 and 3 July 2018 (**Exhibit AB/07 INQ0014692**), which suggests this would have occurred in early July 2016. I do not believe that I was aware that there were concerns about specialist neonatal services at the Hospital before this date. The Hospital did not inform me that concerns had been raised within the Unit prior to this date, or that consultants on that Unit had requested an external peer review of outcomes on the Unit, or that there were concerns about an individual member of staff at the Hospital.

127. Mortality data for neonates flowed into the Specialised Commissioning (North West) Team through two principal routes. First, all neonatal units in the country are required to submit quality data, which includes data on outcomes including mortality data, to an organisation called MBRRACE-UK, who carry out a detailed analysis of the data and prepare an annual report. This annual report is then shared with specialised commissioners in each of NHS England's regions. The timeline for reporting, collating and analysing this data and preparing the accompanying report is lengthy, and we typically received mortality data for neonatal units from MBRRACE-UK eighteen months after the end of period covered by the report. Secondly, we may be alerted to concerns about neonatal outcomes by the Neonatal Network, who support us in commissioning specialist neonatal services across the region.

128. The Neonatal Network are not commissioners, but they do support us by coordinating and facilitating the delivery of high quality, safe and efficient specialist neonatal services across the region. The role of the Neonatal Network, which is one of many operational delivery networks, is described in more detail in NHSE/1 at paragraphs 121 to 126. I produce, as **Exhibit AB/08 INQ0018014**, the terms of reference for the Neonatal Network as they stood on 20 September 2020 (having first been ratified on 27 September 2017). I was a member of the Neonatal Network's Board, but I delegated this responsibility to the Head of Quality, Specialised Commissioning (North West) in accordance with NHS England's scheme of delegation (see paragraph 36 above).

129. As the Neonatal Network works closely with each neonatal unit in our region, they are in frequent contact with providers and can provide us with a more contemporaneous view on outcomes. The Neonatal Network would typically inform the Specialised Commissioning (North West) Team if they had concerns about a service that we commissioned. For example, they recently alerted us to increased mortality rates on the neonatal unit at the Women's Hospital in Liverpool. The Neonatal Network worked with the Women's Hospital to understand the reason for the anomaly. The conclusion reached was that an increased incidence of low-birth-weight babies at the hospital was affecting the local mortality rate.

130. On 5 July 2016, at 7:57am I received an email from the Network Director of the Neonatal Network updating me on the steps that the Neonatal Network was taking with the Hospital to downgrade the Unit from level 2 (local neonatal unit, capable of caring for neonates with a gestational age of greater than 27 weeks and an anticipated birth weight above 800g) to level 1 (special care baby unit, capable of caring for neonates with a gestational age of

greater than 32 weeks and an anticipated birth weight above 1,000g) with effect from 6 July 2016. I produce a copy of this email as **Exhibit AB/09 INQ0102982**.

131. Later that day, I was copied into an email from the Director of Nursing for Specialised Commissioning (North) to the NHS West Cheshire Clinical Commissioning Group's Director of Quality and Safeguarding (**Exhibit AB/10 INQ0102984**). The Director of Nursing for Specialised Commissioning (North) reported that:

"We have been made aware of some serious issues relating to the Countess of Chester Hospital Neonatal Services. I had a conversation with their [Director of Nursing] yesterday. A set of triplets were born at 34 weeks, well at birth, however two have now died and the third is currently in the care of the Liverpool Women's. These cases are with the coroner but are currently not on [the Strategic Executive Information System (STEIS)] as of today.

The [Unit] was under some local scrutiny earlier in the year following an infection concern. A thematic review was undertaken 10 cases reviewed with no clinical issues identified. The Director of Nursing has confirmed that there are other issues coming to light now, that have not necessarily been reported, the recent deaths identify the [Trust] as an outlier.

The [Trust] were speaking with their [Clinical Commissioning Group] late yesterday and the [Neonatal Network] have met with the [Trust] to look at some immediate actions as follows:

- *Downgrade unit to level 1: 34 weeks and above babies (3 cots less). An action plan is being developed by their clinicians.*
- *External review of all aspects of the unit to include staff / equipment / pathways / competency / incidents reported.*

Whilst willing to support these steps temporarily this will put strain on an already pressured system in the Northwest. [Specialised Commissioning North West] are going to work with the [Neonatal Network] and other units to enable this bed reduction and the potential transfer issues that will arise. The [Hospital] also has some work to do in order for the system to be assured regarding their internal governance within this speciality.

In the longer term Specialised Commissioning aim to accelerate a planned service review of Neonatal services in the Northwest to ensure a sustainable future.
I have discussed this with [the Chief Nurse (North)] who has suggested that the [Director of Commissioning Operations team] coordinate an incident review meeting to look at the impact across Cheshire and Merseyside. I have spoken to [the NHS Improvement Nurse Director] as she has been informed that the [Hospital] are to issue a media statement regarding the above

actions. [The NHS Improvement Nurse Director] has agreed to discuss the next steps with the [Director of Commissioning Operations team] this afternoon via [the Director of Transformation] and will let us know the outcome."

132. At this time, in July 2016, we were aware of an historic infection prevention and control issue at the Hospital which I recall was caused by contamination of their water supply. I recall that our initial thinking when we learned of the poor outcomes on the Unit was that these poor outcomes might have been caused by a similar infection prevention and control issue.

133. I was not aware, before receiving this email, that the Hospital had already carried out a thematic review of outcomes of the Unit. However, generally whenever you found a run of poor outcomes you would review those cases to try and identify a common cause or contributory factors so that action could be taken to address those issues to improve outcomes. While the fact that they carried out a thematic review of these cases was not surprising, I recall that our views on the level of comfort that could be taken from the findings of that review was one of the first significant points of divergence between the Trust and the Specialised Commissioning (North West) Team. I recall that the Trust had been reassured by the fact that the review hadn't identified anything clinically that indicated a cause for concern. Conversely, I recall that we in the Specialised Commissioning (North West) Team were concerned that there had been ten deaths on the Unit, and two of those had occurred in related patients within twenty-four hours of each other, and a third sibling had been transferred to another hospital. We were of the view that there had to be a common factor that was driving such an adverse variance to the Unit's expected mortality rate. So, the fact that the Hospital had carried out a thematic review on cases on the Unit was not particularly surprising, but their interpretation of the findings (or lack of findings) following that review was very different to ours.

134. I think that our concerns are reflected in the scope of the external review that the Trust intended to arrange, which was exceptionally broad and included infrastructure-related issues, staffing-related issues, and process-related issues. This reinforces my recollection that we in the Specialised Commissioning (North West) Team were unclear about what was driving the mortality issues on the Unit at this time, and so we supported an external review with a broad scope as the best means of identifying what might be causing the anomalous outcomes.

135. I did not discuss the concerns raised about neonatal services in July 2016 with anyone at the Hospital, but members of the specialised commissioning team for the North region would have done, as shown in the Director of Nursing's email. Typically, those discussions with the Hospital would have been led by either the Director of Nursing, or the Medical Director, because the concerns at the hospital at that time were understood to be clinical / quality issues, and this fell within the clinical leads' portfolios of responsibilities rather than mine.

136. I recall that we were also concerned about internal governance issues, both within the neonatal specialty at the Hospital and more widely at the Trust. These concerns were largely around the reporting of serious incidents. We recognised that reporting was not very good, and looking back now, particularly considering the timelines that I have been directed to by the Rule 9 Request (**Exhibit AB/07 INQ0014692**) and **Exhibit AB/11 INQ0005216** (a chronology of events in respect of neonatal mortality data prepared by the Trust on 7 July 2016), it is clear that a number of serious patient incidents were not reported properly through the Strategic Executive Information System as we would have expected and as the Trust were contractually obliged to do. It appeared that either the Unit was not reporting within the Trust what they needed to, or the Trust's quality team were not actioning such reports on the Strategic Executive Information System. This apparently poor quality governance at the Trust did give me cause for concern. However, I did not consider that the lack of reporting through the Strategic Executive Information System would make it difficult for the Trust to investigate the concerns around outcomes on the Unit, because any review would refer to the medical records of the patients concerned, which would be held locally, rather than the information that was reported into other parts of the NHS through our reporting systems. All the information that an external reviewer would need to investigate the issues on the Unit would have been available from the patients' records, which were kept securely at the Hospital. When we became aware that there were cases that should have been reported on the Strategic Executive Information System, we brought these to the attention of the Hospital so that they could make the necessary reports and consider whether investigations were required. If, ultimately, this informal intervention did not result in the required improvements then we could have fallen back on more formal interventions, such as the issuing of a contract performance notice.

137. The decision to downgrade the Unit from level 2 (local neonatal unit, capable of caring for neonates with a gestational age of greater than 27 weeks and an anticipated birth weight above 800g) to level 1 (special care baby unit, capable of caring for neonates with a gestational age of greater than 32 weeks and an anticipated birth weight above 1,000g)

was discussed and agreed between the Neonatal Network and the Hospital. While I was not directly involved in these discussions between the Neonatal Network and the Hospital, the decision to downgrade the Unit was tested with me, and I then briefed the North West Senior Leadership Team on that decision by teleconference on 7 July 2016.

138. At this stage, in commissioning terms, the appropriate and proportionate action was to downgrade the Unit to ensure that more premature, and therefore higher risk, babies would be treated elsewhere while we worked to identify what was causing the poor outcomes at the Hospital. While I was not directly involved in that downgrading decision, it was one I that supported.

139. We in the Specialised Commissioning (North West) Team were involved in implementing this downgrading decision once it had been taken, in collaboration with our system partners, the West Cheshire Clinical Commissioning Group and the Neonatal Network, as it necessitated diverting higher risk babies to other providers in our sub-region. I was also involved in various conversations, both within the Specialised Commissioning (North West) Team and with our wider partners (including the West Cheshire Clinical Commissioning Group, the Neonatal Network and the Trust) about what was underlying the data, and how we could reach a conclusion about the cause of deaths. Those discussions were largely led by the Director of Nursing, Specialised Commissioning.

140. We did not consider contacting the police at this stage, as the thematic review had not identified any clinical issues or common factors that might be causing the apparently poor outcomes, we were not aware that anyone at the Hospital had raised concerns about a particular individual, and we had no reason to suspect that there was a bad actor at the Trust who might be causing harm to babies on the Unit. The most likely explanation was a failure in clinical practice, or an infection prevention and control issue, and we were reasonably confident at that stage that an external review would identify the cause.

141. I understand from a timeline prepared by the Hospital's Director of Human Resources and Organisational Development (**Exhibit AB/12 INQ0002926**) that a meeting took place on 7 July 2016 between members of the Trust's executive team, the West Cheshire Clinical Commissioning Group and the Specialised Commissioning (North West) Team. I was invited to this meeting, but I was unable to attend as I had another meeting in London on the same date. Having reviewed the details of the meeting in my calendar, I can see that the other invitees were as follows;

a. the Director of Nursing, Specialised Commissioning (North), NHS England

b. the Head of Quality, Specialised Commissioning (North West), NHS England

c. the Deputy Director of Quality and Safeguarding, Director of Commissioning Operations Team (Cheshire and Merseyside), NHS England

d. the Director of Nursing and Quality, the Trust

e. the Nurse Director (North West), NHS Improvement

f. the Director of Quality and Safeguarding, West Cheshire Clinical Commissioning Group.

142. As I did not attend the meeting myself, I do not who was present at this meeting. However, I believe that I would have been briefed after the event by one of the other NHS England attendees.

143. The Rule 9 request refers me to a spreadsheet, **Exhibit AB/13 INQ0006455**. I am not familiar with this spreadsheet, and I cannot recall seeing this document before now. That spreadsheet records, at row 4, that the Hospital provided the specialised commissioning team with a tabular chronology of events on 7 July 2016. I am asked if the chronology that was provided to the regional specialised commissioning team is the chronology of events in respect of neonatal mortality data prepared by the Trust on 7 July 2016 (**Exhibit AB/11 INQ0005216**). I cannot say for certain, but I note that the document appears from its header to have been produced by the Trust, that it is titled 'Chronology of Events: Neonatal Mortality July 2016' and that it dated 7 July 2016. Therefore, I think it would be reasonable to assume that this is the document that was provided to the regional specialised commissioning team. However, this document would most likely have been provided to the Head of Quality, Specialised Commissioning (North West) and the Director of Nursing, Specialised Commissioning (North), as they would have led the discussions with the Trust around quality and patient safety.

144. On 8 July 2016, I was copied into an email from the Network Director of the Neonatal Network to the Director of Nursing, Specialised Commissioning (North) (which I produce here as **Exhibit AB/14 INQ0102985**) in which the Network Director of the Neonatal Network reported on the actions that had been agreed with the Hospital regarding the

downgrading of the Unit. The Network Director also enclosed a copy of a proposal that had been agreed with the Trust, which I produce here as **Exhibit AB/15 INQ0102983**. The Network Director reported that the Neonatal Network would be monitoring capacity across the network daily and reporting on the impact of the downgrading at the Hospital. The Network Director also provided feedback on a teleconference that had taken place between the Hospital and Arrow Park Hospital to prepare a collaborative plan to transfer babies who were currently receiving intensive care or high dependency care at the Hospital to Arrowe Park Hospital. It was not unusual for me to be copied into these sorts of emails, for information purposes, although any actions arising would have been led by the Director of Nursing, Specialised Commissioning (North) and her team.

145. I now know that the Trust took the decision to move LL from the Unit at around this time. However, I was certainly not aware of this decision at the time.

146. In July 2016, the Trust was telling the Specialised Commissioning (North West) Team that they did not know what had caused the run of poor outcomes on the Unit. While I now understand that clinicians at the Hospital had raised concerns about LL this was not disclosed to me and, as far as I am aware, this was not disclosed to anyone else in the Specialised Commissioning (North West) Team at NHS England.

147. On 12 August 2016, I chaired a teleconference with the Hospital and other stakeholders. This call included the Hospital's Director of Nursing and representatives from the West Cheshire Clinical Commissioning Group, NHS Improvement, and NHS England's Cheshire and Merseyside team. This call would have served two purposes: first, to seek updates and assurances around the steps that the Hospital was taking to understand what was driving the run of poor outcomes on the Unit, and secondly, to discuss the operational management of the Unit following the downgrading of that Unit. I produce here, as **Exhibit AB/16 INQ0014679**, an email that I sent to the Head of Quality, Specialised Commissioning (North West); the Regional Lead for Safeguarding (North); the Nurse Director, NHS Improvement and the Director of Quality and Safeguarding, NHS West Cheshire Clinical Commissioning Group and copied to the Director of Nursing, Specialised Commissioning (North) summarising the contents of that call.

148. We discussed the outputs from the enhanced monitoring arrangements that had been put in place for the Unit. The Hospital was collating data daily from the Unit, on things like the number of cots occupied, the number of nurses on the Unit, and any incidents that occurred on the Unit, no matter how serious they were. This would have included reporting

on any adverse outcomes for any neonatal patients on the ward. This data was being reviewed on a weekly basis by the Trust's executive team and reported to the Head of Quality, Specialised Commissioning (North West). There was nothing significant to report in this enhanced monitoring data.

149. The threshold for enhanced surveillance is relatively low, and enhanced surveillance may be triggered by any level of concern our quality team had about patient care, quality, or outcomes, with any of our providers. It is a logical first step when a problem is identified to wish to more closely monitor performance. At any one time, several of our providers are likely to be subject to some level of enhanced monitoring, whether in respect of a particular specialised service or at a trust level. As this is a routine intervention, no specific governance meeting needs to be convened or decision-making process followed. Decisions of this nature would typically be taken during a meeting of relevant team members, or huddle.

150. We were happy with the data we were receiving, as it was coming straight from the Unit and was shared with the Trust and us simultaneously. This meant that we were receiving the raw, unfiltered data. Had we needed to, we could have verified the data that was being received by reviewing clinical records at the Hospital, so we were confident that the data that we were receiving was accurate.

151. At the same time, the Trust as a whole was subject to enhanced surveillance. While I was not involved in this enhanced monitoring of the Trust directly, I understand that this was introduced following an inspection by the Care Quality Commission.

152. During the call on 12 August 2016, we also discussed the Royal College of Paediatrics and Child Health's forthcoming review. The purpose of that review was to undertake an external independent review of the deaths on the Unit, to try and identify a cause for the high mortality rate. The Royal College of Paediatrics and Child Health were brought in to carry out a case note review of all cases of concern on the Unit. I recall that the Specialised Commissioning (North West) Team at NHS England contributed to the development of the terms of reference for this review. The Royal College of Paediatrics and Child Health planned to attend the Hospital for two days to carry out a detailed review of relevant case notes, which seemed appropriate. I was informed during the call with the Hospital that the dates for this review had been delayed to 1 and 2 September 2016, at the Royal College's request.

153. The briefing paper I referred to in my note of this call was going to summarise the findings of the previous internal review. However, as that internal review had not identified a common cause or any contributory factors that might provide a clinical explanation for the outcomes on the Unit, I did not expect this paper to provide an explanation for the concerns that we had. I would have asked for a copy of this report as a matter of routine, but I am fairly sure that this was never received.

154. I note that the Trust's Medical Director had also requested an internal review of still births on the Unit. This would have reinforced my understanding at the time that the Trust did not know what was causing the poor outcomes and that they were therefore searching for a potential cause or explanation in different places, as we were.

155. My intention, captured in my note of this call, was that we would sit down face-to-face with staff at the Trust following receipt of the Royal College of Paediatrics and Child Health's report to review the Royal College's findings and agree next steps. I do not recall a face-to-face meeting ever taking place with the Trust. However, as I explain at paragraphs 157 to 159, 164 to 170, and 177 to 178 below, we had great difficulty obtaining a copy of the Royal College's report, which in any event failed to identify a clinical cause for the outcomes on the Unit. I suspect, therefore, that my intention to sit down with the Trust to discuss the issues in the Unit in person was overtaken by events, although I did meet with the Trust following disclosure of the Royal College's report (see paragraphs 183 to 186 below).

156. By mid-September 2016, we had expected to have received the Royal College of Paediatrics and Child Health's report following its review of cases on the Unit on 1 and 2 September 2016.

157. On 13 September 2016, the Senior Local Service Specialist, Specialised Commissioning (North West) emailed the Director of Nursing, Specialised Commissioning (North) and the Head of Quality, Specialised Commissioning (North West), copying me in, to inform them that the situation at the Hospital had been raised at a meeting of the Neonatal Network's Board the previous day and placed on the Neonatal Network's risk register as a red risk. The Senior Local Service Specialist sought an update on the current position and assurance that the Trust's contract with NHS England had been updated to reflect the downgrading of the Unit. I produce a copy of this email as **Exhibit AB/17 INQ0103021**.

158. The timeline that was prepared by staff members at NHS England North on 3 July 2018 (**Exhibit AB/07 INQ0014692**) records that on 14 September 2016 commissioners from the Specialised Commissioning (North West) Team requested a copy of that report. I cannot recall whether I personally made that request, or whether it was made by a colleague in the Specialised Commissioning (North West) Team. However, I was involved in discussions at that time with colleagues in specialised commissioning and I would have been aware that we were collectively chasing the Trust for a copy of the report.

159. I recall that we were growing increasingly frustrated that we were not receiving the information that we wanted or that we expected to receive from the Trust, and we were exploring whether there were other levers that we could pull to obtain the information we needed, including the Royal College of Paediatrics and Child Health's report.

160. Both the Trust and the Unit were already subject to enhanced monitoring, but this had not revealed any concerns or an explanation for the higher than expected mortality rate on the Unit. It is important to understand that at this time, we did not know that clinicians had raised concerns with the Hospital about a particular individual, or that this individual had been moved off the ward. Consequently, the enhanced monitoring merely showed us that outcomes on the Unit were as expected, and there had been no unexplained deaths on the Unit during this period.

161. Decisions on enhanced monitoring would have been taken by the quality leads, most likely through the relevant quality surveillance group. I did not sit on these groups and was not directly involved in these decisions, but the Director of Nursing, Specialised Commissioning (North) was.

162. Colleagues in the Specialised Commissioning (North West) Team, who would probably have been the Director of Nursing, Specialised Commissioning (North) and the Head of Quality, Specialised Commissioning (North West), were already speaking with the regulators, who at that time would have been NHS Improvement and the Care Quality Commission, about their concerns. While I understood that the specialised commissioning team for the North region were having conversations at a national level with NHS Improvement and with the Care Quality Commission, I was not involved in these conversations.

163. We did consider issuing a contract performance notice, but didn't feel that this would add much value, as both the Trust's Board and the Care Quality Commission were already

aware of our concerns about the outcomes on the Unit, and one of the main benefits of issuing a formal notice like this is that it places an obligation on the provider to escalate to board members at a trust and to the relevant regulator. I had no doubt, at that time, that the Trust's Board was aware of our concerns about the Unit, as that Unit had been downgraded as soon as the increased mortality rate came to light (see paragraph 130 above) and it was conceivable that the Trust's Board would not have been sighted on that downgrading decision not least because the Trust had made a public announcement about it. I was also aware that concerns around the Unit were being discussed through our Quality Surveillance Groups, and the Care Quality Commission was a member of those Groups.

164. On 16 December 2016, I wrote to the Director of Nursing at the Trust about "*the issues faced by the Trust over the* Summer relating to Neonatal Critical Care, and the subsequent temporary down grading of the Unit to a Special Care Service in July 2016 and internal and Royal College investigations into the higher than expected levels of mortality". I produce a copy of this letter as **Exhibit AB/18 INQ0102994**.

165. I requested that the Director of Nursing provide the following information:

> "• *An update regarding progress towards the reinstatement of the neonatal cots*
> • *A copy of internal and external reports relating to the neonatal unit*
> • *Immediate risks or concerns*
> • *Formal action plan*
> • *Communications plan*"

166. I also sought assurances that the Trust was "*progressing with the investigations and resulting outcomes are being actioned*", and informed the Trust that "*the Specialised Commissioners have taken the decision to place the neonatal unit on Enhanced Quality Surveillance until such time as we received the required assurances that the unit can safely re open to accept admissions*". I requested a response within 5 days.

167. I recall that we were really quite frustrated at the time it was taking the Trust to share a copy of the Royal College of Paediatrics and Child Health's report with us, and to update us on the actions that the Trust intended to take in response to that report. Our expectation, at that time, was that the report might identify a gap or deficiency in clinical practice that would explain the increased mortality rates on the Unit, and we were keen to understand

what those gaps or deficiencies might be so that we could ensure that corrective action was taken on the Unit.

168. On 21 December 2016, I received a letter from the Director of Nursing at the Trust, which I produce here as **Exhibit AB/19 INQ0008077**. She informed me that the "d*raft report had been received and was being checked by us for factual accuracy, this was sent back accordingly and we have only just received the final approved document from the Royal College*". She also informed me that:

> *"One of the recommendations of the report was that a further independent case review was required of relevant cases. This is being undertaken by a Neonatologist from London and they require a secondary pathology review on a small number of cases before their final report is completed. As a consequence, we currently do not have a final report of this part of the review and therefore are not comfortable in sharing the Royal College report until we have the details of the case review."*

169. She confirmed that "*on the day the review team left the Trust, they assured us that there were no immediate actions or concerns*", and that "*in light of the above, the relevant report will be shared with you as part of our communication plan and until that time, we will not be able to comment on the timescales or plan going forward*".

170. I was concerned, although not necessarily surprised, by this response to my letter. As commissioners, our expectation is that providers of specialised services would share a report of this nature with us as soon as the final report was received. Indeed, NHS trusts and foundation trusts are contractually obliged to share these with us. However, it was clear to me that the Trust regarded us as analogous to any other stakeholder and felt that we needed to be managed as part of their wider communication plan.

171. While it was reassuring to learn that the Royal College of Paediatrics and Child Health had not identified any significant clinical issues requiring immediate action, we were concerned that the Royal College had seemingly failed to identify a cause for the increased mortality rates on the Unit.

172. Our understanding was that a further review was required as the Royal College of Paediatrics and Child Health did not come to any specific conclusions, and that they recommended a further independent review with the aim of identifying what might have caused the increase in mortality rates. I think at this point we were aware that the review

had not been very helpful, but no more than that. We were not surprised that additional work was required based on the general messages we were receiving about the review's findings from the Trust (as exemplified by the letter referred to in paragraph 168 above).

173. I do not recall seeing Dr Jane Hawdon's report (**Exhibit AB/20 INQ0009428**), or her letter of 29 October 2016 (**Exhibit AB/21 INQ0002771**). To the best of my recollection, the first time I saw these documents was when they were provided to me with the Rule 9 Request. Having reviewed Dr Hawdon's report while preparing this statement, I note that it does not appear to reach any specific conclusions and makes several very broad recommendations. However, the report does confirm that Dr Hawdon was unable to determine a cause of death in four cases and recommends that a forensic review should be carried out for these cases.

174. I would certainly have expected the Trust to have shared Dr Hawdon's report with us when it was received. As I explained at paragraph 170 above, I consider that NHS Trusts and Foundations Trusts are contractually obligated to provide reports of this nature to us promptly upon receipt of the final report. I don't recall specifically requesting a copy of this report, but on reflection I'm not sure how I would have known of the report's existence if the Trust had not voluntarily disclosed this. If I wasn't aware that the Trust possessed this report, then I would not have known to specifically request it from them.

175. I note that Dr Hawdon is critical of the records that were provided to her by the Hospital (**Exhibit AB/21 INQ0002771**), and I would have expected the Hospital to have maintained better record keeping practices than those described by Dr Hawdon. However, record keeping practices have moved on significantly since 2016, and NHS trusts and foundation trusts now maintain electronic records in an electronic patient record system.

176. We again considered using our contractual levers to obtain a copy of the report, but felt that the regulators, NHS Improvement and the Care Quality Commission, were more likely to be successful in obtaining a copy of the report.

177. On 21 December 2016, the same day that I received the letter from the Director of Nursing at the Trust, the Specialised Commissioning (North West) Team asked NHS Improvement for help in obtaining a copy of the Royal College of Paediatrics and Child Health's report. We felt that NHS Improvement had more levers than us as they had regulatory powers over NHS providers, whereas we had merely contractual powers. We hoped that NHS Improvement may be able to exercise this leverage over the Trust to assist us.

178. I recall that NHS Improvement were very receptive to helping us, and I believe that our Regional Clinical Director, Specialised Commissioning (North) liaised directly with the Medical Director, NHS Improvement. In turn, the Medical Director, NHS Improvement spoke directly with the Medical Director at the Trust. I did not recall seeing any specific correspondence between the three medical directors, but my impression at the time was that there was a verbal conversation between the Medical Director, NHS Improvement and the Medical Director Trust.

179. The timeline that was created by staff members at NHS England North on 3 July 2018 (**Exhibit AB/07 INQ0014692**) records that the Medical Director at the Trust informed the Medical Director, NHS Improvement that "the i*ssues are complex and we will have a copy of the report once it is available*". I recall being told that the Trust had told NHS Improvement that the matter was complicated, and that they had asked for further time.

180. At the time, I understood the Trust's description of complex or complicated issues to mean that this further external review was inconclusive as the Royal College of Paediatrics and Child Health's report that preceded it had also been, and that the Trust were still struggling to identify a cause of the run of poor outcomes on the Unit. I thought the Trust were in the position of not having answers and not knowing what the next steps should be.

181. With the benefit of hindsight, and the knowledge now that paediatricians working on the Unit had raised specific concerns about an individual nurse, I wonder if the Trust was in fact trying to reconcile two very different narratives at this time. On the one hand, they had clinicians making allegations about the conduct or performance of a specific member of staff, and on the other hand the Trust had a number of independent reports that had failed to identify a clinical cause for the increased mortality rate on the Unit, but had also failed to identify specific clinical failings, poor practices, or other factors that might have contributed to those poor outcomes.

182. The Rule 9 Request directs me to the minutes of an extraordinary meeting of the Trust's Board of Directors that was held on 10 January 2017 (**Exhibit AB/22 INQ0003237**). I was not aware that this Board meeting had taken place on 10 January 2017, and I was not aware that the Board had discussed permitting LL to return to the Unit. However, I note that this Board meeting was held in private, so the minutes of this meeting would not have been published and were not, therefore, available to the Specialised Commissioning (North West) Team. It is also important to reiterate that at this time, in January 2017, we

remained unaware that clinicians at the Hospital had raised concerns about a member of staff on the Unit, or that the Trust had previously moved that individual from the ward, and was now considering permitting her to return. If we had been aware that clinicians had expressed concerns about an individual and the Trust had subsequently moved that individual onto administrative duties, then we would of course have been concerned about a proposal to reintroduce that individual into clinical practice without first understanding what had caused or contributed to the poor clinical outcomes on the Unit.

183. On 3 February 2017, I received a copy of the Royal College of Paediatrics and Child Health's report by email from the Director of Nursing and Quality at the Trust. I produce the email that I received from the Director of Nursing and Quality on 3 February 2017 as **Exhibit AB/23 INQ0103029**, and the Royal College of Paediatrics and Child Health's report as **Exhibit AB/24 INQ0002457**. I note that the Director of Nursing and Quality at the Trust refers to "*a media handling protocol*" and "*pending media interest from the Sunday Times this weekend*" in her email. It is my clear recollection and understanding that Royal College of Paediatrics and Child Health's report was only shared with the Specialised Commissioning (North West) team and published by the Trust a few days later because the report had been leaked to the Sunday Times.

184. My team did carefully scrutinise the report, but I understood from them that the report was somewhat inconclusive. The report did identify areas for improvement, in areas like governance, inter-personal relationships on the Unit, and staffing, but it did not identify any direct cause or indicator of what might have driven the increased mortality rate.

185. I did not have any direct contact with the reviewers myself. We generally would only have a dialogue with external reviewers if we had contributed financially to the review, either directly or where we were working with another commissioner or another provider to jointly sponsor a review. For example, we were involved in a joint review into spinal surgery outcomes in Warrington, and that review was jointly arranged by the relevant NHS trust, the clinical commissioning group, and specialised commissioning. In that example, all three organisations had conversations with the Royal College undertaking the review. Here the report was requested solely by the Trust, and they dealt directly with the Royal College.

186. I met with the Medical Director of the Trust, the Director of Nursing, Specialised Commissioning (North), and the Regional Clinical Director, Specialised Commissioning (North) on 23 February 2017. The purpose of the meeting was to review the

recommendations from the Royal College of Paediatrics and Child Health's report and to assure that the Hospital was taking appropriate action to implement those recommendations. While, we still had not identified the cause of the increased mortality rate on the Unit, the Royal College had identified actions that should, if implemented, have improved outcomes on the Unit. We were therefore keen to ensure that those actions were put in place quickly, as we would have expected this to have resulted in an improvement in outcomes overall.

187. We were informed by the Trust's Medical Director that the Trust intended to arrange for a second independent report. While I now understand, having read Dr Hawdon's report (**Exhibit AB/20 INQ0009428**), that this second independent review related to her recommendation that there should be a forensic review of the four deaths she identified as unexpected and unexplained, as we had not received a copy of her report or clarity from the Trust on her specific recommendations, I am not sure that I fully understood this at the time. I do not recall being sighted on the need for a further forensic review or discussing this specifically with the Trust's Medical Director during our meeting.

188. We certainly did not discuss LL, or any individual clinicians, during this meeting as we were still unaware that concerns had been raised internally within the Trust about an individual member of staff. However, the Royal College of Paediatrics and Child Health's initial report, which the Trust had by this time shared with us, reported on the culture on the Unit and the need to strengthen the relationship between nurses and consultants. We understood that that the Trust needed to carry out a piece of work to address the cultural fractures within the Unit and to get to a place where clinical teams were working together and pulling in the same direction to deliver the best possible care.

189. I produce a copy of the minutes of this meeting as **Exhibit AB/25 INQ0006081**.

190. I understand from the timeline prepared by NHS England in July 2018 (**Exhibit AB/07 INQ0014692**) that a quality risk profile was undertaken on 25 February 2017. I was not involved in this action, which would have been led by our quality colleagues in the North region. I note from the timeline that this action appears to have been led by the Cheshire and Merseyside Director of Commissioning Operation's team, and I think that it might have been conducted in connection with the Care Quality Commission's previous findings in relation to the Hospital.

191. A quality risk profile is a usually undertaken where a specific concern or issue is identified that might indicate wider failings within an NHS Trust or Foundation Trust. It involves trawling the data submitted by providers across a wide range of metrics and using this data to analyse risk across the piece to understand whether an individual trust is an outlier across that wide range of metrics against a spectrum (broadly, five categories of concern). It helps to build a picture of a trust's performance in totality. While this quality risk profile (**Exhibit AB/26 INQ0014647**) did not highlight any specific risks around neonatal services, it did reaffirm our view that the Trust were not in a good place in respect of their governance. The Specialised Commissioning (North West) Team would not have taken any action around this, as such action would have been done more broadly by colleagues in NHS England and NHS Improvement. Our quality colleagues, such as Director of Nursing, Specialised Commissioning (North) would likely have participated in that process, but I did not.

192. I was, however, provided with a copy of the quality risk profile by the Head of Quality, Specialised Commissioning (North West) on 4 April 2017. I produce a copy of the email I received from the Head of Quality, Specialised Commissioning (North West) as **Exhibit AB/27 INQ0103064**.

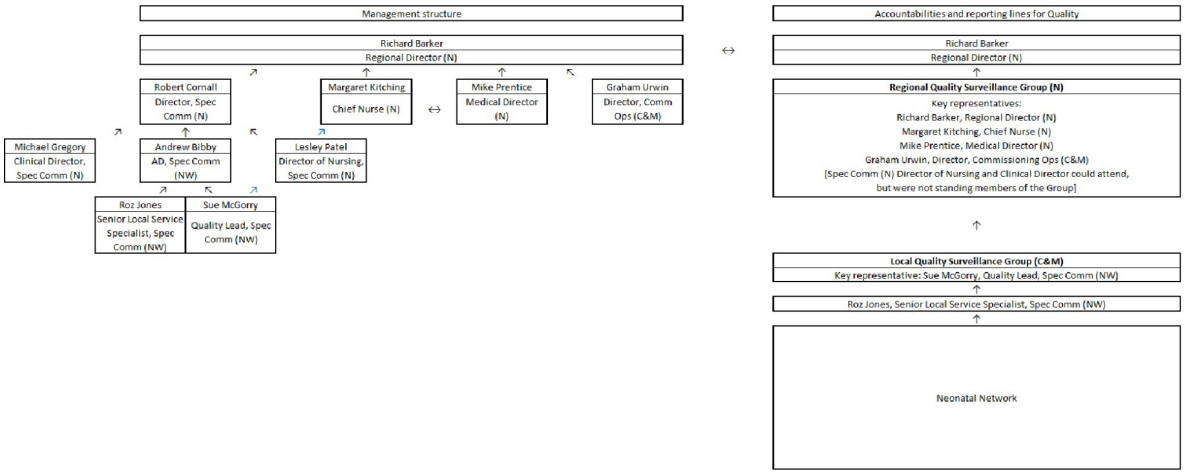
193. I understand from the NHS England timeline (**Exhibit AB/07 INQ0014692**) that a meeting took place on 10 March 2017 between members of the Specialised Commissioning (North West) Team and the Trust. However, I have checked my calendar and confirmed that I did not attend this meeting, so I am unable to comment on what might have been discussed there.

194. A further timeline entry dated 29 March 2017 indicates that the Specialised Commissioning (North West) Team were contacted by the Neonatal Network to inform us about an internal meeting at the Trust. The action column of that timeline records "*Trust had concerns relating to additional cases paediatricians felt required review. ? Whether a police investigation required.*"

195. As I explain in paragraphs 128 and 129 above, the Neonatal Network have close working relationships with all 20 neonatal providers in the North West sub-region, and they are in regular contact with trusts, hospitals and clinicians working in specialist neonatal services. They gathered a lot of information by talking to clinicians on the ground, so where the timelines records that they told us about a meeting inside the Trust, I would expect that they would have heard that directly from clinicians working at the Hospital, although I

cannot say for certain that this is where the information came from. The Senior Local Service Specialist, Specialised Commissioning (North West), who reported to me, managed the acute service team for our sub-region and led on women's and children's services, including neonatal critical care. She was the link between the Neonatal Network and the Specialised Commissioning (North West) Team, and she would have been in close contact with the Neonatal Network during this period. Any intelligence received from the Neonatal Network would have been fed through the Senior Local Service Specialist, Specialised Commissioning (North West) into our quality structures. However, I am also certain that the Senior Local Service Specialist would have told me immediately if the Neonatal Network had learned of concerns about LL through their liaison with clinicians on the Unit.

196. The following figure reflects how this information from the Neonatal Network fed into the Specialised Commissioning (North West) Team and, through the quality surveillance infrastructure, into NHS England's North region.



197. I was involved in discussions within specialised commissioning at around this time regarding whether the police should be involved. The underlying factors that influenced this discussion were: the mortality rate on the Unit was an outlier and higher than we expected; the Trust had been unable to explain these outcomes; multiple independent reviews had failed to identify a clear cause or contributory factors that might have led to higher mortality rates on this Unit; and having considered and eliminated all the usual factors (such as infrastructure issues, process issues, and staffing issues) we were still unable to explain the higher mortality rate on this Unit. At that stage, we felt quite strongly that there were no other plausible avenues to explore, and in those circumstances the only other line of inquiry would be to involve the police. I don't think that we ever specifically

suspected that a malicious actor might be causing harm to patients, but having eliminated all the usual causes, we had to turn to investigating less common causes and, in those circumstances, it was appropriate to involve the police.

198. These conversations within the Specialised Commissioning (North West) Team were led by the Regional Clinical Director, Specialised Commissioning (North) and the Director of Nursing, Specialised Commissioning (North). I was included in these discussions, as well as the Head of Quality, Specialised Commissioning (North West). I was included to provide a commissioning perspective, but I recall that we were all in agreement that the police needed to be involved. We agreed that the Trust should be afforded an opportunity to take this decision itself and to contact the police directly. However, we also agreed that the Trust should be informed that if they declined to contact the police, then NHS England would make the call.

199. On 29 March 2017, I received an email from the Regional Clinical Director, Specialised Commissioning (North) summarising a conversation that he had with the Trust's Medical Director that day, which I produce here as **Exhibit AB/28** **INQ0103060.**

200. I note that the Regional Clinical Director, Specialised Commissioning (North) refers in this email to a conversation that I had earlier that day with the Neonatal Network Director. I cannot specifically recall speaking with the Neonatal Network Director on this date, but it is entirely possible that the Neonatal Network Director would have contacted me if she was concerned by what she had learned from clinicians at the Hospital. I would have shared that intelligence with the specialised commissioning team for the North region, including the Regional Clinical Director, Specialised Commissioning (North), and I suspect that this intelligence from the Neonatal Network is what prompted the Regional Clinical Director, Specialised Commissioning (North) to contact the Trust's Medical Director. It appears to me that this is what the Regional Clinical Director was referring to when he spoke of our "mounting concerns" with the Medical Director at the Trust.

201. The Trust's Medical Director told the Regional Clinical Director, Specialised Commissioning (North) that "*there is a staff member whose presence has been seemingly disproportionate but ... this matter was best dealt with when they make the significant announcement about the decision they have taken to speak to an "appropriate body" on Monday*". As far as I am aware, this is the first time that the Trust informed NHS England that clinicians at the Hospital were concerned about a possible connection between a particular individual and the neonatal deaths.

202. While I cannot say for certain what the Trust's Medical Director meant by an "appropriate body", it appears to me that at this point the Trust was coming round to our view that the concerns around neonatal deaths at the Hospital needed to be referred to the police. However, they could have been referring to escalation to an appropriate regulatory body like the Nursing and Midwifery Council.

203. I replied to the Regional Clinical Director, Specialised Commissioning (North) the same day suggesting that we should request an embargoed copy of any press release prior to it being issued and that we should book a conference call with the Trust on the following Monday or Tuesday to discuss the implications of their announcement. My reference, in that email to "*whatever they announce*" reflects the fact that we were not sighted on their proposals or plans, and reflects my growing frustration with their lack of transparency and openness with us. I produce a copy of my email as **Exhibit AB/29 INQ0103060**. I understand that there were further discussions at this time among more senior officials, but I was not party to those discussions.

204. On 4 April 2017, I attended a meeting of the NHS England North Regional Specialised Leadership Group. I produce here as **Exhibit AB/30 INQ0014655** the agenda for that meeting, and as **Exhibit AB/31 INQ0014654** an email that I received summarising the key messages from that meeting.

205. Meetings of the Regional Specialised Leadership Group were held weekly at this time, and the headlines from those meetings were routinely cascaded to specialised commissioning staff working in the region following those meetings. This acted as a routine team brief on current issues in specialised commissioning in the region. The Hospital was a regular agenda item at this time, as it was a significant concern for our region and the Regional Specialised Leadership Group provided a forum where all those involved in our interventions with the Trust could feedback, and the Group could take stock and consider what we knew, what we still needed to know, and what we needed to do next. The fact that it was mentioned specifically on that week was not particularly unique or significant, although we obviously would have discussed the intelligence we had received from the Neonatal Network, and the Trust's response to our concerns.

206. At the same time, I was also involved in discussions that were taking place between members of the next tier up in the regional governance structure. Those discussions were principally between the members of the North Region Specialised Commissioning

Leadership Group (see paragraph 39 above), the Director of Commissioning and Operations (Cheshire and Merseyside), the Chief Nurse (North) and the Executive Regional Director for the North Region. These discussions focussed on the action we needed to take, and I believe that it was the Chief Nurse (North) who suggested that we needed to follow the Child Death Overview Panel procedure (which is explained in paragraph 558 of NHSE/1). I believe that this decision was what ultimately triggered the series of events that resulted in the police commencing an investigation into the events at the Hospital.

207. On 5 April 2017, the Regional Clinical Director, Specialised Commissioning (North) forwarded me an email that he had sent to the Trust's Medical Director requesting various documents, including a copy of the Royal College of Paediatrics and Child Health's report. I produce here as **Exhibit AB/32 INQ0014657** a copy of the Regional Clinical Director, Specialised Commissioning (North)'s email to me, and as **Exhibit AB/33 INQ0003126** a copy of the Regional Clinical Director, Specialised Commissioning (North)'s email to the Trust's Medical Director.

208. On 6 April 2017, I received an email from the Director of Nursing and Quality at the Trust enclosing a draft action plan that the Trust had prepared in respect of the Royal College of Paediatrics and Child Health's report. I produce a copy of the email from the Trust's Director of Nursing and Quality as **Exhibit AB/34 INQ0103066**, and a copy of the draft action plan as **Exhibit AB/35 INQ0103022.**

209. On 10 April 2017, I was copied into an email exchange between the Regional Clinical Director, Specialised Commissioning (North), the Head of Quality, Specialised Commissioning (North West), and the Director of Nursing, Specialised Commissioning (North) in which they discussed the contents of the Royal College of Paediatrics and Child Health's report and the fact that the second independent report (which I now understand to be Dr Hawdon's report (**Exhibit AB/20 INQ0009428**) was still awaited. I produce a copy of that email exchange as **Exhibit AB/36 INQ0103028**.

210. On 13 April 2017, I received a copy of an amended copy of draft action plan that the Trust had prepared in respect of the Royal College of Paediatrics and Child Health's report from the Head of Quality, Specialised Commissioning (North West). The Head of Quality, Specialised Commissioning (North West) informed me that the Director of Nursing, Cheshire and Merseyside had arranged for a copy of the draft action plan to be reviewed by a midwife in her team and she, the midwife, had made some comments on the draft

action plan. I produce a copy of the email I received from the Head of Quality, Specialised Commissioning (North West) as **Exhibit AB/37 INQ0103027**, and a copy of the marked-up draft action plan as **Exhibit AB/38 INQ0014659**

211. On 26 April 2017, the Regional Clinical Director, Specialised Commissioning (North) emailed me, the Regional Director of Specialised Commissioning for the North and the Director of Nursing, Specialised Commissioning (North) to update us on the Trust's Medical Director's response to a request for a meeting following the Trust's meeting with the Child Death Overview Panel. I produce a copy of that email as **Exhibit AB/39 INQ0014673**.

212. In that email, the Regional Clinical Director, Specialised Commissioning (North) refers to a discussion that had taken place at a meeting of the Regional Management Team, led by Executive Regional Director for the North Region, the previous day. I did not attend that meeting; it would have been attended by my line manager, the Regional Director of Specialised Commissioning for the North.

213. By this time, there was a consensus view within the specialised commissioning team for the North region that the Trust had been given long enough to refer this matter to the police themselves, and that we had reached the point where NHS England should make the referral if the Trust declined to do so. This is a view that I shared, and I note that this is reflected in the email sent by the Regional Director of Specialised Commissioning for the North Region at 15:22 that same day (**Exhibit AB/39 INQ0014673**).

214. On 27 April 2017, I received an email from the Regional Clinical Director, Specialised Commissioning (North) informing me that the Child Death Overview Panel, which included a police officer, had met with representatives from the Hospital. He reported that the police were aware of the issues that we in specialised commissioning were concerned about and that the police were going to discuss the matter with the Chief Constable to scope the work that the police needed to do. A decision was likely to be taken the following week. The Child Death Overview Panel would continue with its planned review of cases causing concern. The Clinical Director, Specialised Commissioning (North) reported that the Chief Nurse, Specialised Commissioning (North) and the Medical Director, NHS Improvement were satisfied with what had been agreed and that the Chief Nurse, Specialised Commissioning (North) "*feels that as commissioners we need to step back and allow the police and [Child Death Overview Panel] to proceed*". I produce a copy of this email as **Exhibit AB/40 INQ0014674**.

215. I cannot recall precisely when I learned that the police had decided to commence an investigation, although I recall that some time passed while the police considered the matter before they took the decision to commence an investigation. I was not involved in any discussions with the police, either during this interval or subsequently. I would have been briefed by someone else in NHS England of the police's decision, but I cannot recall specifically who this was.

LL

216. I did not hear the name LL or have any awareness of her involvement in the events at the Hospital until I read her name in press reports following her arrest on 3 July 2018. Consequently, I did not discuss LL with anyone at the Trust.

217. However, I do strongly believe that the Trust should have been significantly more transparent with us, and with their regulators, parents, and other stakeholders, about the concerns that had been raised by clinicians regarding LL, and about what the Trust knew. There were key pieces of information that should have been shared with the Specialised Commissioning (North West) Team, that would, I think, have led us to the conclusion that the police should be involved much sooner. We were of the understanding throughout the Relevant Period that there was no known or suspected cause for the poor outcomes on the Unit. Consequently, we followed our standard processes and worked to eliminate the most likely causes, before turning to consider the alternatives. Had we known that consultant paediatricians had identified a link between the poor outcomes on the Unit and a particular individual, that individual had been moved off the Unit in June/July 2016, and outcomes had thereafter improved, we would likely have viewed the Royal College of Paediatrics and Child Health's findings very differently and I am certain that we would have pushed for greater scrutiny of LL's performance and conduct on the Unit, and for the police to be involved, much sooner.

218. As far as I am aware, the Trust did not share the suspicions or concerns about LL with anyone outside the Trust, including the parents of the babies who were ultimately named on the indictment. I do not recall ever discussing the Trust's communications regarding the reviews that were carried out, although I suspect that our quality colleagues would have raised this with the Trust. My priority at that time was ensuring that the Trust was more open with us, as specialised commissioners, so that we could ensure that the appropriate

action was taken at each stage to identify the cause of the poor outcomes on the Unit and to improve quality and patient safety on the Unit.

Culture and atmosphere within the Trust

219. The Rule 9 Request asks when I first became aware that there had been a deterioration in the relationship between executives at the Trust and the consultant paediatricians. However, I do not believe that I was aware ever of this. As I explain in paragraph 199 above, I was aware from on or around 29 March 2017 that consultant paediatricians at the Hospital had identified other cases that they felt warranted review, through intelligence received from the Neonatal Network. I also received a copy of the Royal College of Paediatrics and Child Health's report, which reported on the culture on the Unit and the need to strengthen the relationship between nurses and consultants, on 3 February 2017 (see paragraph 183 above). However, that was not a particularly unusual finding at that time, and certainly did not lead me to think that there had been a significant deterioration in the relationship between the consultant paediatricians and the Trust's senior executives.

220. I am not in a position to say what did or did not influence the Trust's reporting to the Specialised Commissioning (North West) Team, or lack of it. However, I do not believe that the Trust's interactions with me or my team were particularly influenced by their relationship with the consultant paediatricians at the Hospital. The Trust's apparent unwillingness to be open and transparent with the Specialised Commissioning (North West) Team seemed to me to reflect a broader culture within the Trust, and a desire to avoid or mitigate adverse assumptions about what might be causing the increased local mortality rate on the Unit until a definitive cause had been determined. I suspect that reputational considerations may have been a factor in this, but I personally doubt that the internal dynamics between clinicians and executives directly caused or contributed to this culture. I suspect that the fact that each of the external reviews failed to identify a specific cause for the poor outcomes on the Unit may have made it easier for executives at the Trust to close their minds to the concerns of the clinicians working on the Unit, or to rationalise these in terms of generally poor relationships between doctors and nurses on the Unit.

221. I have also been asked by the Rule 9 Request whether I ever considered approaching the consultant paediatricians at the Hospital directly to discuss their concerns about LL. However, as I was unaware of the consultant paediatricians' concerns about LL, I had no cause to do so. By the time we were alerted to the fact that there were concerns about a

potential link between an individual member of staff and poor outcomes on the Unit on 27 March 2017 (see paragraph 200 above), we had already escalated our concerns about the Unit to NHS Improvement and the Care Quality Commission (see paragraph 177 above) and through the regional specialised commissioning and quality structures to the Director of Nursing, Specialised Commissioning (North) and the Regional Clinical Director, Specialised Commissioning (North), and through them to executive leadership of the North region in NHS England (see paragraph 41 above).

222. As a general rule, we as a Specialised Commissioning (North West) Team would not approach clinicians directly without first discussing the merits of such an intervention with the trust concerned. We generally worked to support trusts to improve their structures and processes and would not wish to actively undermine them by working around them.

Reflections

223. I have reflected carefully on the events at the Hospital in the period following LL's arrest and subsequent prosecution. I believe that a lot has changed since the Relevant Period; in particular I would draw out the following key points:

a. In my view, the Specialised Commissioning (North West) Team responded promptly and robustly when we learned that neonatal outcomes at the Hospital were poorer than expected. The Unit was immediately placed on enhanced monitoring (see paragraph 148 above) and downgraded from level 2 to level 1, effectively amending the criteria for admission to the Unit, while we worked to understand the cause of the increased mortality rate on the Unit (see paragraph 131 above).

b. From that point on, and despite improved outcomes on the Unit, we continued to press the Trust to investigate the poor outcomes on the Unit. While no clear cause was identified, we continued to monitor and scrutinise until the police commenced their investigation. I do believe that this scrutiny ultimately was a key driver in the establishment of the Child Death Overview Panel, which in turn triggered the police's involvement and subsequent investigation.

c. This process was made much more difficult by the Trust's reluctance to be open and honest with us about i) concerns being raised by clinicians at the Hospital, ii) the findings of independent reviews, and iii) the action that the Trust was taking. I

do not think that the Trust kept me, or my team, sufficiently informed and this made our role as commissioners much more difficult.

d. We in the Specialised Commissioning (North West) Team are not regulators and we only have limited contractual levers available to us. I think that we used those levers as best we could to press the Trust to respond to our concerns. However, I do believe that we have lessons to learn on how we deal with uncooperative NHS trusts. In my view, the reluctance that we experienced from the Trust to engage with us, and with other parts of the healthcare system, was a warning indicator that something was not quite right. We need to respond more quickly and more effectively to those early indicators.

e. I think, in hindsight, that we could perhaps have reached the decision to convene a Child Death Overview Panel or involve the police more quickly. However, at best this might have brought the police investigation forward by a matter of weeks because we would only have taken this step once we knew that external experts had failed to identify a cause for the run of poor outcomes on the ward.

f. I have considered whether the Specialised Commissioning (North West) Team could have provided the Hospital with more support during the Relevant Period. However, the role of supporting providers to improve services falls largely elsewhere in the health service infrastructure; it was not a function of specialised commissioning to provide this support. While we did, and do, work alongside providers as they implement actions to address quality or other issues and concerns identified through our contractual monitoring and management function, I did not feel at any point during the Relevant Period that the Trust required support and indeed our attempts to engage in open and constructive dialogue with them about what was happening on the neonatal unit were rebuffed. Consequently, I do not consider that the issues at the Countess of Chester Hospital NHS Foundation Trust could or would have been overcome by the provision of more support.

g. The Rule 9 Request asks whether I should have intervened in the running of the Hospital and how it was dealing with the concerns raised about LL. However, it is important to reiterate that the Specialised Commissioning (North West) Team are not regulators, and do not have the power to take over the running of a hospital in our sub-region. Ultimately, whether or not an intervention such as this could or

should have been taken will need to be addressed by the regulators with the powers to intervene more directly, principally the Care Quality Commission.

h. I believe we worked with regulators well, particularly NHS Improvement. In hindsight, we could perhaps have worked more closely with the Care Quality Commission but as that relationship was held by the quality leads at a regional level, I'm perhaps not the best person to comment on the quality of that engagement or how it could be improved.

i. The data only ever tells part of the story, and we in the Specialised Commissioning (North West) Team are reliant on providers of healthcare reporting unexpected deaths and other serious incidents to us promptly. I do feel that the quality of reporting of, and investigations into, serious incidents has improved. Bringing commissioners like me closer to the clinical experience, and bringing commissioning and enforcement together through the integration of NHS England and NHS Improvement, has also improved the timeliness and efficacy of our interventions.

j. I have reflected above on the fact that NHS England took on the function of specialised commissioning from its establishment, and that NHS England's internal infrastructure pertaining to how the specialised commissioning function inter-related to NHS England's wider functions was continuing to develop, and evolve, and improve during the Relevant Period. That process of integrating specialised commissioning into NHS England's wider functions and wider NHS structures (including through the establishment of integrated care boards) continues to this day.

k. The NHS England roadmap articulates the direction of travel whereby specialised commissioning will be more coherently planned alongside other services as part of a unified patient pathway in order to join up care. These developments have the potential to improve oversight of the planning and delivery of specialised services, and the services that are on the same patient pathways as those specialised services.

l. The move from clinical commissioning groups as the principal local commissioning bodies within the NHS to integrated care boards with a larger geographical footprint will help improve objectivity in gauging quality and performance in local NHS

providers, as they look after more providers and are therefore better able to benchmark.

m. I am not best placed to comment on how NHS England could provide support for hospitals dealing with safeguarding incidents, as this is outside my professional responsibilities and is not something that I can offer an informed view on.

n. I have carefully considered whether CCTV could or would have prevented the crimes of LL. However, the use of CCTV in clinical settings does raise very significant ethical questions, particularly in relation how you balance the need to protect patients who lack the mental capacity or physical capability to protect themselves from harm with the need to ensure that patients' rights, particularly to privacy and dignity, are appropriately safeguarded. I do not personally feel equipped to come down on one side or the other of this complex moral and ethical debate. Consequently, while I do not doubt that the use of CCTV could potentially prevent similar crimes in future, or at least facilitate their earlier detection, I would not go so far as to say that this means that it is the right thing to do.

o. I have been asked to comment on security systems relating to the monitoring of access to drugs and babies in neonatal units, but I find it difficult to provide an informed view, as I am not a clinician and I have never had an operational role on a hospital ward. In light of my operational inexperience, I do not feel able to give an informed view on the question of whether other security systems relating to the monitoring of babies on neonatal wards should be implemented, or could prevent deliberate harm to patients. Despite not being in a position to offer an informed view, I would have questions about security measures being put in place that could delay access to medications that need to be administered immediately in life-saving situations, as there is a danger that the unintended consequence of the introduction of such measures is that it may have a negative impact on a greater number of patients.

p. The Rule 9 Request asks for my view on whether the training and regulation of nurses could be improved. These areas of healthcare management are so far outside my professional expertise that I am unable to give an informed opinion on this topic.

q. The Rule 9 Request also asks for my views on whether managers in the NHS should be regulated. In my view, this is ultimately a political question. In my

experience, accountability mechanisms within the NHS work very well, and managers in the NHS do a good job of holding individuals to account for their performance and for creating a culture in which continuous improvement is an embedded way of working. It could be argued that those individuals who sit at the very top of the structural charts of NHS bodies, such as the chief executives of NHS trusts and foundation trusts, represent weak points in the NHS's otherwise robust and effective accountability chains. However, as I do not perform a regulatory function, it is perhaps for others to comment on how accountability at this point in the chain could be improved.

r. There are steps that we are already taking in the neonatal space that will have a positive impact on both patient outcomes and patient experience, and I am aware of an ongoing modernisation programme led by NHS England to improve maternity and neonatal care across the country.

s. There is also, potentially, work to be done to improve our analysis of information on neonatal outcomes.

t. One further area where I think the NHS as an organisation could improve, is how we create a culture in which leadership teams feel able to admit earlier mistakes and take a different course of action. We need to continue to facilitate a culture in which boards feel able and are willing to reflect on earlier decisions, to admit mistakes, and to correct them.

u. It is important that the Inquiry reflects on the fact that the overwhelming majority of the more than one million people who work in the NHS come to work every day to do a good job, to provide good patient outcomes, and to continuously improve the patient experience. It is important that in mitigating the risks posed by those few individuals who may be minded to cause harm, that we do not lose sight of the exceptional commitment of our workforce and their desire to provide the best possible care for every patient. It is easy to look back with the benefit of hindsight to suggest that we should have suspected a malicious actor sooner, and taken appropriate steps more quickly. We need to take care that in trying to avert the one-in-a-million occurrence, we don't inadvertently prejudice or delay our ability to identify and rectify other more common issues as this would potentially cause much greater harm to a larger cohort of patients.

224. I have never given any interviews or otherwise made any public comments about the actions of LL or the matters of investigation by the Inquiry.

Statement of Truth

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

Signed: Personal Data

Dated: 16 July 2024

Statement ref. AB/01

Index of Exhibits

Exhibit	Relativity reference	Title	Author	Dated
Exhibit AB/01	INQ0103037	Career history	Assistant Regional Director of Specialised Commissioning (North)	undated
Exhibit AB/02	INQ0103034	North Region Specialised Commissioning Team Governance Arrangements	NHS England	December 2015
Exhibit AB/03	INQ0009232	Neonatal Critical Care (Intensive Care, HDU and Special Care) Specification	NHS England	undated
Exhibit AB/04	INQ0009226	Direct Commissioning Assurance Framework	NHS England	28 November 2013
Exhibit AB/05	INQ0012901	The Mandate: A mandate from the Government to NHS England: April 2015 to March 2016	Department of Health	December 2015
Exhibit AB/06	INQ0009236	Serious Incident Framework	NHS England	27 March 2015
Exhibit AB/07	INQ0014692	Countess of Chester Neonatal Services Timeline	Head of Quality, Specialised Commissioning (North West) and Director of Nursing, Specialised Commissioning (North)	3 July 2018
Exhibit AB/08	INQ0018014	North West Neonatal Operational Delivery Network Terms of Reference	North West Neonatal Operational Delivery Network	20 September 2020
Exhibit AB/09	INQ0102982	Email from the Network Director of the North West Neonatal Operational Delivery Network	Network Director, North West Neonatal Operational Delivery Network	5 July 2016
Exhibit AB/10	**INQ0102984**	Email from the Director of Nursing for Specialised Commissioning (North)	Director of Nursing, Specialised Commissioning (North)	5 July 2016
Exhibit AB/11	INQ0005216	Chronology of Events: Neonatal Mortality July 2016	Countess of Chester Hospital NHS Foundation Trust	7 July 2016
Exhibit AB/12	INQ0002926	Neonatal Unit Timeline	Director of People and Organisational Development, Countess of Chester Hospital	3 April 2017
Exhibit AB/13	INQ0006455	Spreadsheet, showing information submitted by the Countess of Chester NHS Foundation Trust	unknown	unknown

Exhibit AB/14	INQ0102985	Email from the Network Director of the North West Neonatal Operational Delivery Network	Network Director, North West Neonatal Operational Delivery Network	8 July 2016
Exhibit AB/15	INQ0102983	Proposed provision of neonatal care at Countess of Chester Hospital NHS Foundation Trust pending external peer review 2016	Countess of Chester Hospital NHS Foundation Trust	July 2016
Exhibit AB/16	INQ0014679	Email to the Head of Quality, Specialised Commissioning (North West); the Regional Lead for Safeguarding (North); the Nurse Director, NHS Improvement and the Director of Quality and Safeguarding, NHS West Cheshire Clinical Commissioning Group	Assistant Regional Director of Specialised Commissioning (North)	12 August 2016
Exhibit AB/17	INQ0103021	Email from the Senior Local Service Specialist, Specialised Commissioning (North West)	Senior Local Service Specialist, Specialised Commissioning (North West)	13 September 2016
Exhibit AB/18	INQ0102994	Letter to the Director of Nursing at the Countess of Chester Hospital NHS Foundation Trust	Assistant Regional Director of Specialised Commissioning (North)	16 December 2016
Exhibit AB/19	INQ0008077	Letter from the Director of Nursing, Countess of Chester Hospital NHS Foundation Trust	Director of Nursing, Countess of Chester Hospital NHS Foundation Trust	21 December 2016
Exhibit AB/20	INQ0009428	Advisory Medical Report of Dr J M Hawdon	Dr J M Hawdon	October 2016
Exhibit AB/21	INQ0002771	Letter from Dr J M Hawdon	Dr J M Hawdon	29 October 2016
Exhibit AB/22	INQ0003237	Minutes of Extraordinary Board of Directors Meeting, Countess of Chester Hospital NHS Foundation Trust	Countess of Chester Hospital NHS Foundation Trust	10 January 2017
Exhibit AB/23	INQ0103029	Email from the Director of Nursing, Countess of Chester Hospital NHS Foundation Trust	Director of Nursing, Countess of Chester Hospital NHS Foundation Trust	3 February 2017
Exhibit AB/24	INQ0002457	Service Review: Countess of Chester Hospital NHS Foundation Trust	Royal College of Paediatrics and Child Health	November 2016
Exhibit AB/25	INQ0006081	Action notes of progress meeting with Medical Director, Countess of Chester Hospital NHS Foundation Trust	NHS England	23 February 2017
Exhibit AB/26	INQ0014647	Countess of Chester Hospital NHS Foundation Trust Quality Risk Profile	NHS England	25 February 2017

Exhibit AB/27	INQ0103064	Email from the Head of Quality, Specialised Commissioning (North West)	Head of Quality, Specialised Commissioning (North West)	4 April 2017
Exhibit AB/28	**INQ0103060**	Email from the Regional Clinical Director, Specialised Commissioning (North)	Regional Clinical Director, Specialised Commissioning (North)	29 March 2017
Exhibit AB/29	INQ0103060	Email to the Regional Clinical Director, Specialised Commissioning (North)	Assistant Regional Director of Specialised Commissioning (North)	29 March 2017
Exhibit AB/30	INQ0014655	NHS England North Regional Specialised Leadership Group meeting agenda	NHS England	4 April 2017
Exhibit AB/31	INQ0014654	NHS England North Regional Specialised Leadership Group key messages	NHS England	4 April 2017
Exhibit AB/32	INQ0014657	Email from the Regional Clinical Director, Specialised Commissioning (North)	Regional Clinical Director, Specialised Commissioning (North)	5 April 2017
Exhibit AB/33	INQ0003126	Email from the Regional Clinical Director, Specialised Commissioning (North) to the Medical Director, Countess of Chester Hospital NHS Foundation Trust	Regional Clinical Director, Specialised Commissioning (North)	5 April 2017
Exhibit AB/34	INQ0103066	Email from the Director of Nursing and Quality, Countess of Chester Hospital NHS Foundation Trust	Director of Nursing and Quality, Countess of Chester Hospital NHS Foundation Trust	6 April 2017
Exhibit AB/35	INQ0103022	Neonatal External Review Action Plan	Countess of Chester Hospital NHS Foundation Trust	February 2017
Exhibit AB/36	INQ0103028	Email exchange between the Regional Clinical Director, Specialised Commissioning (North), the Head of Quality, Specialised Commissioning (North West), and the Director of Nursing, Specialised Commissioning (North)	NHS England Specialised Commissioning (North) team members	10 April 2017
Exhibit AB/37	INQ0103027	Email from the Head of Quality, Specialised Commissioning (North West)	Head of Quality, Specialised Commissioning (North West)	13 April 2017
Exhibit AB/38	INQ0014659	Neonatal External Review Action Plan, amended	Director of Nursing, Cheshire and Merseyside	April 2017
Exhibit AB/39	INQ0014673	Email from the Regional Clinical Director, Specialised Commissioning (North)	Regional Clinical Director, Specialised Commissioning (North)	26 April 2017

Exhibit AB/40	INQ0014674	Email from the Regional Clinical Director, Specialised Commissioning (North)	Regional Clinical Director, Specialised Commissioning (North)	27 April 2017
Exhibit AB/41	INQ0102987	North West Performance Report for the 3 month period to end June 2016	Assistant Regional Director of Specialised Commissioning (North)	19 July 2016
Exhibit AB/42	INQ0102989	North West Performance Report for the 3 month period to end July 2016	Assistant Regional Director of Specialised Commissioning (North)	16 August 2016
Exhibit AB/43	INQ0103070	North West Performance Report for the 3 month period to end August 2016	Assistant Regional Director of Specialised Commissioning (North)	20 September 2016
Exhibit AB/44	INQ0102991	North West Performance Report for the 3 month period to end September 2016	Assistant Regional Director of Specialised Commissioning (North)	24 October 2016
Exhibit AB/45	INQ0103000	North West Performance Report for the 3 month period to end February 2017	Assistant Regional Director of Specialised Commissioning (North)	March 2017
Exhibit AB/46	INQ0103002	North West Performance Report for the 3 month period to end March 2017	Assistant Regional Director of Specialised Commissioning (North)	24 April 2017