

Witness Name: Michael
Gregory

Statement No.: 1

Exhibits: MG/01-MG/55

Dated: 25 July 2024

THIRLWALL INQUIRY

WITNESS STATEMENT OF MICHAEL GREGORY

I, Michael Gregory, will say as follows:

1. As a doctor, the health and wellbeing of my patients has always been my first consideration. In my role as a medical director, I have the same consideration for the populations of patients that I serve. Whilst undergoing treatment, patients place their trust in the hands of the clinicians that care for them. Sick children, particularly very young babies, are reliant on the choices made by their parents and clinicians. I cannot imagine the distress and suffering caused to the parents of the babies in this case and I offer my deepest condolences to the families.
2. By the time I became involved with the issues at the Countess of Chester Hospital ("the Hospital") neonatal unit, LL had been suspended from work. When I did get involved, I did not know of her involvement, but I developed an awareness that something serious was happening. I tried, within my powers and with the experience I had at that time, to understand what was happening so that, as commissioners, we could help the Hospital. It will be seen from my correspondence and note taking at that time, that I was frustrated with the responses that I was receiving from the Hospital, and I escalated my concerns to more senior people in NHS England. Once I learnt of LL's arrest, I co-ordinated a collection of files relating to the case as I suspected the day might come when those actions would be scrutinised in public.

3. Whilst, thankfully, the delays I experienced did not affect the lives of any babies, I believe there are lessons to learn about what happened in our dealing with the Hospital that can improve culture and transparency such that patients remain our primary concern.

My statement

4. 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 those external solicitors in writing and by video conference.
5. I previously contributed to the process through which section 2 of NHS England's Corporate Witness Statement ("NHSE/1") was drafted. This focused on what NHS England knew about the events that took place at the Hospital). I have explained below where evidence overlaps what is contained within NHSE/1.
6. As explained in more detail below, my current role at NHS England is Regional Medical Director for the North West Region. Between 2016 and 2018, I was the Clinical Director of the Specialised Commissioning team in the North region. I no longer have direct access to the files of the Specialised Commissioning team. I also no longer retain in my inbox the emails I would have sent or received during my time as Clinical Director. However, I did save separately most of the key correspondence relating to the Hospital during this period. I provided this correspondence to NHS England in 2023 to assist in what I know understand was known as Project Columbus. In addition, NHS England has provided me with copies of the documents it has located relating to my role as Clinical Director, which I have exhibited to this statement where relevant.
7. During the preparation of NHSE/1 and this statement I have also searched my records and provided the Inquiry with all documents and information that are relevant to its terms of reference.
8. I have sought to set out below any additional evidence that I am able to provide from my knowledge and experience generally. I have not given any interviews or otherwise

made any public comments about the actions of LL or the matters of investigation by the Inquiry.

Career / background

Background

9. I trained as a doctor between 1984-1989 at Liverpool University and gained my Bachelor of Medicine, Bachelor of Surgery (MB ChB) in 1989. I gained a Diploma of the Royal College of Obstetricians and Gynaecologists in 1992. In 1994, I gained a Diploma of Child Health and qualified as a member of the Royal College of General Practitioners. In 2004 I received a Diploma in Medical Jurisprudence and in 2009 was awarded a Fellowship of the Faculty of Forensic & Legal Medicine of the Royal College of Physicians. In 2010 I achieved the Post Graduate Certificate in Leadership for Quality Improvement.
10. As a General Practitioner, I was a partner in practice in Altrincham, Cheshire for twenty-four years before leaving to join NHS England in 2016. The practice was innovative and forward thinking. It was paper free in 1997 and embraced several technology solutions to improve patient care and workflow within the practice such as telemedicine for skin lesions, remote consulting and population screening tools. I was a GP appraiser and a member of the Local Medical Committee.
11. During my time as a GP, I had undertaken different roles outside the practice. In 2010, I became the Medical Director of Trafford Community Services Provider, and worked with the Nuffield Hospital to support early thinking about integration. During this time, I was asked to lead the development of a quality improvement training programme for the Trafford healthcare economy. With the support of the NHS Institute of Innovation and Improvement, The King's Fund, AQuA and the Nuffield Hospital, we constructed a curriculum for a National Health Service audience.
12. The introduction of Clinical Commissioning Groups provided the opportunity to move to a new post of clinical director for strategy and policy. I was the clinical lead for the development of the Trafford Care Co-ordination Centre which started operation in January 2016.

13. The role also included Board level responsibilities, co-chairing the System Resilience Group and other committees and sitting on individual funding request panels. These funding requests were for treatment that fell outside agreed Clinical Commissioning Group commissioning policies and required a panel decision on whether to approve an individual request for funded treatment. I also sat on the Greater Manchester Effective Use of Resources clinical development group.

Advancing Quality Alliance (AQuA)

14. Alongside the roles set out above, and in a separate capacity as a clinician, I was a Board Member and held appointments with AQuA, which is a membership based organisation and works as an improvement partner with integrated care systems, organisations, teams and individuals to:
- a. Enable safe care by developing people and culture,
 - b. Develop leadership,
 - c. Co-produce person-centred care with lived experience partners,
 - d. Embed continuous improvement, and
 - e. Enable effective governance and regulatory preparedness.
15. As part of this, in 2014, I became an AQuA Integrated Fellow. The year long programme enabled me to visit various international health systems and conferences and incorporate the learning into the development of the care co-ordination centre. I have written a perspectives paper "*Developing a Patient Care Co-ordination Centre in Trafford, England: lessons from the International Foundation for Integrated Care (IFIC)/Advancing Quality Alliance integrated care fellowship experience*"¹ which was published in March 2015 and presented at the IFIC Conference in Edinburgh in May 2015.

NHS England roles

16. I took up the role of Clinical Director, Specialised Commissioning North on 12th July 2016. Although the Job Description for the role was Clinical Director for Specialised Commissioning, as I was a doctor, we referred to the post as Medical Director for Specialised Commissioning. I was responsible for clinical oversight of the

¹ (2015) International Journal of Integrated Care, volume 15, issue 2.

commissioning of specialised services for the North of England. I also contributed to national policy development, national Individual Funding Requests panels and programmes of care work. In the North region I was part of the regional medical directorate and was involved in regional assurance and strategy work.

17. In 2018, NHS England and NHS Improvement joined, and the regional teams changed from four to seven teams. I successfully applied for the Regional Medical Director for Commissioning NHS England and Improvement North West Region which covered primary and specialised commissioning, health and justice commissioning, immunisation and screening.

18. In July 2022, I was appointed as the Regional Medical Director for NHS England North West Region, which is my current role. As the regional medical director, I am responsible for the regional medical directorate team and am a member of the Regional Executive Team. I have direct line management of six people, one of whom is the current Regional Medical Director of Commissioning.

My role as Clinical Director of Specialised Commissioning (North)

19. The information and facts set out in this witness statement concern the period of time that I was Clinical Director of Specialised Commissioning North. Specialised services are one of the areas of care that is directly commissioned by NHS England. The commissioning of these services is largely conducted through regional teams. I was aware of the Direct Commissioning Assurance Framework which sets out the outline arrangements for direct commissioning assurance **[Exhibit MG/01, INQ0009226]**. However, as the Framework was published in 2013, it reflects the Specialised Commissioning structures that were in place at that time and does not account for subsequent structural changes in governance. The commissioning of specialised services is now carried out by the regions, rather than the areas teams, who performed this role when the Framework was published.

20. During my time as Clinical Director of Specialised Commissioning North, I reported to Robert Cornall, the Regional Director of Specialised Commissioning. I had a professional line of reporting as a doctor to the Regional Medical Director, Mike Prentice. I did line manage colleagues within the Electronic Staff Record from an HR point of view, such as approving leave requests. This was to share pastoral administrative work so that Robert Cornall had a manageable amount of people to look

after. I would also work alongside nursing, commissioning and finance colleagues but had nobody directly under me whose work I managed other than for one project officer.

21. My role was to provide clinical leadership and advice and to support the delivery of NHS England's objectives in the commissioning of specialised services across the North of England region. I led a clinically focused team who ensured the commissioning of services that delivered safe, high quality care and a good patient experience consistent with commissioning policy, specifications and standards. Part of my role was to ensure that inequalities in health outcomes from specialised services were reduced by ensuring that services are commissioned to meet the needs of vulnerable and disadvantaged people.
22. In 2016, Specialised services were grouped into six national programmes of care as follows:
 - a. Cancer
 - b. Mental health
 - c. Blood and Infection
 - d. Internal Medicine
 - e. Trauma
 - f. Women and Children (which includes neonatal services).
23. These national programmes of care principally operated through a network of affiliated clinical reference groups. The Women and Children National Programme of Care covered services in women and children, congenital and inherited diseases.
24. The programmes of care had a regional Medical Director lead. There were six programmes of care but only four Specialised Commissioning Regional Medical Directors, so two programmes did not have a regional Medical Director lead. I sat on the Internal Medicine Programme of Care. There were regular national and regional updates on the work being done by the programmes of care.
25. I would have calls with service specialists who represented programmes of care in the region and they would be my link to the national Programme of Care as a source of information of what was being done. We had four Programme of Care leads in the North region, covering Internal Medicine, Women and Children, Trauma and Blood and Infection. The role of the Programme of Care lead was to act as a link between regional

and national teams and to support certain hospitals which we commissioned specialised services from in their strategic development.

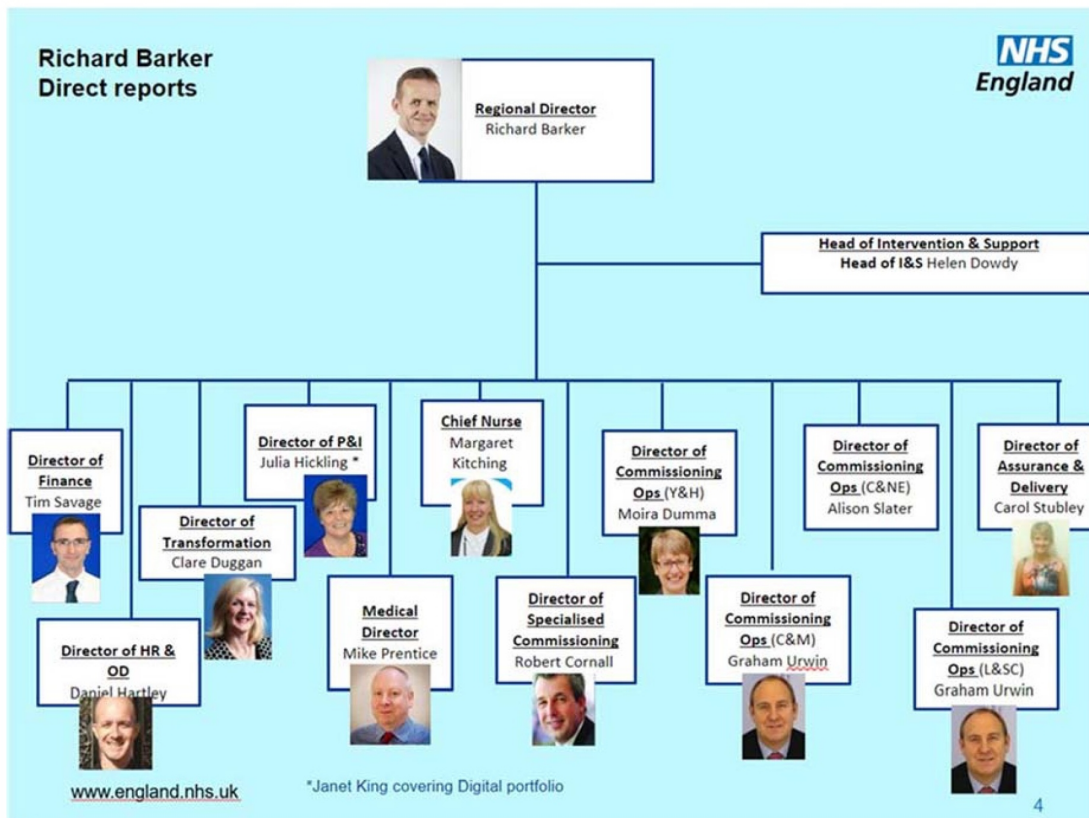
26. At an individual hospital level, I would have professional contact with the Medical Directors of hospitals where we commission services. However, I had no line management role with them and they were not directly accountable to me professionally. The nature of my interactions with the Medical Directors was largely as a liaison between a hospital and NHS England. I would assist with the implementation of new commissioning policies and service specifications and help with queries on commissioning policies. If we had concerns about the quality of services, we would raise it. I was a point of contact into NHS England about individual funding requests or commissioning policies and acted as a professional liaison.

27. In my role I was generally aware of the legal duties imposed on NHS England to secure continuous improvement in the effectiveness and safety of services and the quality of experience undergone by patients as well as the duty to make arrangements to ensure our functions are discharged, having regard to the need to promote the welfare of children. I was also aware of the NHS Mandate which provides that patients should be able to expect to be treated in a safe and clean environment and to be protected from avoidable harm. [Exhibit MG/02, INQ0012901]. However, I was not responsible for the performance of these duties and I am unable to comment on the specific statutory provisions that the Inquiry has referred to me in its Rule 9 letter.

Regional oversight by NHS England North

The North regional team

28. I have set out below three organograms taken from slides that set out the NHS England North structure. They cover: Specialised Commissioning North Regional Team, Specialised Commissioning North – North West Hub and the direct reports of Richard Barker, who was the Regional Director for NHS England North (the Regional Management Team). The organograms are correct as of August 2017, so do not cover the whole period covered in this statement.



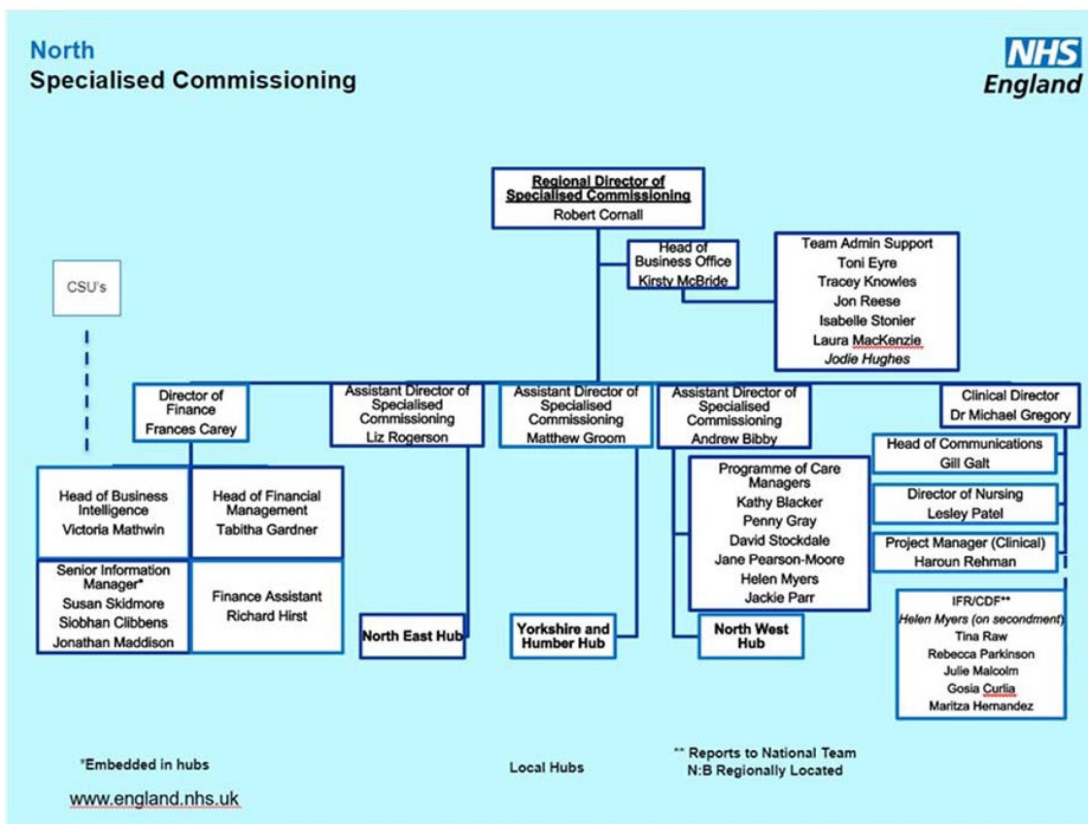
Slide 1: NHS England - North Structure [Exhibit MG/03, INQ0103058].

29. During the time period covered in this witness statement, I was not directly part of the NHS England North Regional Team (non-Specialised Commissioning). However, my understanding was that Robert Cornall would report into that team, which was led by Richard Barker as the Regional Director of NHS England North.

Specialised Commissioning North

30. The role of Specialised Commissioning within NHS England is set out in NHSE/1, at paragraphs 79 and 93 – 112. I also exhibit to this statement the North Region Specialised Commissioning Team Governance Arrangements as of March 2016 [Exhibit **MG/04** INQ0103055]. Within the North of England, Specialised Commissioning had oversight of the specialised services directly commissioned by NHS England.

31. Set out below is the organogram for the North region specialised commissioning team.



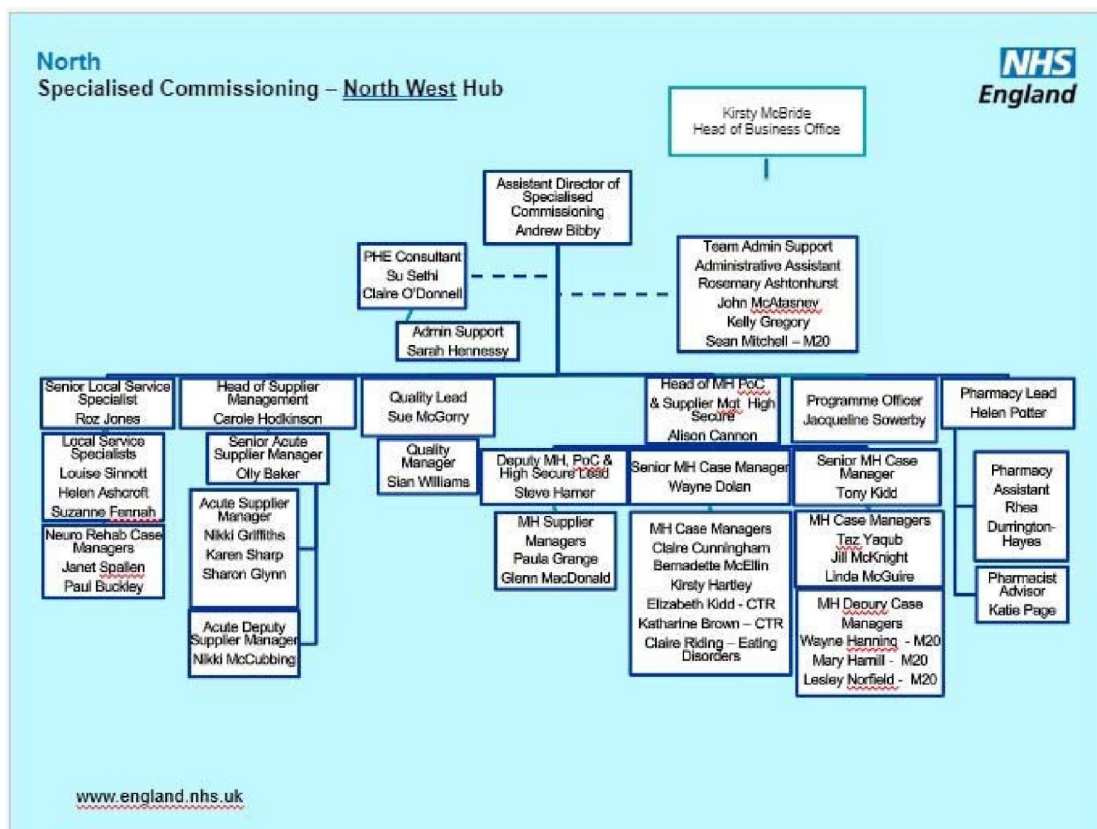
Slide 2: NHS England – Specialised Commissioning (North)

32. Within Specialised Commissioning North, there were three subregions: North West, North East and Yorkshire and Humber. Each had their own Associate Director that attended the Regional Leadership Group. The Programme of Care leads mentioned above were responsible for the whole North region.
33. Specialised Commissioning North had responsibility for the strategic development of specialised services and high level oversight of operational and financial matters. I was an attendee at the NHS England North Regional Specialised Leadership Group. This was a weekly meeting and covered operational, quality, finance and strategic issues for Specialised Commissioning in the region. This group consisted of the Regional Director for Specialised Commissioning, the clinical, finance and nursing regional directors of Specialised Commissioning, finance directors and the leads for communications human resources and the three regional hubs and a business manager.

34. I did not sit on the national Specialised Services Commissioning Committee or the Specialised Commissioning Oversight Group. My understanding was that regional quality concerns were reported up to the committee and these went into more detail on specific concerns about the commissioning of services. Specialised Commissioning quality issues would go through the Director of Specialised Nursing to national colleagues.
35. Specialised Commissioning North did not produce any guidance or policy for use by hospitals. Guidance and policies would either be produced by the national team or another national body. Specialised services would have a national set of service specifications which were the same for every region. This was to avoid a risk in duplication in issuing policies and guidance. Service specifications define the standards of care expected from organisations funded by NHS England to provide specialised care. However, when a hospital submitted its compliance with national service specifications, the region could decide if the hospital could derogate from them. A “derogation” was an agreement between the Trust and the commissioner that a Trust could continue to provide a service even if it did not exactly meet the service specification. Usually there was an improvement plan to oversee the derogation, and this was monitored closely alongside the derogation status.
36. In addition to guidance and policies from the national bodies, there was also local guidance. Operational Delivery Networks would look at service specifications in their specialities regionally and write their own protocols and procedures accordingly to support their operational management.
37. Safeguarding guidance and training would be delivered through the safeguarding team which is run through the nursing directorate. Freedom to Speak Up was a whole work stream in NHS England. If there was an unexpected death of a baby, the Trust should notify the issue on STEIS and conduct an internal review. Depending on the findings, they would involve other parties for advice and support. These were wide ranging matters, and it would not be appropriate for Specialised Commissioning to provide training and guidance on them.
38. Grievance procedures from an employee in a hospital would be a human resources matter within that hospital. NHS England or Specialised Commissioning would not get involved with individual grievances of people employed at hospitals. If an individual in the North NHS England region had a grievance with a manager, then that would be dealt with through NHS England.

39. Specialised Commissioning North would not normally be informed about investigations in respect of a sudden unexpected child death in hospital. Typically, there would be a referral to the Coroner from the hospital and likewise to CDOP. The police would be involved at the discretion of those two organisations. Specialised Commissioning North would only become involved if the coroner issued a Regulation 28 letter with NHS England which involved a Specialised Commissioned service. If the police were called regarding an unexpected death, then I would expect to be informed by the hospital's Medical Director as a matter of professional courtesy but there was no formal need to notify me. I understand that there might be other more formal reporting requirements to others in my organisation.

40. As set out at paragraph 32, the Specialised Commissioning North region was split into three subregional hubs, each led by an Assistant Director of Specialised Commissioning who would report into Robert Cornall, and would have a team reporting into them, including a quality lead. Below is the organogram for the North West hub.



Slide 3: NHS England – Specialised Commissioning (North West)

41. In the North West team, there were service specialists covering certain programmes of care. These service specialists had more direct links with hospitals and operational oversight. In the North West subregion, I recall it was Roz Jones for the Women and Children Programme of Care. Roz reported to Andrew Bibby, who was the Associate Director for the North West Specialised Commissioning subregion. I recall that the Programme of Care lead for Women and Children in the North region was Penny Gray. Sue McGorry was the quality lead in the North West Specialised Commissioning subregional team.

Regional quality assurance

42. As set out in NHSE/1 paragraphs 477 – 478, the North West Specialised Commissioning team commissioned 21 neonatal units across the region. Specialised Commissioning North's commissioning role in relation to the Hospital was the same as any other neonatal service, in that it had primary responsibility for monitoring and managing contractual performance. Specialised Commissioning North did not have a specific role in relation to the Hospital as distinct from any other neonatal service in the region. My role did not just cover neonatal services in the region, but all specially commissioned services. As a result, my involvement with individual providers and services was at a high level.

43. The assurance function of NHS England commissioned services is delegated to regional teams, who carry out quality assurance on commissioned services in their area. In the context of Specialised Commissioning, quality assurance is the checking and acting on the assessment of findings across the delivery, capability and development needs of specialised services in the region. It is intended to identify areas within the six assurance domains where performance is achieving the required standards as well as where performance is challenged. The structure of the Direct Commissioning Assurance Framework seeks to build an assurance process that demonstrates to NHS England's stakeholders that its direct commissioning function is making effective use of public funds to commission safe and sustainable high quality services. The six assurance domains are:

- a. Domain 1: A strong clinical and multi-professional focus which brings real added value, with quality at the heart of governance, decision-making and planning arrangements.
- b. Domain 2: Meaningful engagement with their communities, citizens, patients and carers.
- c. Domain 3: Clear and credible plans with delivery against improved outcomes within financial resources and are aligned to Clinical Commissioning Group commissioning plans and local Joint Health and Wellbeing Strategies.
- d. Domain 4: Robust NHS England governance arrangements are embedded locally, with the capacity and capability to deliver all their duties and responsibilities to effectively commission all the services for which they are responsible.
- e. Domain 5: Collaborative arrangements for commissioning with other direct commissioning functions, Clinical Commission Groups, local authorities and external stakeholders.
- f. Domain 6: Great leadership that contributes to making a real difference to the health, wellbeing and healthcare services of local communities.

44. The assurance domains set out in the Direct Commissioning Assurance Framework were not part of my role. That function would be held by operational teams. The Specialised Commissioning North regional team leadership group members wouldn't have been involved in writing service specifications and standards. The clinical reference groups would be responsible for drafting these, with reference to the legal duties imposed on NHS England. The service specification would then be approved by the parent Programme of Care, who had representatives from national and regional programme of care teams, a regional medical director of commissioning, quality, public health, pharmacy and patient groups.

45. Specialised Commissioning North did not have assurance responsibility for the Hospital as a whole, only quality assurance for the specialised services being delivered, this included neonatal care.

46. In carrying out quality assurance functions, hospitals would submit a quarterly compliance self-declaration. This would be done via the Specialised Services Compliance Dashboard ("SSQD") and would go to the quality teams who would collate the information. This compliance self-declaration was primarily concerned with

compliance to the contracted service provision levels of a hospital and the general delivery of care.

47. SSQDs are designed to provide assurance on the quality of care by collecting information about outcomes from healthcare providers. SSQDs are a key tool in monitoring the quality of services, enabling comparison between service providers and supporting improvements over time in the outcomes of services commissioned by NHS England.
48. For each SSQD, there is a list of agreed measures for which data is to be collected. Healthcare providers, including NHS hospitals, NHS Foundation hospitals and independent providers, submit data for each of the agreed measures. The information provided by the SSQDs is used by NHS England specialised services commissioners to understand the quality and outcomes of services and reasons for excellent performance. Healthcare providers can use the information to provide an overview of service quality compared with other providers of the same service.
49. For maternity and neonatal care there were the SSQDs, Specialised Commissioning North also had sight of the MBRRACE data. The MBRRACE report is the Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries report. It is published online but reports on data collected for a period which occurred two years before the report is published. For example, the 2023 report would provide data from 2019-2021.
50. As explained in NHSE/1 at paragraph 357, hospitals would also notify the quality teams in the region or the Director of Commissioning Operations hubs of a particular incident through the Strategic Executive Information System (StEIS).
51. Specialised Commissioning North had a set of quality dashboards that would flag concerns which would then be reported into the regional specialised quality meetings. These acted as the early signs of potential concerns. Monitoring and reporting of standards happened through the Overarching Performance Dashboard, which were externally set standards and through Specialised Commissioning Dashboards, which were service specific. By way of illustration, I have exhibited to this statement the quality dashboards from September 2016, November 2016, December 2016 and January 2017 **[Exhibit MG/05, INQ0103091] [Exhibit MG/06, INQ0103097] [Exhibit MG/07, INQ0103093] [Exhibit MG/08, INQ0103095]**.
52. Assurance was also done through the monitoring of incidents flagged through StEIS and the National Reporting and Learning System. Hard and soft intelligence would also

be shared at North Regional Quality Surveillance Group meetings. The Specialised Commissioning Quality Assurance and Improvement Framework is exhibited **[Exhibit MG/09, INQ0103056]**. Concerns about quality often came through a national colleague looking at a particular database and finding an alert that they were concerned about or through a number of quality committees that were held.

53. Specialised Commissioning North was also supported by a number of clinical reference groups, which were established on a service-specific basis. The clinical reference groups were grouped into each of the programmes of care and wrote service specifications and clinical policies. The Neonatal Clinical Reference Group was in the Women and Children's Programme of Care. These Groups acted as forums in which issues relating to service specifications were considered. Each clinical reference group would have a chair, clinical representatives, patient participation voice members and representatives from affiliated stakeholders. In my role, a chair or clinical member could contact me and say if they were worried about a particular service such as a shortage of consultants or the quality of the service.
54. The Neonatal Critical Care Clinical Reference Group covered specialist neonatal services which provide care for all babies of up to 44 weeks corrected gestational age that required ongoing medical care in a neonatal critical care facility. The arrangements for the Neonatal Critical Care CRGs are set at a 113-117 NHSE/1 and the Neonatal Critical Care Service Specification is exhibited. **[Exhibit MG/10, INQ0103057]**.
55. The North Specialised Services Quality Committee had oversight of assurance functions in relation to the Hospital and its neonatal service in 2016 to 2017. This function was primarily performed by nursing colleagues in the regional team, led by the Director of Nursing. Exhibited are the refreshed terms of reference for the Regional Quality Board from 2017 **[Exhibit MG/11, INQ0103032]**.
56. The North Specialised Services Quality Committee reported to the North Regional Quality Surveillance Group and provided monthly Clinical and Quality Reports, along with dashboards to the Specialised Commissioning Regional Leadership Group. These papers would be produced by my programme manager and the quality leads in each area, who would take information from quality leads in hubs. These papers operated as a specialised commissioning reporting mechanism on the key quality and safety issues over the last month. I have exhibited the reports NHS England has sent me for the period November 2016 – February 2017 **[Exhibit MG/12, INQ0103090]** **[Exhibit MG/13, INQ0103096]** **[Exhibit MG/14, INQ0103092]** **[Exhibit MG/15,**

INQ0103094].

57. As well as this, a more detailed quarterly paper for the Specialised Commissioning Regional Leadership Group was produced by the Director of Nursing and signed off by me. These papers allowed for a more detailed discussion and for more serious issues to be escalated either to the Regional Management Team or the national specialised commissioning team. Generally, these papers were sent to the national specialised commissioning team as their update on quality for the region. The quarterly reports for the period July 2016 – May 2019 are exhibited **[Exhibit MG/16, INQ0014640] [Exhibit MG/17, INQ0103040] [Exhibit MG/18, INQ0102997] [Exhibit MG/19, INQ0103042] [Exhibit MG/20, INQ0103044] [MG/21, INQ0103008] [Exhibit MG/22, INQ0103045] [Exhibit MG/23, INQ0103012] [Exhibit MG/24, INQ0103046] [Exhibit MG/25, INQ0103047] [Exhibit MG/26, INQ0103048] [Exhibit MG/27, INQ0103020].**

58. In addition, quality information could be gained through concerns raised through a clinical reference group within a Programme of Care or through the regulators.

The North Regional Quality Surveillance Group

59. The North Regional Quality Surveillance Group had overall responsibility for quality surveillance in the North region. It provided support and assurance to local quality surveillance groups, ensuring that the network was operating as effectively as possible. The group offered an escalation mechanism for local quality surveillance groups, as they could assimilate risks and concerns from the local groups across the region and identify common or recurring issues requiring a regional or national response. The terms of reference are exhibited. **[Exhibit MG/28, INQ0106981]**

60. The North Regional Quality Surveillance Group would meet quarterly. There were no standing members from Specialised Commissioning North, but Robert Cornall would attend if there was something of relevance to Specialised Commissioning and I would attend in his place on occasion. I attended North Regional Quality Surveillance Group meetings on 16th September 2016, 3rd March 2017, 16th December 2019, 23rd March 2020 and 20th April 2020. Membership was comprised of representatives from NHS England including the Regional Director for the North, the Nursing Director and Medical

Director and local quality surveillance group chairs. Representatives from the Care Quality Commission, NHS Improvement, Public Health England, the General Medical Council and the Nursing and Midwifery Council also attended the meetings. Exhibited are the minutes of the meetings that I attended between June 2016 and May 2017. **[Exhibit MG/29, INQ0014687]. [Exhibit MG/30, INQ0107004].**

61. As I was not a standing member of the group, I was not aware how the group reached and made decisions. My impression was that there was not a voting structure. Rather, the decisions would be made by consensus whereby a member would propose something and the group would then decide what to do. I exhibit Quality Surveillance Group national guidance **[Exhibit MG/31, INQ0103059].**
62. The North Regional Quality Surveillance Group would receive information about individual hospitals from updates presented by quality leads representing the regional hubs. Hospitals would also make the SSQD self-declarations of compliance which would be signed off by the Medical Director. This information would be fed into the regions and there would be a business lead in the Specialised Commissioning North team who would compile a spreadsheet and present it to the North Regional Quality Surveillance Group.
63. Nationally the spreadsheet gave an oversight of the regions, how many submissions were done and the number of declarations that were compliant. These would be displayed as a high level overview about themes that were being picked up across services and hubs. This would be presented to the group via both written and verbal reports. I would receive a line of compliance for each of the four quarters on whether hospitals submitted their data.
64. Issues were escalated to the North Regional Quality Surveillance Group via the individual representatives to the meetings. These could be brought via meeting papers and a summary of the concerns. Where concerns arose within a Trust, depending on the severity, we would expect that to be dealt with internally in the first instance, rather than be escalated to the North Regional Quality Surveillance Group. Individual staff members also had the option to pursue the Freedom to Speak Up route.
65. Individual hospitals received surveillance levels from the North Regional Quality Surveillance Group. This was done through the compliance dashboard, dependent on the outcomes from the documents that the group received. Non-compliance on the

specialist service quality dashboard would lead to a particular hospital or service being flagged. Reports were also received through StEIS and the Operational Delivery Networks. There was therefore an accumulation of intelligence that would lead to a decision on whether to escalate to a higher surveillance level.

66. There were four levels of surveillance increasing in severity. They were “routine”, “further information”, “enhanced” and “Risk Summit”. The table below displays the four levels:

Level	What does this mean? What is the assessment of risks to quality?	What actions may be taken by the QSG in response to this assessment?
Routine	No specific concerns identified	Schedule for routine discussion as part of QSG business cycle
Further information required	Potential for concern. More information required to determine the level of risk	Agree who will follow up to gain necessary information to assess risk
Enhanced	Quality concerns identified	Agree actions, and schedule for discussion at each QSG meeting until concerns are resolved
Risk Summit	Serious, specific risk to quality identified, including where there is a need to act rapidly to protect patients or staff	Trigger Risk Summit process

67. When a hospital was put on enhanced surveillance, that meant it started to be flagged as a potential area of concern. It would not mean that Specialised Commissioning teams were going into the hospital and directly monitoring its services, rather that additional questions were being asked and commissioners were scrutinising data more closely than for hospitals on routine surveillance. A Hospital being on enhanced surveillance was not an exceptional event and there would be a number of hospitals on enhanced surveillance at any one time.

68. If a surveillance level was at Risk Summit, then that indicated a serious, specific risk to quality and the Risk Summit process would be triggered which would act rapidly to protect patients and staff. A Risk Summit was to be considered where serious quality failings were identified by any organisation or part of the system and the organisation

or part of the system believed that there was a need to act rapidly. It was for NHS leaders to exercise professional judgement when considering whether or not to call a Risk Summit and they were only to do so as a last resort, where there are no other mechanisms that were more appropriate for dealing with the issue.

69. I do not recall the surveillance level for the Hospital from 2015 onwards. At the North Regional Quality Surveillance Group in September 2016 that I attended in place of Robert Cornall, I was informed that the unit had been returned to routine surveillance. It was a nursing led decision whether to escalate the surveillance level of a particular hospital. The North Regional Quality Surveillance Group would become aware of a service when it was escalated to Risk Summit as then it would become a single item at the meeting of the group. I would not personally have known the surveillance levels for all of the specialised commissioned services in the region as I was not part of the nursing team conducting the enhanced surveillance on the service. I would only be alerted by the quality teams if there were plans for a Risk Summit or if there was a particular concern that might require my input. I was therefore not aware that the Hospital had an enhanced surveillance level in the period before September 2016.

Identifying issues and responding to concerns

Operational Delivery Networks

70. Operational Delivery Networks are focussed on coordinating patient pathways between providers over a wide area to ensure access to specialist resources and expertise. The scope of Operational Delivery Networks was driven by commissioners, through a requirement in the contract specification. It will then be for the host provider and other network members to determine how best to meet the outcomes and outputs set out in the commissioning specification. Some of the information that Specialised Commissioning North received about individual hospitals came through the Operational Delivery Networks who would discuss data about the hospitals in the network. There was a triangulation of information from different sources to bring issues to our attention. Specialised Commissioning would have mortality statistics that came through independent data like MBRRACE. However mortality records through MBRRACE data were published two years after the period being reported. There were a lot of quality dashboards curated by different organisations. We would not see individual post mortem reports or referrals to the coroner.

Freedom to Speak Up

71. NHS England Freedom to Speak Up is a process whereby NHS staff members can raise concerns regarding the effective running of an NHS organisation. All NHS organisations and providers of NHS healthcare services are required to adopt the Freedom to Speak Up Policy and appoint Freedom to Speak Up Guardians. Freedom to Speak Up is its own workstream within NHS England and is therefore not something Specialised Commissioning is involved with. The National Guardian's Office would be the point of escalation for a hospital's Freedom to Speak Up Guardian.
72. Complaints and specific questions about a unit would normally be dealt with at hospital level. Complaints data would be looked at local level, not in Specialised Commissioning, unless it was a specific complaint about a Specialised Commissioning Service to NHS England. Given the number of individual complaints and responses that might exist at any one time with regard to specialised services, it would not be practical for Specialised Commissioning to directly receive this data.
73. Specialised Commissioning would not receive minutes of Board of Directors meetings or internal committees from hospitals. Hospitals publish minutes of their public meetings on their websites. These minutes would cover a large number of topics, most of which were not relevant to NHS England. In addition, given the number of Trusts in the region, Specialised Commissioning North could not read these as a matter of routine and would only request or access them if there was a specific reason to do so.

How the regional Specialised Commissioning team would respond

74. If Specialised Commissioning North had concerns about a hospital I would, or the Director of Nursing Lesley Patel would, contact the Medical or Nursing Director to understand what was happening. If we were not satisfied with what we heard, we would then escalate it to the Regional Quality Surveillance Group and the Specialised Commissioning Regional Leadership Group. In 2016 we did not have direct regulatory powers to intervene as that would have been the role for NHS Improvement.
75. Staff members who had concerns would normally raise issues within their own hospital, rather than escalate them to Specialised Commissioning. During my time with Specialised Commissioning North I was never contacted by a staff member or director

at a hospital raising concerns about the hospital they worked at or their colleagues. I was never contacted by someone raising concerns about a particular nurse.

76. There was no mechanism for individual staff members to escalate concerns directly to Specialised Commissioning North. It was not my place or responsibility to get involved with issues at hospital level. Freedom to Speak Up was available to escalate concerns. If there was a concern about a particular individual, then that could be taken through the professional standards route.

77. If in my role in 2016 someone did contact me about a colleague and their fitness to practice, having previously tried all of the usual routes, I would have informed the regional Medical Director with oversight of the relevant professional standards. But in my role as Clinical Director of Specialised Commissioning I would not get into the details of specific concerns about staff members.

78. In my experience there can be a culture of people being worried about speaking up and raising concerns due to the consequences and how they will be treated by their senior managers. Many staff are reluctant to bring attention to their unit, leading to a general reluctance to speak up. The role of the hospital Board and senior leadership should be to encourage people to speak up where there are concerns about patient safety.

79. NHS England can help to mitigate safety concerns through various operating models and quality documents. There are a multitude of publications mandating an open, honest and safe culture in which to report issues, however in practice a lot is reliant on the individual hospital and their reporting mechanisms.

Concerns about the Countess of Chester Hospital

80. It is my understanding that concerns about the Hospital were first brought to the attention of NHS England North around the same time that I commenced my role in July 2016. I was not aware of the increased mortality rate at the Neonatal Unit at this time and, as described below, I was not directly involved in conversations with the Hospital about the increased mortality rate in the neonatal unit until February 2017.

81. During my first month in the role there were wide range of inductions and the concerns about the neonatal unit at the Hospital were not raised with me. My predecessor left in

April 2016 and in my handover note exhibited there is no mention of the Hospital. **[Exhibit MG/32, INQ0103053]**.

82. The Inquiry has asked me to comment on an email Lesley Patel sent on 5th July 2016 to a number of colleagues within the Specialised Commissioning North team about “serious issues” with neonatal services at the Hospital, following a conversation with Alison Kelly, the Director of Nursing at the Hospital. **[Exhibit MG/33, INQ0012667]**. As I did not commence my role as Clinical Director of Specialised Commissioning North until 12th July 2016 I was not copied into this email or any emails before this date.
83. I now understand that Alison Kelly and Ian Harvey, the Medical Director at the Hospital, met with the West Cheshire Clinical Commissioning Group and Specialised Commissioning North on 7th July 2016. Again, as this was before my role at Specialised Commissioning North started, I was not involved in this meeting and am unable to comment on who attended and what was discussed. For the same reason, I am unable to comment on the spreadsheet that the Hospital provided Specialised Commissioning North with a “Tabular Chronology of Events”.
84. I am now aware that LL was moved from the Neonatal Unit to the risk team in July 2016 because of concerns raised about her. I was not made aware of this by the Hospital. If the Hospital had informed us at the time, then that would have prompted a series of questions from Specialised Commissioning and might have led to a recalibration of the risk profile for the Hospital. Clinicians raising concerns about an individual in relation to increased mortality is something that I would expect Specialised Commissioning to have been informed of by the Medical or Nursing Director at a hospital. I would regard making both Specialised Commissioning and the regulators aware a matter of good practice.
85. On 12th August 2016 Andrew Bibby had a call with someone at the Hospital. **[Exhibit MG/34, INQ0014679]**. I was not aware of the call at the time and was not informed of what was discussed. I was still new in the role and Specialised Commissioning North had, at any one time, a number of units under surveillance, so I would not be copied into all correspondence as a matter of course.
86. I was not a standing member of the North Regional Quality Surveillance Group, however Robert Cornall or myself would attend meetings that related to Specialised Commissioning. One such meeting I attended was the North Regional Quality

Surveillance Group on 16th September 2016. This was the first of the North Regional Quality Surveillance Group meetings that I attended and I was still new in the role. I did present the Specialised Commissioning update, but this did not include the Hospital as it was not a specific area of concern at that time for Specialised Commissioning and it was covered in the Cheshire and Merseyside report. I made notes on anything relevant to Specialised Commissioning to report back to Robert. During the meeting the group discussed the plans to downgrade the neonatal intensive care cots to Level 1 while a comprehensive investigation was carried out. The Cheshire and Merseyside DCO feedback was that a Royal College of Paediatricians and Child Health ("RCPCH") Review was carried out which "went well" and therefore it was agreed that the level of surveillance should be downgraded to "routine". The draft minutes and action points from the meeting are exhibited **[Exhibit MG/29, INQ0014687]**.

87. I understood the reference to the phrase that the RCPCH review "went well" to mean that the reviewers received reassuring messages from the Hospital and they did not have substantial concerns about the quality of care being provided. The level of surveillance for the Hospital going back down to routine added another level of reassurance.
88. The North Regional Quality Surveillance Group did not receive a copy of the RCPCH report at the meeting or subsequently and our knowledge of its contents would have been limited to what was provided in the minutes. We were not made aware in the meeting that the RCPCH had made recommendations for a further forensic review of cases.
89. On 16th November 2016 Commissioners agreed that the Neonatal Unit should be placed on enhanced surveillance. I was not party to this decision as decisions around surveillance levels were made by the nursing directorate.
90. On 16th December 2016, Andrew Bibby wrote to the Hospital requesting a copy of the RCPCH Report. On 21st December 2016 Alison Kelly replied stating that the draft report had been received and was being checked for factual accuracy **[Exhibit MG/35, INQ0008077]**.
91. In the email, Alison Kelly stated that one of the recommendations of the report was that a further independent case review was required of relevant cases. The review required a secondary pathology review on a small number of cases before the report

could be completed. As a consequence, the Trust did not have a final report of this part of the review and were therefore not comfortable in sharing the RCPCH report until they had received details of the case review.

92. I was not aware at the time of the email from Alison Kelly to Andrew Bibby declining to share the report, or that a second review was recommended. However, in December 2016 I was aware of attempts by the Commissioners to request timescales for the conclusion of the review and the publication of the report. My knowledge of what was going on at this stage was limited as I was not particularly involved in discussions. It was not until February 2017 that myself and Andrew Bibby were liaising in relation to issues at the Hospital. We raised at regional leadership team meetings the fact that we had not received a copy of the report and we required that to inform the action plan we were formulating with the Hospital. During this period we did not contact the RCPCH reviewers directly to discuss their findings. The report had been directly commissioned from the RCPCH by the Hospital and there was no formal mechanism by which we could compel them to disclose it to Specialised Commissioning.

93. I was not involved with the compilation of the RCPCH report. My understanding is that hospital requests a review from the respective College. After the review team have been to the Hospital the Royal College reviewers will provide a brief verbal feedback before it is formally reviewed by the Hospital ahead of the final report being submitted. My recollection is that the accuracy check occurred around November 2016 and then the Hospital and RCPCH began the process of agreeing the final report.

94. On 21st December 2016 Specialised Commissioners requested support from NHS Improvement regarding the inadequate response from the Hospital. Nursing colleagues were growing increasingly concerned about the responses from the Hospital and believed that we should be involving NHS Improvement. The decision was taken in part due to the lack of information coming from the Hospital and wanting to gain a better picture of what was happening. As a regulator, NHS Improvement had a governance role and powers to investigate issues at the Hospital around quality.

95. I was not personally involved in the decision to request support from NHS Improvement or copied into communications with them. Vince Connolly was the NHS Improvement Medical Director. We would escalate issues to him by raising them within our own NHS governance structure and then Margaret Kitching, as Regional Chief Nurse, would liaise with him.

96. On 11th January 2017 Specialised Commissioning North received an email from Vince Connolly stating that he had a discussion with Ian Harvey who said that the issues were complex and that they would provide a copy of the RCPCH report when available. At that stage I was not aware of what the complex issues referred to. However, I inferred that something must have been going on internally at the Hospital which meant that the RCPCH report could not be published.
97. On 10th January 2017 an Extraordinary Meeting of the Board of Directors at the Hospital was held that supported the nurse going back on the unit [**Exhibit MG/36, INQ0003237**]. I did not know about this meeting at the time any my understanding is that the board papers were not made public or shared with NHS England.
98. I do not believe that the board papers for the meeting were public. At that stage I was not aware that an individual was involved or that a nurse had ever been taken off the unit. Had Specialised Commissioning North been told that an individual had been moved off the Neonatal Unit due to concerns from clinicians, we would also have expected to have been informed of the decision to reinstate her onto the unit. However, we were never informed that there were concerns with regard to an individual nurse. In my role, I had experiences with other Medical Directors and hospitals who have rung me up to inform me about concerns with particular individuals. Informing us of these concerns and decisions is part of having an open and transparent culture of patient safety, which I came to believe was lacking at the Hospital.
99. On 23rd February 2017 I met with Ian Harvey, Andrew Bibby and Lesley Patel. The meeting arose as Lesley Patel was raising concerns about the Hospital's response to the review and their failure to share the recommendations of the external report. It was at this point my concerns around the failure of the Hospital to volunteer information and its reluctance to share the RCPCH report first arose. At the meeting Ian Harvey discussed progress to date following the external review, recommendations and the neonatal units continued status as a special care baby level 1 unit. Ian Harvey confirmed that the Hospital had completed the external review of babies who had died from January 2015 to July 2016. It was at this meeting Ian Harvey first referred to the external review being more in depth than the previous high level thematic review that was undertaken by the Hospital. [**Exhibit MG/37, INQ0006081**].
100. The notes prepared for the meeting do not refer to the completion of Dr Jane Hawdon's review. At that time the assumption was that the external review referred to

the one carried out by the RCPCH. Following the Hospital's own internal review, which was high level and thematic, we were informed by the Hospital that a more in depth review was being carried out. My understanding was that this was the review into the individual cases, which would inform the action plan that we were drawing up with the Hospital. The language we were receiving from the Hospital throughout this period was ambiguous and I was confused as to the number of reviews being conducted and what the recommendations were.

101. At the meeting Ian Harvey confirmed that there was learning for the Hospital that had been identified in the review and that an action plan was being developed that would be completed by the end of March and shared with Specialised Commissioning. During the meeting, Ian Harvey did not discuss the recommendations of the review but did agree that the Hospital would share the completed review with the affected families and then Specialised Commissioning would receive a copy.

102. On 25th February 2017 a Quality Risk Profile was undertaken for the Hospital. The decision to conduct one was a nursing decision and although I understood its function and the circumstances it was done in, the decision to do so was not one that I was involved with. At this stage the Cheshire and Merseyside Hub was in much closer liaison with the Hospital. The preparation of Quality Risk Profiles was not something that I was personally close to. On 4th April 2017 myself, Lesley Patel and Andrew Bibby were sent the final Quality Risk Profile for the Hospital. The Clinical Commissioning Groups, Specialised Commissioning and the CQC had all contributed to the final Quality Risk Profile. **[Exhibit: MG/38, INQ0014648]**.

103. In a call with Ian Harvey on 29th March 2017 I raised the possibility that an individual member of staff might be involved with the increased mortality on the Neonatal Unit. I had no information or evidence that this was the case, but I felt it was a question that needed to be asked. At this stage I was considering all possibilities. I recall also discussing the question of an individual having a disproportionate involvement in a meeting with Ian Harvey and Lesley Patel on 23rd February, however I did not document it. When I asked in the 29th March meeting, Ian Harvey stated that they had looked into an individual being involved as a possibility but, due to a combination of skill mixture and rotas, it had been discounted. He explained that, given the severity of the cases, the rotas meant that certain, more experienced members of staff would naturally have greater contact with these babies. In addition, some babies had fallen ill after being transferred off the unit and this would seem to discount an

individual on the unit having involvement. The Inquiry have provided me with a copy of Ian Harvey's handwritten notes of the meeting which accord with my recollection of the discussion. **[MG/39, INQ0003246]**.

104. When I pushed Ian Harvey on the involvement of an individual staff member, he stated that he did not want to go into any more detail until the Hospital had made a significant announcement about the decision they had taken to speak to an "appropriate body" on the following Monday. He did not indicate what that announcement was, nor what "appropriate body" he was referring to. I do not believe that an announcement was ever made on the Monday. Ian Harvey told me that he was handling a very difficult situation and was asking for more time so that he could handle matters within the Hospital. When I pressed Ian Harvey as to what this difficult situation was, he indicated that the Hospital were having some issues with the paediatricians.

105. It was at this meeting that I first learnt about a clinician that raised concerns about the babies that had died or needed resuscitation in the Hospital or other units. My understanding was that the clinicians were picking up signs and symptoms that they didn't understand. Ian Harvey mentioned that the clinicians were confused about the signs that they were seeing and that they had observed mottling of skin, which they had not seen before. However, Ian Harvey also seemed to suggest that one clinician had some other sort of agenda. I got the impression that there was a complex situation going on and Ian Harvey was trying to piece together a consistent thread in the unexpected mortalities and illnesses. At no point during my involvement was I informed by the Hospital that two clinicians were concerned about an individual nurse, and I was not aware that this individual was LL until her arrest in 2018.

106. At this time it felt like we were going to the Hospital repeatedly and having to ask questions, rather than them volunteering the information and giving us updates. This lack of co-operation from the Hospital meant that I did not feel as though Specialised Commissioning North was able to fulfil its assurance role. Every time that we went to the Hospital we were met with obscure terminology and a lack of explanations. As Ian Harvey was the Medical Director of a Hospital, I did not feel that I had the clear lines of escalation which I would if I was regional Medical Director. I escalated my concerns within NHS England who could escalate to NHS Improvement, who had the power to take regulatory action.

107. I outlined my concerns in an email to Andrew Bibby, Lesley Patel and Robert Cornall on 29th March 2017. **[Exhibit MG/40, INQ0014651]**. I informed them that Ian Harvey had said that the Hospital intended to make a significant announcement on the Monday, and we had to wait until this was made. As stated, I do not believe an announcement was ever made. I highlighted to colleagues that the clinicians were concerned with a list of cases, but that Ian Harvey seemed to think that one of them had an agenda. I also relayed Ian Harvey's explanation of a member of staff having a disproportionate presence as being down to rotas and skill levels.

108. On 30th March 2017 I had a call with Ian Harvey and Tony Chambers regarding the Hospital's management of the media. I am now aware of a Sunday Times article relating to one of the cases on the Neonatal Unit around this time, however I do not recall that article being discussed at the time. However, I do remember them saying that they had no immediate safety concerns at the Hospital and that they did not want to go public as there would be a media backlash and this would cause concerns with the families. The Inquiry have also provided me with a copy of Ian Harvey's handwritten notes of this meeting. They accord with my memory of the meeting insofar as discussions about the media and there being no immediate safety concerns at the Hospital are concerned. However I do not remember being told that the clinicians were unconvinced that the reviews had excluded "unnatural causes". My understanding was that the clinicians were concerned about the external review and they were picking up unusual signs and symptoms in the affected babies. I do not recall any discussion of involving the police in this meeting. **[Exhibit MG/41, INQ0003245]**.

109. By this stage we had several phone calls and I felt that things were escalating and becoming increasingly serious. Neither the RCPCH review nor the case reviews had been disclosed to me. Nursing colleagues had done a Quality Risk Profile and I was becoming increasingly concerned by the lack of answers from the Hospital. We had asked for the action plan which would have been due by the end of March 2017 and I chased this in early April.

110. Specialised Commissioning North were getting pushback from the Hospital with regard to the publication of the case review. I was personally confused as to which review was being referred to as they were mentioned without specific nomenclature in emails. There were references to "internal processes", a "broad forensic review" and the need to go to the Board and discussions that had to be had within the Hospital. I was growing increasingly concerned as to why the Hospital was not being open and

the emails that we were receiving from the Hospital were not reassuring us. I was escalating our concerns by raising them within NHS England to Robert Cornall, who was my line manager, and to Margaret Kitching as she was the clinical nursing lead for the region. **[Exhibit MG/42, INQ0103060]**.

111. Around this time we were talking within Specialised Commissioning North about involving the police. We were informed by the Hospital that they had got an external QC in as they wanted a legal view of the situation. In an email to Ian Harvey on 5th April 2017 I requested a copy of the brief that was given to the QC for the work that they had been asked to do for the Hospital, but I did not receive this. We couldn't understand this decision to involve a QC as they do not have the investigative powers of the police. It increasingly felt like the Hospital were making concerted effort to avoid going to the police. We felt as though it was appropriate to involve them as we were unsure what we were dealing with. The language coming from the Hospital was adding to the confusion.

112. On 4th April 2017 I spoke to Kieran Murphy who was the Chief Medical Officer for Cheshire and Merseyside DCO and made him aware and updated him on my discussions with the Trust. I followed up the call with an email on the same day informing Kieran Murphy that my understanding from Robert Cornall was that Margaret Kitching had spoken to Tony Chambers regarding the concerns and that she was reassured. **[Exhibit MG/43, INQ0103065]**.

113. On 4th April 2017 I attended a meeting of the NHS England North Regional Specialised Leadership Group. In this meeting we discussed the calls we had been having with the Hospital and in the region with the Cheshire and Merseyside DCO. I fed back on conversations I had with Ian Harvey and Robert Cornall. The agenda for the meeting is exhibited **[Exhibit MG/44, INQ0014655]**.

114. In the meeting we discussed persisting concerns in relation to the Neonatal Service following the RCPCH review into the increased mortality. Members of the Regional Leadership Group were continuing to work with the Hospital and the North Regional Team to understand the issues more fully. The following day the business manager, Kirsty McBride, circulated an email summarising the "key messages" from the meeting. These were updates on the region and a high level overview of what the Regional Specialised Leadership Group had on their radar. **[Exhibit MG/45, INQ0014654]**.

115. Following concerns raised in the meeting I emailed Ian Harvey on 5th April 2017, copying in Margaret Kitching, and requested an update in writing on the meeting that we had on 23rd February 2017. I attached the notes of the meeting and communicated a number of further requests. I reminded Ian Harvey that an action from the meeting was for him to forward a copy of the external review report by the end of March. I also requested a copy of the brief given to the QC, a record of the concerns expressed by the two clinicians and a proposed timeline of events. **[Exhibit MG/46, INQ0003126]**.
116. On 6th April Margaret Kitching replied to my email saying that she had a very helpful conversation with Tony Chambers at the Hospital, who had provided an overview of the Hospital's position and potential future actions. Margaret informed me that Tony would brief us when their process regarding the clinicians had concluded and that we may need to go further depending on the results. Margaret also said that she was copying in Vince Connolly as he was fully briefed on this. **[Exhibit MG/47, INQ0103067]**.
117. On 6th April Alison Kelly sent the draft action plan in respect of the RCPCH to Lesley Patel, Andrew Bibby and Sue McGorry. Lesley Patel forwarded this to me the same day noting that the action plan was only for the recommendations of the first report and not the independent review that followed. **[Exhibit MG/48, INQ0103066]**.
118. On 10th April 2017, Ian Harvey replied to my email of 5th April requesting a copy of the external report. **[Exhibit MG/49, INQ0103061]**. He attached a copy of the RCPCH report to this email. In the email he did not mention that a section was missing, it was only by reading the report that I realised that it was incomplete. At paragraph 3.7 the report made reference to an Appendix 4 which was not attached. My understanding was that was the section that looked into the individual cases. My expectation was that the RCPCH report would provide a high-level list with the initials of the affected babies in the Annex with a summary of what happened. I was then expecting another report that would go into each case in more detail. I now know that there was another report, but this was never shared with me. The same day I contacted Margaret Kitching to alert her to the fact that Appendix Four was missing. **[Exhibit MG/50, INQ0103062]**.
119. I raised my concerns about the missing Appendix with Sue McGorry and Lesley Patel. **[Exhibit MG/51, INQ0103063]**. Lesley Patel replied the same day, stating

that what we received was the original report that recommended the review of the 13 cases. Lesley's understanding was that the further review of each case was the report which the clinicians had concerns with, which was why the Hospital was not sharing it.

120. I am now aware that Dr Jane Hawdon was contacted by the Hospital on 8th September 2016 who requested that she conduct a case review of the mortalities at the Hospital pursuant to the recommendations of the RCPCH review. The review was completed and received by the Hospital on 31st October 2016. **[Exhibit MG/52, INQ0009428]**. During the meeting with Ian Harvey on 23rd February 2017 he made reference to an external report of the three babies from January 2015 to July 2016. I do not recall that he mentioned the review by name, and I have no documentation of the name of the reviewer. During that meeting he mentioned that the Hospital had just completed an external review and that was more in depth than the high level thematic review that had been undertaken by the Hospital. At the time I assumed in saying "by the Hospital" he was referring to the one they commissioned from the RCPCH, but that was not stated explicitly. However, I now believe that the review he was referring to was the one performed by Dr Jane Hawdon, which I was unaware of at the time. The language from the Hospital was unclear and vague.

121. On 19th April 2017 I wrote to Ian Harvey regarding the clinicians' concerns. In his email attaching the RCPCH report on 10th April, Ian Harvey said that the QC was meeting with the paediatricians on 12th April 2017 and that there would be an extraordinary meeting of the Hospital's Board called the following day to consider the outcome and decide on next steps. I had not heard the outcome the meeting so I was chasing him to provide an update. He replied stating that, having completed the RCPCH review and the further case review, the Hospital has consulted further with the external, independent case reviewer. He informed me that since they had four cases, in the reviewer's opinion, where the death was unexplained, the Hospital were following the process that would be the case in the event of an unexpected death out of hospital and are consulting with CDOP. Ian Harvey was having a phone call with the chair of CDOP the following day and said they he would feed back further following this.

122. In a following email I pressed Ian Harvey on whether the clinicians still held concerns and to explain the "out of hospital procedure" as I was not clear what it meant. Ian Harvey did not directly answer the questions and stated that they were going through the process as there wasn't yet a complete and definitive answer in all cases.

He confirmed that the out of hospital procedure was the process that CDOP run and that CDOP needed to review its processes to see whether they could have detected the cluster earlier. On the independent review, he stated that he did not believe that there was ever an agreement that the individual case report would be shared as it contained identifiable data. A copy of this email chain is exhibited. [Exhibit **MG/53** INQ0014667].

123. My query on whether the clinicians still held their concerns was a simple one and I did not receive clear or helpful responses. I shared the email from Ian Harvey with Robert Cornall, Lesley Patel and Margaret Kitching, noting that there was still no response from the Hospital as to whether the clinicians have had their concerns addressed. We were trying to build a picture of what had happened at the Hospital, and the details of the clinicians' concerns and the independent case review were important parts of this. I felt that the Hospital were not being as candid as they could be in response to our concerns.

124. On 25th April 2017 I was contacted by Ian Harvey who asked me to confirm that I would be happy to meet once the Hospital had completed their process. The following day I emailed Robert Cornall, Lesley Patel and Andrew Bibby proposing a list of questions and requests for Ian Harvey and noting that at the regional management team meeting Margaret Kitching stated that she was prepared to give the Hospital more time to respond before going to the police. My understanding was that I had escalated it to her as the Regional Chief Nurse and that she was having separate discussions with the Hospital and taking the issue forward. [Exhibit **MG/54** INQ0014673].

125. My proposed questions for Ian Harvey included an update on the outcome of the CDOP meeting, whether the concerns of the clinicians had been addressed, what the discussion was with the legal advisors and the clinicians – in particular what was meant by the clinician's saying that the Hospital hadn't completed a "broad forensic review" and the issue with the four unexplained deaths. It also proposed that we request access to the redacted external review.

126. I felt I had challenged Ian Harvey on the responses as much as I could within the authority of my role. I thought it was appropriate to escalate it within NHS England. Whilst I was a Medical Director for Specialised Commissioning, I had no authority over Ian Harvey and was limited in my powers to get an answer. I felt that I had escalated

as much as I could by flagging my concerns to Robert Cornall and Margaret Kitching and copying them into emails.

127. Lesley Patel replied saying that Teresa French, the National Specialised Commissioning Nursing Director, and James Palmer, the National Medical Director for Specialised Commissioning, were discussing this with Robert Cornall the same day so I should await this conversation. Lesley informed me that the CDOP process could take weeks so she was unsure if awaiting "their process" will be timely enough given the level of concern.

128. Following his meeting with Teresa and James, Robert informed me that all three of them believed that we should be referring the matter to the police now and that they were happy to make that call if it helped with Hospital relations. Margaret Kitching said that she would have a call with the Chief Executive of the Hospital to clarify our position and, if our concerns were not addressed, give them the opportunity to seek advice from the police first.

129. Following the Hospital contacting the police, I was included in an email from Margaret Kitching to NHS England colleagues on 9th May 2017 in which she informed us that herself and Vince Connolly, had agreed to be a point of contact with the Hospital and brief to all concerned and involved parties to reduce repetitive communications. Margaret stated that her and Vince Connolly were liaising on a "need to know basis". [Exhibit MG/55, INQ0012682] My understanding of that was these issues were very confidential and that we were to not speak about them unless we needed to. I saw it as senior colleagues taking ownership of it and only disclosing information to me if it was pertinent to my role.

130. I do not recall a specific point at which I found out about the police investigation. I believe I was told and then became aware that Margaret Kitching was acting as the police liaison in her email of 9th May 2017. In that email Margaret stated that the Hospital had met with the police and it had been agreed that there would be an investigation, but that it was being described as an invited police investigation into unexplained deaths, not a criminal process. At this stage I was not aware of a named individual and LL's name had not been mentioned in any of our discussions.

131. During my involvement with the Hospital I was not aware of any communications with the affected parents. It would not have been my role to inquire as to the Hospital's liaison with the parents as that was a matter for the Hospital.

132. During this period it was my responsibility to get a full understanding of what had happened and to have assurance through the action plan that the Hospital was addressing the situation. I was asking questions and seeking clarification on the reviews and the actions the Hospital had taken. I did not consider that the responses I was getting from the Hospital helped with that clarification. If anything they served to create more confusion. I asked direct questions about concerns that were being raised by clinicians and they were not answered. I should not have needed to keep pressing the Hospital for answers. In the interests of patient safety I should have expected that Ian Harvey, as Medical Director, be open and transparent with me and disclose the information that, as Commissioner for the service, we needed to know. The answers that we received never made reference to an individual or the specific concerns that the paediatricians had about LL. The Hospital alluded to clinical issues and the internal processes that they were following but were not clear on what these were. During my dealings with the Hospital I was relatively new in my role as Regional Medical Director of Specialised Commissioning North, however I have not since experienced the same level of lack of cooperation from a hospital since the events I have set out in this statement.

LL's grievance

133. I was not aware of the grievance submitted by LL in September 2016. Grievances at individual hospitals would not normally be escalated to Specialised Commissioning as they were not part of our role. However, with any grievance concerning an individual with whom concerns are being raised by clinicians, we would expect to be told as a matter of good practice. Had Specialised Commissioning been informed of the grievance, and the context of the individual involved, then that would have prompted a discussion internally about whether we needed to take further action. As with the failure to tell Specialised Commissioning that LL had been removed from and then reinstated back on to the Neonatal Unit, the hospital should have been more candid about an individual who was potentially under suspicion from colleagues.

Culture and atmosphere

134. I first became aware that the Hospital was having issues with the Consultant Paediatricians in my call with Ian Harvey on 29th March 2017 where he suggested that a clinician had some sort of agenda. However, I was not aware of a deterioration in the relationship between Hospital executives, senior management and the Consultant Paediatricians. As a result, I have no insight into whether the quality of professional relationships between the Consultant Paediatricians and the executive team affected how the concerns raised by the Consultants were reported to NHS England North.

135. I did not approach the Consultant Paediatricians directly to discuss their concerns. It would not be the role for a commissioner to go to clinicians on the frontline about a service. Bypassing the Medical Director and the Hospital Board would have been highly inappropriate and speaking directly to consultants would have been an unusual step, outside of our normal remit. Given the evasive responses we were getting from the Hospital, if Specialised Commissioning knew at the time that the Consultant Paediatricians were pointing the finger at an individual, then within the NHS England regional team we would have had a discussion internally about how to approach them directly. However, we were never informed by the Hospital of the nature of the Consultant Paediatrician's concerns and so would not have known which individuals to have contacted had we been in a position to do so.

Reflections

136. If the Hospital been more open with us and disclosed the clinician's concerns about the involvement of an individual, then I believe NHS England North and Specialised Commissioning would have taken further action with regard to the Hospital. However, at the time, we could only work with the information we had and, in the case of Specialised Commissioning, act within the powers that we had as Commissioners.

137. I personally first became aware of the increased mortality rate at the Hospital in February 2017 and escalated my mounting concerns in the following months to Robert Cornall, who was the Regional Director for Specialised Commissioning. During

this time NHS England North and the Specialised Commissioning team used what powers it had to subject the Hospital to scrutiny and monitoring. However, we had to be conscious about respecting the normal Hospital governance processes.

138. Specialised Commissioning was not informed that the Consultant Paediatrician's concerns related to one individual. If I knew this, in hindsight, I could have pressed the hospital further, however it is difficult to press on something that I was not informed about and I had limited authority in my role when dealing with a Hospital Medical Director. When I raised the possibility of an individual have disproportionate involvement, this was dismissed by Ian Harvey who informed me that they had undertaken multiple reviews and discounted this as a possibility.

139. From February to April 2017 we pressed the Hospital with calls and emails and I am not sure what much else we could have done in the context of our role in Specialised Commissioning, given the information we were receiving from the Hospital. We were not kept sufficiently informed about the Neonatal Unit's mortality rate, nor the Hospital's subsequent internal and external investigations. As Specialised Commissioning we had limited powers to compel the Hospital to do anything and we certainly had no mechanism to directly intervene in the running of the Hospital.

140. Throughout the relevant period, Specialised Commissioning was willing to offer the Hospital support, however what support we did offer was not being taken. By April 2017 I was growing increasingly frustrated. The Royal College report had a section missing and did not contain the individual case reviews that I thought Ian Harvey had agreed to provide. I felt that there was a lack of transparency from the Hospital, avoidance of answers and wanting to defer the issues we raised. We were still in email contact with the Hospital in April 2017 but when we asked questions, we did not receive straight answers. My sense was that the Hospital was intent on conducting its own process through their board and were evasive in response to our questions. The message that kept coming from the Hospital was that we had to wait until they had done things internally, however what that involved was not relayed to us.

141. Following the merger of NHS England and NHS Improvement, the region was split into the North West and North East and Yorkshire regions. The merger of NHS England and NHS Improvement was to use NHS England and NHS Improvement's collective resources more effectively and efficiently and remove unnecessary duplication and allowing the new region to have combined oversight of Trusts. The replacement of clinical commissioning groups with integrated care boards relationships

have resulted in the ICBs working with NHS England instead of a number of CCGs. NHS England still commission specialised services directly from Trusts but there is now a strategy to delegate some of the commissioning of specialised services to ICBs. In terms of governance, from an operational side the operating model is that national teams should have oversight of regions, and regions have oversight of ICBs.

142. In my role now as regional Medical Director I am part of the regional management team that works with ICBs and the national team in providing assurance in the way ICBs commission services for a Trust. As stated above some of the Specialised Commissioning has been delegated to ICBs. If the ICBs or region have concerns about a Trust for individual or cumulative issue, they can escalate into a recovery support programme which will involve regional or national oversight and support. The Hospital is currently in the recovery support programme and I chair the System Improvement Board. There are now four or five Trusts in the recovery support programme. This could be surrounding issues regarding quality of services, finances, concerns from CQC or any other regulator. My role is to work alongside the ICBs. I don't regularly meet with Trust Medical Directors as they have meetings within their own ICBs, however I do convene events for the whole region on particular themes.

143. ICBs are still only two years old so it is too early to say whether they have improved governance or oversight of Trusts.

144. The delegation of commissioning specialised services from NHS England to ICBs is a good idea. It should allow for the commissioning of a whole pathway of a condition with the opportunity to direct funding into preventative or early intervention. The delegation of specialised services started in April 2024 with the NHS England specialised commissioning team being retained in a "hub" that is hosted by one of the ICBs in the region.

145. Senior managers in the NHS can work for Provider Trusts, primary care networks, general practice, NHS England and ICBs. They can come from diverse professions, including those that have professional regulations. In 2023 NHS England published updated guidance to strengthen Board Governance. Trusts do publish Board meeting minutes for the public part of their meetings. On a Trust Board there will be non-executives to ask questions and hold executives to account. One possible approach could be to bring in some sort of professional regulation for the senior management in the NHS, but that would involve setting up a body such as the GMC or NMC for oversight and revalidation.

146. I am unable to state whether CCTV in the Neonatal Unit would have prevented the crimes of LL. The question assumes that I know the details of the criminal trial and the specifics of what was done to each baby, which I don't. Even with CCTV, it is possible that an individual intent on doing harm might still be able to hide those actions.
147. CCTV in neonatal units also raises issues around privacy and families who want to see their babies. Thought would need to be given as to who is storing the data, who has access and when it is released. There would be a lot of data governance issues to navigate.
148. In theory, if CCTV prevented even one death then it would be worthwhile. But the question then arises as to why CCTV wouldn't also be introduced in paediatric or adult critical care. Like neonatal services, both of these experience vulnerable patients.
149. Hospitals could introduce security systems relating to the monitoring of access to drugs and babies in neonatal units through a system where two nurses are required and one checks against the other. However, that would likely be hugely impractical and would impact the immediate giving of medicine to babies. In addition, electronic systems might make a hospital aware that a certain member has accessed the cupboard, but not necessarily what they had taken out.
150. I was appalled to hear of the actions of LL when she was found guilty in Court. The reporting of the case disclosed the concerns that had been raised by members of staff and the Trusts' approach to managing those concerns. I have seen documents that showed how the unit was staffed and the consistency of LL's attendance when an incident occurred. I have watched documentaries and listened to the stories of the paediatricians involved at the time.
151. Although LL had been taken off the unit after I became involved, I feel that there was a lot of information that was known to the Hospital that was not disclosed to the DCO team or NHS England which would have helped us come to a more informed collective decision about the unit's safety and the actions of an individual that needed to be reported to the Police. I hate to think what might have happened if the Hospital continued to resist the pressure put on them and did not inform the Police, allowing LL back into the unit.

152. I personally do not understand why this important information was not being shared and what the Hospital thought would be gained by avoiding our questions and asking for my time to respond to our requests.

153. At the time I was very frustrated with trying to obtain information from the Hospital and became increasingly concerned. If the Hospital had responded appropriately and fully to our questions, then we could have reached a decision earlier on involving the Police and saved a lot of time trying to understand what was going on at the Hospital. I felt let down by the Hospital and have questioned myself repeatedly as to whether I could have done more given the authority I had at that time and this may be helped 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: 25th July 2024