IN THE MATTER OF THE INQUIRIES ACT 2005
AND IN THE MATTER OF THE INQUIRY RULES 2006

THE THIRLWALL INQUIRY

OPENING STATEMENT OF NHS ENGLAND

A. Introduction

1. Since the events at the Countess of Chester Hospital NHS Foundation Trust ("the Hospital") took place, many things have changed in the NHS, some of which NHS England considers would now address a number of the serious issues highlighted in the Inquiry's Terms of Reference. This Opening Statement acknowledges where NHS England, and the Legacy Bodies that now form part of NHS England, contributed to the missed opportunities to take action following the crimes committed by LL. NHS England recognises the need to ensure that all women and families have confidence in NHS services, are able to put their trust in them and receive safe, compassionate care. Our deepest sympathies are with the families impacted by LL's crimes and we are committed to learning from this Inquiry.

2. A key underlying theme that will be explored throughout the Inquiry is where the appropriate balance between trust and curiosity lies at each level and layer within the NHS - from ward to Board and beyond. NHS England's reflections based on the information known to date are that:

   2.1. Ostensibly in 2015/16, the Hospital was a high performing Foundation Trust, with a recent 'Good' Care Quality Commission ("CQC") rating, appearing to take appropriate action to manage the unexpected increase in morbidity and mortality and to investigate events, with external scrutiny from the Royal College of Paediatrics and Child Health ("the RCPCH"). This meant sufficient curiosity was not engaged by NHS England (and others) at the point of being informed about the increase in cases involving the unexpected decline of neonatal babies who were otherwise considered clinically well.

   2.2. Operational Delivery Networks ("ODN") support the commissioners of neonatal critical care services by coordinating patient pathways between providers to ensure access to specialist resources and expertise. They also provided a way for clinicians to come together and share learning. The North West ODN (described below at paragraphs 15-16) was aware earlier than the NHS England North Specialised Commissioning Regional Team about the increase in morbidity and mortality, but their understanding of their remit and assumptions about others performing their prescribed roles means that this information was assumed to be acted upon appropriately elsewhere, and in particular by the Hospital.

   2.3. The Hospital Board as a whole, and individuals on it, lacked curiosity about what they were being told and relied too much on information presented to them in summary form. There was insufficient challenge to the way in which key information was shared, including the adequacy of time permitted for consideration.

2.4. Too much time was allowed to lapse before the Police became involved. Once those outside the Hospital were aware that potential criminal conduct was suspected, there was an assumption that the Hospital was promptly taking the step of involving the Police.

2.5. Too much trust was placed in the effectiveness of the Hospital's governance by a range of parties; in the conduct and openness of its Board members and its management of the increased morbidity and mortality.

3. Sadly, a key learning is likely to be that a greater willingness openly to accept and confront the possibility that those working in healthcare might transgress the boundaries of expected behaviour and deliberately harm patients is needed. No one working in the NHS, whether in a clinical or non-clinical role, goes to work looking for or suspecting that a colleague might have caused deliberate harm to someone they are meant to be caring for: cases of heinous criminality are rare (but not rare enough). However, there are other types of wrongdoing, such as fraud, that are more openly anticipated and where there are established processes and training for dealing with them, despite these also applying to a minority of healthcare workers.

The Directions

4. The Chair Directions of 6 June 2024 as to the content of written Opening Statements emphasise that: (i) candour is expected; and (ii) Core Participants should acknowledge specific failings and identify mistakes they have made, whether as an organisation or as an individual.

5. Certain Core Participants, including NHS England, were additionally asked to set out (i) the remedial actions it has taken and those that are still required to avoid a repeat of the events under investigation and to keep babies safe in hospitals; and (ii) any meaningful reflection about NHS England's role in respect of the events at the Hospital, including setting out where responsibility lies or whether change is needed and, if so, what it should be.

6. A list of 10 non-exhaustive topics is set out in the Chair's Directions. These topics cover the following: (8a) Awareness; (8b) Information sharing with parents; (8c) Support for parents of babies in hospital; (8d) Advice and help; (8e) The board; its role and skills; (8f) Management in the NHS and Regulation; (8g) Culture; (8h) Previous Inquiries; (10a) Reflections; and (10b) Recommendations. NHS England is directed specifically to address topics (8b), (8c) and (8e). NHS England has followed this directed structure in this Opening Statement – it is acknowledged that this may have the effect of making the Opening Statement appear somewhat legalistic, and therefore at times lacking compassion.

7. NHS England interprets culture to mean the values, beliefs and shared ways of thinking held, and how these influence decisions, actions and behaviours. This includes how things are arranged and accomplished, including the processes followed and policies in place, as well as how they are talked about, actioned and modelled and may vary based on the organisation, work role, profession or speciality. Culture, and the role that this plays in enabling (or, conversely, hindering) high quality and safe care therefore underpins all of the topics that the Chair's Directions ask us to address. It follows that our reflections on this are set out throughout this statement, as are our reflections generally.

8. At this point, and as the Inquiry moves into the Hearings phase, NHS England's understanding about what took place, why and how, is developing. This will continue as oral evidence is heard. NHS England

would emphasise, therefore, that it is not yet able to provide a fully informed view on some of the topics it has been asked by the Chair to address and it may appear that NHS England has given more weight to some topics than others. Where this is the case, this reflects NHS England's emerging knowledge and understanding, not a reluctance to engage with these topics. NHS England is fully committed to understanding and learning from these terrible events.

9. In particular, NHS England notes that some of the evidence of the former Board members who have been granted Core Participant status (the former Chief Executive Officer, Medical Director, Director of Nursing and Quality, and the Director of Human Resources) had not been disclosed to Core Participants at the time that this Opening Statement was written.[1]

10. NHS England has drawn on other evidence to provide initial reflections on the role of the Board, particularly the report of Facere Melius (the Healthcare Improvement Consultancy engaged by the Hospital in 2020 to carry out a review of the Hospital's handling of the events involving LL). It is cautious, however, about forming final conclusions pending full disclosure - noting that the former Medical Director did not participate in the Facere Melius review; the review was paused before a factual accuracy check process on the draft report was carried out; and at least one witness has raised issues around the content of the report that it is reasonable to assume would have been tested through the factual accuracy check.

11. As the Inquiry progresses, NHS England's reflections on its own role in the events at the Hospital and its view on potential areas for further change will develop and become more fully informed.

12. Finally, it is important to recognise the changes that have taken place in the NHS in the period since 2017. The publication of the Five Year Forward View marked a move away from the fragmented structure that formed a core part of the Lansley Reforms towards greater integration. These structural changes addressed some of the 'boundary working' of organisations seen in the events, and that may have contributed to actions not being taken as swiftly as possible. What is described below in terms of the role of NHS England and its Legacy Bodies does not describe how NHS England would operate today in response to an unexpected increase in morbidity and mortality.

B. Background in 2015-2017

13. NHS England was the commissioner of specialised services during this period, which included neonatal critical care services.[2] There are three 'levels' of neonatal critical care services. The Hospital was commissioned by NHS England to provide 'Level 2' neonatal critical care services. The commissioning arrangement between NHS England and the Hospital was managed through the NHS England North Region Specialised Commissioning Team.

14. The North Specialised Commissioning Regional Team worked as part of the NHS England North Regional Team. It was led by a Director,[3] with clinical leadership in the form of a Clinical (Medical)

[1] Although some of these statements have now been disclosed during the course of finalising this statement (such as the statement from the former Chair), NHS England has not yet had the opportunity to review, analyse and assess these in detail in the time available.
[2] The National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012
[3] INQ0107032

Director[4] and Director of Nursing, and arranged into sub-regional 'Hubs'. Each Hub was led by an Assistant Director. The Hospital fell within the North West Hub and was managed by the North West Assistant Regional Director.[5]

15. ODNs supported NHS England as the commissioner of neonatal critical care services by coordinating patient pathways between providers to ensure access to specialist resources and expertise. They also provided a way for clinicians to come together and share learning. Although ODNs existed in the period prior to NHS England's establishment in 2013[6], their role and responsibilities were formalised in the period from 2014. They have continued to develop, evolve and mature since then, with relationships and engagement between ODNs, Trusts, and Specialised Commissioning becoming more embedded.[7]

16. The North West ODN covered all neonatal units in the North West of England. It was organised into three localities. The Cheshire and Merseyside locality included the Hospital in its scope. The ODN was overseen by a Board and was accountable to NHS England Specialised Commissioning. Membership of the ODN was a requirement for all those contracted to provide neonatal critical care services. While the ODN was expected to facilitate comparative benchmarking and audit of providers of neonatal critical care services, it did not have a formal role in monitoring compliance with (for example) the Serious Incident Framework 2015 and it only had access to incident data shared with it through (a) national audit reports, such as those produced annually by MBRRACE-UK and (b) its sub-structures, the key one of which in 2015-2017 was the Clinical Effectiveness Group. The Network Neonatal Clinical Lead, who chaired the Clinical Effectiveness Group, during the period in question was Dr Nim Subhedar.[8]

17. In the period from June 2016, the ODN worked with the Hospital to support the safe delivery of neonatal services in the area following the downgrading (sometimes also referred to as regrading) of the unit, and to support the unit during the review of the mortality concerns.

18. Provider oversight and regulation during this period was the responsibility of two statutory bodies: Monitor and the NHS Trust Development Authority ("NHS TDA"). In mid-2016, they came together to operate in an aligned way under the operational name "NHS Improvement". NHS England took on the functions of Monitor and the NHS TDA as part of the statutory changes implemented in 2022 and is now both commissioner of specialised services and provider regulator.

19. The Hospital was established as an NHS Foundation Trust in 2004 and was therefore subject to Monitor's provider oversight and regulation. Monitor's main statutory duty when exercising its functions was to 'protect and promote the interests of people who use health care services by promoting provision of health care services which (a) are economic, efficient and effective, and (b) maintains or improves the quality of services'.[9]

20. During the period to 2017, Foundation Trusts were generally permitted significant autonomy. This was one of the intentions behind the creation of Foundation Trusts.[10] NHS England had a duty at the time to promote autonomy.[11]

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[4] INQ0107034
[5] INQ0106970
[6] INQ0018010, INQ0106978
[7] INQ0107030 and INQ0018081_0020
[8] INQ0102685
[9] Section 62, Health and Social Care Act 2012
[10] INQ0101414
[11] The duty contained within s.13F of the National health Service Act 2006 was repealed by s.73(1)(b) of the Health and Care Act 2022

21. However, Foundation Trusts remained subject to the financial and governance (including quality governance) requirements set by Monitor/NHS Improvement through the Provider Licence and related guidance[12]. Foundation Trusts were expected to declare non-compliance and make Monitor/NHS Improvement aware of quality issues. Their governance was risk-rated by Monitor on a traffic light system, which indicated the risk of failure for governance arrangements. This was assessed on a quarterly basis through the year.

22. Indeed, in the period prior to the events involving LL, the Hospital was considered a high performing organisation. In early 2015, NHS England launched the New Care Models programme and invited applications from organisations wanting to trial new ways of operating. The Hospital was a successful applicant; was granted 'vanguard' status and its work to develop the 'Cheshire Way' was well regarded.

23. The CQC was (and remains) the regulator responsible for ensuring that registered providers of healthcare services met the fundamental standards of care expected. In 2015/16, these standards were: effective, caring, well led, safe and responsive to people's needs. It carries out inspections of care at hospitals.

24. By early 2015, Monitor and the CQC had formally adopted a common understanding of what a well-led organisation looked like.[13] The respective responsibilities of the two regulators were broadly that Monitor focussed on strategy, planning, capability, culture, process, structures and measurement at Board and committee level, while the CQC provided a 'reality check' of whether the outcomes demonstrated effective operation of the Board's policies.

C. Awareness *(Chair's Directions, 8a)*

25. Except where it is helpful to distinguish between its role and that of NHS Improvement, references to NHS England below should be read as meaning "NHS England and NHS Improvement".

26. On the basis of the information known to date, it appears that the North West ODN was aware in the period February-March 2016 of the concerns that Dr Stephen Brearey had that morbidity and mortality on the Hospital's neonatal unit was higher than expected. This knowledge was gained through Dr Nim Subhedar's involvement in a thematic review Dr Brearey carried out in early 2016. NHS England has not been able to find evidence of this information being shared with it, despite Dr Subhedar suggesting to Dr Brearey in March 2016 that he should share his concerns with NHS England. Neither NHS England nor NHS Improvement knew, therefore, about the deaths and unexpected decline of babies at the Hospital while LL was offending.

27. In early July 2016[14] the ODN was aware that a member of staff on the neonatal unit had been removed from the unit and was undergoing HR processes. To the best of NHS England's knowledge, these concerns around potential criminal conduct were not shared with the ODN at this point. This information was also not shared with NHS England and so, as with awareness of the unexpected increase in morbidity and mortality, it did not know of the possibility that an individual could be involved in the deaths until March 2017.

[12] INQ0017495
[13] INQ0017495, Well led briefing update feb 15 300115 (publishing.service.gov.uk)
[14] INQ0107030_0011 paragraph 40

28. Apart from the knowledge the ODN had, NHS England and NHS Improvement were only made aware in July 2016 of an increase in mortality on the unit, after LL was removed from the neonatal ward. As the commissioner, NHS England should have been made aware of this information sooner. The fact that NHS England was not aware until after 30 June 2016 reflects a significant failure of the Hospital's governance and, specifically, a failure to report incidents through either of the patient safety incident reporting systems in place at the time.

Incident reporting

29. In the period 2015 to 2016, when LL was offending, the Hospital was required to comply with the Serious Incident Framework, which NHS England had updated in 2015 (following the events at Morecambe Bay and as part of implementing the recommendations arising from that investigation). It is worth reflecting on what a Serious Incident under the Framework is, namely: an "event in health care where the potential for learning is so great, or the consequences to patients, families and carers, staff or organisations are so significant, that they warrant using additional resources to mount a comprehensive response." Clearly the deaths and unexpected declines suffered by babies on the neonatal unit met this definition. From its initial review of the witness evidence, it appears to NHS England that there was confusion within the Hospital about what a Serious Incident was and, potentially, a reluctance to formally report incidents as Serious Incidents. This is an area that requires further exploration during oral evidence.

30. The Hospital's expected annual neonatal mortality in the period prior to 2015 was relatively stable, varying from between 1-4 deaths. In June 2015 there were 3 deaths in one month. This did raise concerns within the neonatal unit but for reasons that remain incompletely explained, only one of the deaths was raised as a Serious Incident. As concerns mounted through the remainder of 2015, there were further missed opportunities when incidents could have been reported but were not.

31. In total, only four Serious Incidents were reported by the Hospital that appear to be connected to the death of a baby named on the Indictment. None of the incidents involving harm short of death were reported.

32. None of the four Serious Incident reports indicated a concern about a specific individual and it was not until the final Serious Incident was raised on 5 July 2016 that broader concerns about a general increase in morbidity and mortality was reported. The Inquiry may wish to explore why the overall increase in morbidity and mortality was not reported earlier. Whether there was a positive incident reporting framework at the unit at the time, as suggested by Dr Subhedar, will be a matter that is likely to be investigated further during the course of the Inquiry.

33. NHS England is aware that Facere Melius also questioned the apparent decision by the Hospital to move away from a process whereby all child deaths were automatically considered a Serious Incident. Although not every death is automatically a Serious Incident, it is possible that confusion over what/was not a Serious Incident contributed to missed opportunities in terms of the use of Serious Incident reporting as a way of making external bodies aware of patient safety issues.

34. On the basis of what is known currently, it appears to NHS England that the failure of the hospital to report each incident of unexpected collapse or death as a Serious Incident in 2015-2016 and/or an

earlier report of the unexpected increase in overall morbidity and mortality could have been a missed opportunity to enable NHS England (and others) to have been alerted while LL was still on the unit. Further, and while NHS England has no desire to add to the suffering of the families by speculating about what might have been, the Inquiry might explore further whether – based on the action taken following the declaration of a Serious Incident in June 2016 – this could have been a missed opportunity through which LL's offending could have been stopped at an earlier stage.

35. The other way in which patient safety concerns could have been raised was through the National Reporting and Learning System. This System was monitored by the NHS England National Patient Safety Team. The purpose of this monitoring is to detect novel and unknown patient safety risks. Reports are not monitored in the same way as incidents reported through the Serious Incident Framework and so it is harder to say whether incidents reporting through this means would have resulted in any direct action being taken. However, NHS England can see no evidence that concerns about increasing mortality or the Hospital's investigation of the cause of this were raised as patient safety incidents. Learning points identified in the Hospital's internal thematic reviews of neonatal mortality carried out in this period also do not appear to have been reported when they should have been. This appears to be a further example of a failure of the Hospital's governance.

36. NHS England was reliant on incident reporting as one of the main ways that it would be alerted to patient safety issues because the other data systems in place at the time that monitored mortality did not facilitate timely signalling of an increase in mortality. The ODN's ability to monitor and interrogate mortality data was also limited by the availability and timeliness of reporting data. The Operational Delivery Network Specification has since been developed to support consistency and set expectations on ODNs.[15] Critically, ODNs have a far greater presence at a unit level and the relationships between Provider Trusts and the networks has evolved since 2015. Further work is underway to review and standardise reporting across the networks, including work being done by the National Clinical Director for Neonatology with the British Association of Perinatal Medicine (which will be overseen by the Maternal and Neonatal Programme Board) to develop a framework for the reporting of neonatal mortalities.

Quality Surveillance Groups

37. Structures and processes were in place to enable early warning signs of quality issues to be shared between stakeholders. Quality Surveillance Groups, which operated at a local, regional and national level, were a key way in which this information sharing and multi-agency working was enabled. However, to be effective, these structures and processes rely on active and transparent information sharing and on connections being drawn between what information there was; on participants being curious:

    37.1. The Regional Quality Surveillance Group included representatives from NHS England, the CQC, NHS Improvement, Public Health England, the General Medical Council and the Nursing and Midwifery Council. It met on a quarterly basis and the chairs of local quality surveillance groups

[15] INQ0017495_0270 paragraph 1008

also attended. To the best of NHS England's knowledge, no concerns had been raised through these structures about raised mortality on the neonatal unit in the period prior to June 2016.

37.2. The Quality Surveillance Group framework was utilised at key points during the period from June 2016 on; meeting in July, September, November and December 2016 and in March 2017. However, its effectiveness was impacted as it did not have the full factual picture. The possibility that the increased mortality was the result of an increase in complexity of the babies being treated at the unit was seemingly supported by the fact that the enhanced surveillance following the units change in designation from Level 2 to Level 1 showed there were no further incidents.

Other regulatory oversight

38. As far as NHS England is aware, there were no other regulatory 'red flags' during this period that suggested there were systemic issues at the Hospital. Indeed, in its June 2016 inspection report, the CQC gave the Hospital a generally positive review, rating the Hospital as "Good" overall, with only one area rated as 'Requires improvement' – responsiveness.

39. The limitations of the Inspection process, as described in the CQC's evidence, will be familiar reading in light of the findings of previous inquiries, investigations and reviews. Having considered this evidence, it appears to NHS England that a reasonable conclusion could be reached that the positive view put forward by the Hospital around the robustness of its incident reporting and risk management systems was accepted with minimal interrogation by the CQC.[16] It also seems that the clinicians working on the neonatal unit who had concerns about the increase in mortality feel that they did try to raise concerns about patient safety on the unit but were not heard by the CQC.[17] This was likely to have been a missed opportunity through which concerns could have been raised and external scrutiny applied. The Inquiry will likely want to reflect on the evidence given by the CQC as to its response.

40. The NHS West Cheshire Clinical Commissioning Group was the lead commissioning body responsible for overseeing the Hospital (although it was not responsible for the commissioning of neonatal services in particular). It also did not raise any concerns with NHS England about the Hospital's governance, incident reporting or the quality of services generally.

41. Further external scrutiny and oversight was available at the time through the Coronial process and through safeguarding structures and processes, including the Child Death Overview and Scrutiny Panel and Sudden Unexpected Death in Infancy and Childhood. While it is correct that the primary route through which such referrals could be made was via the treating clinician, any clinician (whether on the unit or at Board level) could have used these routes to raise concerns. These external scrutiny and oversight routes have since been strengthened with the implementation of the Medical Examiners system (with full statutory implementation due to be completed on 9 September 2024). NHS England has expanded on this later in this Statement.

Steps taken by NHS England after becoming aware

42. On 30 June 2016, the same day that LL was removed from the unit, the Hospital raised, via the Strategic Executive Information Management System, two Serious Incident reports. Both reports related to what

[16] INQ0102622
[17] INQ0103104

was described as the "unexpected deterioration and death of a neonate".[18] These incident reports were logged on the same day by the North Regional team. There was nothing in the incident reports to make NHS England aware of the wider issues around mortality and neonatal incidents at the Hospital. However, the fact that the incidents related to two related babies (Child O and Child P) was highly unusual and raised concern. Immediate steps were taken by NHS England, working with the Clinical Commissioning Group, to ensure that the Hospital was taking appropriate action as per the Serious Incident Framework to investigate the incidents.

43. Around a week later, on 7 July 2016, the Hospital raised another Serious Incident report. In this incident report the Hospital declared an unexplained pattern of raised mortality. This was the first time that NHS England was made aware of issues around systemic mortality concerns.

44. In this incident report the Hospital informed NHS England that it had commissioned an external review of their neonatal service from the Royal College of Paediatrics and Child Health ("the RCPCH") and the Royal College of Nursing (NHS England subsequently became aware that the reference to the Royal College of Nursing was an error). The Hospital informed NHS England that the deadline for completion of the review was expected to be the end of August.[19]

45. The July Serious Incident report also confirmed that a press release had been "drafted for release today, with identified patient families to be contacted". Immediate steps were taken by NHS England in response to the 7 July incident report, namely:

    45.1. Review of the situation by the North Quality Surveillance Group, the multi-agency forum through which quality issues could be managed and which included stakeholder representation from NHS England, NHS Improvement, the CQC and others.

    45.2. Approval of the proposal by the Hospital and the Network that the unit step-down its level of care from Level 2 to Level 1.

    45.3. Enhanced reporting and scrutiny requirements in relation to the neonatal unit, requiring daily monitoring and "weekly executive reviews of any transfers out/capacity issues/incidents of Maternity and NNU [neonatal unit]".[20]

46. In the immediate period following the 7 July incident report, the fact that the Hospital had commissioned the RCPCH to carry out a review provided assurance to NHS England. This was considered an appropriate step for the Hospital to take in the circumstances (as they were known at the time) and the timescale for completion (August) gave further confidence as it seemed sufficiently timely. It would have been of assistance to NHS England to have received the Terms of Reference sent to the RCPCH but this did not happen and, in hindsight, this should have been requested. To the best of its current knowledge, NHS England is not aware that the Terms of Reference or other information about the scope of the review was shared with NHS Improvement.

[18] INQ0017495 paragraph 515
[19] INQ0014636, INQ0017495 paragraph 522
[20] INQ0014760

47. The ODN Manager was made aware around this time that an individual had been moved from the unit and was going through a HR process at the Trust. At this point, there was no indication of the concerns being related to criminal acts and the ODN Manager did not know the name of the individual.

48. In the period from July to September, NHS England sought and was provided with intermittent updates regarding the Hospital's actions in relation to the neonatal unit. At the Quality Surveillance Group meeting on 16 September 2016, it was noted that the RCPCH review had been carried out and had gone well. It was agreed that the surveillance should be stepped down from enhanced to routine. However, by November 2016 – despite frequent requests from NHS England for a copy of the report and an overall update regarding the Hospital's action plan – no further information had been provided and it was agreed, therefore, on 16 November 2016 that surveillance should be increased back up to enhanced.

49. A month later, the North Region Specialised Commissioning Team were becoming increasingly frustrated by the responses they received from the Hospital's Medical Director, Ian Harvey, and the Hospital's Director of Nursing and Quality, Alison Kelly. On 16 December 2016, therefore, the Assistant Director for the North West Hub wrote to Alison Kelly formally requesting that the Hospital provide copies of internal and external reports relating to the Neonatal Unit, a formal action plan and a communications plan.

50. In her reply, dated 21 December 2016, Alison Kelly informed NHS England that the Hospital was not "comfortable" sharing the draft report[21]. The reason given was that the report recommended that a further independent case review was required of the relevant cases and, as a consequence, the Hospital did not have a final report on a small number of cases. She went on to explain that the Hospital was in the process of developing a communications plan and action plan and that these would be shared some time in the new year. No specific timeframe was given as to when this would be. This response prompted the decision by NHS England to request the involvement of NHS Improvement.

51. NHS England's understanding on the basis of information known to date is that NHS Improvement had not been kept updated as to the Hospital's investigation of the increase in mortality by the Chair or other members of the Executive team, as might have been expected. The NHS Improvement North Regional Medical Director was briefed by his NHS England colleagues and the steps he took are described below at paragraph 53.

52. NHS England involved NHS Improvement in this way is because the latter had greater regulatory leverage over providers, particularly Foundation Trusts, and NHS England's contractual levers were less effective. Reflecting on this now, it was a missed opportunity annot seek further, or different, intervention by NHS Improvement.

NHS Improvement become involved

53. On 3 January 2017, the North Regional Medical Director of NHS Improvement met with Ian Harvey[22]. In hindsight, it took too long for NHS England to involve NHS Improvement. It seems that because they had not been exposed to the Hospital's lack of openness in the period from July-December 2016 (as

[21] INQ0008077
[22] INQ0014771

NHS England had), NHS Improvement were assured by the direct and apparently reasonable response provided by Ian Harvey, who maintained his position that the Hospital could not share the report with NHS England or NHS Improvement. The NHS England North Region Specialised Commissioning Team remained concerned and there were ongoing discussions within the team about what more could be done to try and gain more information about the issues at the Hospital.

54. The split between NHS Improvement and NHS England no longer exists. The two organisations came together under an operational alignment from 2018 and were formally merged in July 2022, with NHS England taking on responsibility for the statutory functions that had previously been Monitor. This means that there is now one NHS oversight and regulation framework for providers like the Hospital (although other regulatory frameworks continue exist, such as that operated by the CQC) and, in responding to an incident of this nature, NHS England is now better placed than it was previously to develop an integrated action plan that considered all available levers as both commissioner and provider regulator.

Concerns mount

55. In the period between 3 January and 27 March 2017, the North Specialised Commissioning Regional Team's concerns and frustration with the Hospital, and with Ian Harvey, and to a lesser extent Alison Kelly, continued to mount. The following key events took place during this period:

    55.1. On 24 January 2017, NHS England became aware that the Hospital had developed a communications plan for managing the publication of the RCPCH report. A request for sight of the report was again refused.

    55.2. The RCPCH report was leaked to the media sometime in late January/early February, with NHS England becoming aware on 3 February 2017 that this had taken place. A copy of the report was finally provided to NHS England and discussed at the North Regional Leadership Group on 13 February 2017.

    55.3. The North Specialised Commissioning Regional Team meet with Ian Harvey on 23 February 2017 and become aware that Queen's Counsel had been engaged by the Hospital to carry out a review of the RCPCH report. The reason given for this was that the clinicians at the Hospital did not accept its "content".[23]

    55.4. A further meeting with Ian Harvey took place on 10 March 2017, at which the issue of the clinicians not accepting the RCPCH report was discussed further, with Ian Harvey explaining that further information was being sought from the Coroner.[24]

    55.5. In a meeting with executives at the Hospital on 27 March 2017 the Network Manager posed the question to the clinicians whether, on balance of probability, they believed illegal action had caused the deaths, to which they indicated that they did. The Network Manager informed NHS England North Specialised Commissioning of these concerns immediately following this meeting. On the basis of information known to date, this was the first knowledge NHS England had that there were concerns about an individual's role in relation to the events at the Hospital.

[23] INQ0014692
[24] INQ0014653

55.6. On 29 March 2017, the North Specialised Commissioning Regional Team Clinical Director spoke with Ian Harvey. His note of this call[25] records that he was made aware, for the first time, that the consultants were concerned about a connection between a particular individual and the neonatal deaths. Ian Harvey disclosed that a "significant announcement" would be made after the Hospital had spoken to an "appropriate body". No further details were provided but the impression that the North Specialised Commissioning Regional Team had is that Police were about to be called in.

55.7. Over the next three weeks, the North Specialised Commissioning Regional Team discussed internally the delay in the Hospital informing the police and whether they should instead go to the police directly.

55.8. On 19 April 2017, following a request made to Ian Harvey by the Clinical Director of the North Specialised Commissioning Regional Team for an update, the Hospital confirmed that they were consulting with the Child Death Overview Panel in relation to 4 cases where the cause of death remained unexplained despite the external reviews commissioned. This provided the North Regional Specialised Commissioning Team with some assurance as they knew that the Police were members of the Child Death Overview Panel.

55.9. The Police formally launched its criminal investigation in May 2017.

Were NHS England's actions in the period from 30 June 2016- May 2017 good enough?

56. NHS England's response to this question incorporates its reflections on the role of both NHS England and NHS Improvement. NHS England considers that its response in July 2016 to the three Serious Incidents reported by the Hospital over 8 days (which included the reported increased mortality rate in the neonatal unit) was appropriate based on the information available to it at the time.

57. However, NHS England (on its own and on behalf of NHS Improvement) accepts with the benefit of hindsight, and particularly the knowledge it now has about the criminal offences that occurred, that it could have done more during the intervening 9 month period to scrutinise the actions taken by the Hospital and this contributed to the delay in the Police becoming involved.

58. It accepts that too much deference appears to have been given to senior Directors at the Hospital during this period; and to Ian Harvey and Alison Kelly in particular. In part, this can be explained by the legislation in operation at the time, which placed an emphasis on organisational sovereignty and autonomy for Foundation Trusts. While there remained an expectation that information was shared by a Foundation Trust with Monitor/NHS Improvement, the otherwise high-performing status of the Hospital may have impacted on the strength and speed of regulatory oversight.

59. Once the Police became involved, NHS England was (appropriately) restricted in terms of what actions it was able to take. NHS England/NHS Improvement would not generally commence a regulatory investigation simultaneously with an active police investigation[26]. However, notwithstanding this general principle, NHS England's reflections on its involvement in subsequent positions held by former Board members are set out below at 115.

[25] INQ0014649
[26] INQ0101414_0005 Paragraph 18

D. Information sharing with parents *(Chair's Directions, 8b)*

60. Compassion and candour should be the touchstones for all engagement, including information sharing, with parents of neonatal babies. Neonatal care can be especially stressful and daunting for parents. Kindness, compassion and an emphasis on ensuring that the voices of mothers and their families are heard are essential in ensuring personalised care. The Service Specification for Neonatal Critical Care Services reflected these expectations, with one of the overarching aims, as per the Service Specification, was to provide a family-centred approach to care, including through helping parents understand their baby's needs.[27] The Hospital also had to comply with the requirements around information sharing and candour in the Serious Incident Framework.

61. In its February 2016 Inspection Report of the Hospital, the CQC confirmed the following: (i) the trust had a duty of candour process in place; (ii) they had seen evidence of the policy being applied appropriately; and (iii) there was mandatory staff training and the duty of candour was included in the policy for investigating incidents.

62. Information sharing has also been a theme in previous inquiries, investigations and reviews. For example, one of a number of key themes identified in the Final Ockenden report published in March 2022 in relation to neonatal care was listening to and supporting families. Another was bereavement care, which NHS England has addressed below at 80. The Kirkup Report (October 2022) further emphasised the importance of giving care with compassion and kindness. NHS England published the Three Year Maternity and Neonatal Delivery Plan in March 2023. Compassionate, person-centred care is a central theme of the Plan.

63. The principles of kindness, compassion and candour are particularly important where a patient safety incident has occurred. One of the four key aims of an effective patient safety incident response system, which the recently introduced Patient Safety Incident Response Framework is intended to support, is 'Compassionate engagement and involvement of those affected by patient safety incidents'.

64. From NHS England's review of the evidence disclosed to date, it is clear that information sharing and engagement with affected families; ensuring they knew what was going on; the steps that the Hospital was taking and why; and had an opportunity to ask questions and receive a compassionate response, was not given sufficient thought throughout the period from when concerns first arose in 2015. To the extent that information was shared with the families by the Hospital it appears to have been done in a reactive way, in response to direct requests for information from families or as a result of media coverage. The information provided appears minimal and the correspondence that NHS England has seen from the Hospital to the families often lacks compassion and is not open or candid.

65. NHS England also acknowledges instances the families describe where they feel the clinical information shared with them about the circumstances of their child's death, or aspects of their care, was unclear, insufficient or lacking in candour. They describe, for example, becoming aware of information for the first time during the inquest[28]. NHS England notes that in some of the cases where the deaths were referred to the Coroner, concerns were raised with the Coroner, including by solicitors

[27] INQ0009232 paragraph 3.1(2)
[28] INQ0000037_0014, INQ0101364_0185

acting for the family concerned, about the adequacy of the Hospital's investigations[29] and the Coroner himself raised concerns with the Hospital about how information was shared with the families following publication in the Sunday Times of information about the RCPCH review.

66. Concerns around the way in which information was shared with families were raised in the Facere Melius draft report, with Facere Melius concluding that families of the babies who died or were harmed were not looked after.[30] NHS England agrees with Facere Melius that the tone of the correspondence from Ian Harvey lacked empathy and put the onus on the families to contact him if they wanted further clarification.[31]

67. Compliance with the statutory duty of candour is only one aspect of this. While NHS England is not the responsible regulatory body for the statutory duty of candour (that responsibility resting with the CQC) a sustained focus on improving candour is the responsibility of all those operating as part of the NHS. The effectiveness of the statutory duty of candour rests on the existence of wider organisational cultures and processes that support openness and transparency.

68. As NHS England is not the responsible statutory body it does not have a ready benchmark against which to the assess the evidence provided about compliance with this duty by the Hospital and so cannot make an informed view. However, it seems that the Hospital experienced difficulties in getting engagement from clinicians and others around duty of candour[32] and that external stakeholders, including the Coroner had raised concerns about this.

69. NHS England supports the Department of Health and Social Care's current consultation on potential reforms to the duty of candour. NHS England has contributed its reflections on the potential expansion of the duty of candour ('the Hillsborough law').

70. In 2015-2017, the following could all have played a role in how information was shared with parents:

    70.1. Any individual providing care to a neonatal baby or, on bereavement, to a family member;

    70.2. the Provider themselves, in response to a complaint or as part of a patient safety incident investigation, and as part of its routine analysis of data to inform risk management and escalation;

    70.3. a Coroner, as part of the Inquest process;

    70.4. the Parliamentary and Health Service Ombudsman, in response to a complaint made to them by a parent or family member;

    70.5. the relevant professional regulatory body (such as the General Medical Council or the Nursing and Midwifery Council), in response to a regulatory referral made to the professional regulatory body and as part of revalidation;

    70.6. NHS Resolution, as part of considering any claim brought against the Hospital in relation to alleged clinical negligence;

[29] INQ0002042_0155 and INQ0101364_0145
[30] INQ0003719_0207 paragraph 11.11
[31] INQ0012617_0001, INQ010364_0169
[32] INQ0102365

70.7. Independent reviewers, such as the RCPCH or clinicians providing a second opinion or peer review;

70.8. regulatory bodies including NHS England, the CQC, NHS Improvement.

71. Today, this list can be expanded to include Medical Examiners and the expansion of the roll out of the 'Call for Concern' service.

72. All these routes are ways in which information sharing opportunities arise and through which families can ask questions or raise concerns.

Difficulties with the statutory duty of candour

73. In her expert evidence, Professor Mary Dixon-Woods notes that examples of the CQC taking enforcement action in relation to breaches of the duty of candour are now appearing, with the powers being used for the first time in 2019.[33] NHS England also notes the difficulties she describes in 7.4.4 in terms of implementing the duty of candour and assessing compliance.

74. NHS England anticipates that the CQC will want to address these points and we make no further comment on these at this stage save to note that the Department of Health and Social Care's consultation on the statutory duty of candour and potential reform to this remains ongoing.[34] Coordinating any recommendations around candour with potential reforms coming from the consultation would be helpful to avoid duplication and/or unintended consequences.

How should information be shared with parents by a hospital where there are suspicions about a member of staff's conduct?

75. The principles set out above concerning compassionate and candid information sharing and engagement remain just as appropriate in cases where there are suspicions about a member of staff's conduct. However, there will be, as there appears to have been here, understandable concerns about what information could be shared when it related to suspicions about a member of staff's conduct.

76. The Patient Safety Incident Response Framework emphasises the need to ensure a clear delineation between patient safety incident response and any related disciplinary/regulatory/criminal investigations. This did not happen in relation to LL, with the management of the patient safety incident and employment aspects being blurred.

77. In such cases, NHS England would expect that the hospital concerned seeks appropriate case-specific advice to help inform its approach. This would generally include the police themselves, HR, legal and/or regulator support. The Hospital does not, in this case, appear to have sought early external advice and when advice was sought, only a limited amount of information was shared with those advising. This undoubtedly contributed to the apparent lack of a clear and coherent strategy for how the allegations around LL's conduct were managed, including how, when and what information could be shared with parents of affected babies.

78. NHS England considers that updated guidance, co-produced with the Police, would be beneficial to the NHS as a whole, to help guide how the two systems work together when carrying out investigations.

[33] INQ0102624, paragraph 7.3.1
[34] INQ0015468

Professor Bowers KC, in his expert employment law evidence, agrees that 'a protocol for determining when employers should refer matters to the police would be useful'. As the Inquiry is aware, there is no current, up-to-date Memorandum of Understanding to replace the version that was used in 2017 by NHS England to manage the Police investigation at the Hospital.

Reflections on information sharing

79. Reflecting on what information it appears was shared with the families, NHS England considers that:

    79.1. The families whose babies' care was in-scope for the external reviews should have been informed about each relevant review, including the purpose, scope and timeframe. They should have been kept updated at appropriate intervals throughout the review process, unless they had asked not to be. This would have been consistent with data protection expectations, regulatory and statutory duties relating to the duty of candour and incident investigation but also with the general expectations around good, open clinical care.

    79.2. A named primary point of contact should have been provided to each bereaved family and appropriately regular follow-up actioned by the named contact.

    79.3. It appears that consideration was given to who was best able to respond to questions from families, but the responses were often matter of fact, taking a literal clinical response to each question.

    79.4. The onus was placed on families to arrange follow-ups or ask questions.

    79.5. Candour was often lacking or slow to be actioned. The evidence suggests it was seen as a one-off duty, rather than an ongoing one.[35]

    79.6. Contact by the Trust appeared to be reactive; driven by information leaked to the media or by questions received from the families. There did not seem to be a proactive desire to ensure families understood what had happened or any awareness of the need to continue to provide updates as events progressed.

E. Support for parents of babies in hospital *(Chair's Directions, 8c)*

Bereavement support

80. Bereavement support specifically includes a number of different services, some or all of which may need to be accessed by a mother or other family member following the death of a baby. Charities and other third sector providers play a crucial role in bereavement support and this can be beneficial in providing 'lived-experience' support. NHS England's guidance on 'Engaging and involving patients, families and staff following a patient safety incident', which forms part of the Patient Safety Incident Response Framework Toolkit, emphasises that "Families and staff may need to be signposted to support at any point during engagement or involvement in a learning response".

81. NHS England's expectation as the commissioner of neonatal critical care services is that palliative care and bereavement support is available and can be accessed at any point during the neonatal care pathway (i.e. pregnancy, delivery room, neonatal unit, home). But it does not mandate what is to be

[35] INQ0102365

provided or the actions that should be taken by NHS providers in individual circumstances. NHS England's view is that these are matters to be determined by the trained professionals working with families. However, NHS England is a member of a core group of baby loss charities and professional bodies who have jointly developed the National Bereavement Pathway. Working with members of this core group, NHS England has supported the development of the Neonatal Death Full Guidance Document[36]. NHS England expects NHS providers to refer to the pathway in delivering bereavement care to parents and families.

82. NHS England commissions specialist perinatal mental health services and this remains an ongoing area of focus in terms of further investment and implementation of the commitments in the Three Year Delivery Plan, including to ensure that that appropriate perinatal and maternal mental health services are available. Previous inquiries and reviews have also recognised the need for improvements in bereavement support. Although there remain further improvements to be made in relation to bereavement support, NHS England's view is that the position today is better than it was in 20152017.

83. The National Medical Examiner has described[37] the role that Medical Examiners can play as part of an overall package of bereavement support. A Medical Examiner is one step removed from the care team and this can provide beneficial independence in terms of providing explanations and interpretations. This can help allay worries and doubts and avoid stressful complaints, because the Medical Examiner has been able to answer questions, explore issues and provide the family with the information they need to understand what happened. It can also help identify cases where there are remaining issues that cannot be resolved and facilitate these being referred to the relevant authority, such as the Coroner. The Medical Examiner also enables a high quality review of all aspects of care that may have contributed to an individual's death by looking at the individual's journey through all applicable aspects of the health and care systems. In contrast, most organisation-based patient safety incident investigation will focus on what happened at each individual organisation.

F. Advice and help *(Chair's Directions, 8d)*

84. There are a number of routes through which nurses and doctors can seek advice and help from their unions, regulators or any other organisation in circumstances where they are worried about the safety of any baby in hospital. These have evolved and developed since 2015-2017. The position today is summarised below at 88.

85. The views and experiences that NHS staff and others have included in their witness statements, as well as the Nuffield Trust and Picker Reports, warrant careful review and reflection. NHS England will continue to do this as the Inquiry proceeds. At this stage, NHS England simply notes that work is already underway to address some of the issues identified by the Nuffield Trust and Picker Reports in relation to culture, staffing, incident reporting and the freedom to speak up in the complex environment that is neonatal care. These steps are described in NHS England's corporate witness statement and also outlined at paragraphs 144-149 below, including in particular the action being taken in the Three Year Maternity and Neonatal Delivery Plan, and the implementation of the Learn from Patient Safety Events Service and Patient Safety Incident Response Framework.

[36] INQ0014721
[37] INQ0014570, paragraphs 112-114, 148

86. NHS England is also keen to understand more about the specific experience of staff at the Hospital who sought to raise concerns about the increase in mortality and LL's potential connection to this. Whilst NHS England has not completed its review of this evidence, in terms of initial reflections NHS England observes:

86.1. some clinicians working on the neonatal unit did not use the internal processes within the Hospital to raise concerns (including through reporting the incidents as patient safety incidents);

86.2. safeguarding processes at the Hospital were not utilised;

86.3. none of the non-executive directors, including the non-executive director with responsibility for Freedom to Speak-Up, report being approached directly by any of the clinicians (NHS England notes it has not yet received the Chair's evidence);

86.4. clinicians did not feel that the CQC heard attempts by clinicians to share concerns around patient safety on the unit when it was onsite in February 2016;

86.5. no concerns were raised, or request for advice made, direct to either NHS England or NHS Improvement, or (as far as NHS England is aware) the West Cheshire Clinical Commissioning Group.

87. We understand that the neonatal clinicians initially raised concerns directly with the Executives at the Hospital. It appears that the events in question were not logged in the serious incident reporting system. NHS England is still considering the evidence from those at the Hospital to understand the arrangements in place at the time for raising concerns. On the basis of its review to date, NHS England notes the following:

87.1. Some witnesses speak positively about the approachability of many in the Executive team and it may have been that this encouraged the clinicians to seek to raise concerns with them directly;

87.2. Several witnesses have commented that the neonatal unit was a 'closed specialty'.[38] The structures arrangements, including divisional governance, in place at the time at the Hospital may not have facilitated internal scrutiny; the neonatal service was a relatively small service within the Urgent Care Division. There was also a divisional split between obstetrics and paediatrics and Dr Stephen Brearey reflects in his evidence on the impact this had.[39] The evidence suggests that it was known within the Hospital that this divisional split was not working and did not reflect the findings of recent Inquiries and Reviews, including Morecambe Bay and the Berwick Review into Patient Safety.

87.3. There seems to have been a perception by some clinicians that the quality and risk management systems were not fit for purpose[40]. The Medical Director's role may have contributed to a sense that the quality and risk systems were 'nurse led', and is likely to be an aspect the Inquiry may want to consider further;

[38] INQ0102622
[39] INQ0103104_0032
[40] INQ0103104, INQ0102622, INQ0101081

87.4. As time went on and the concerns around raised mortality expanded to include concerns about the role an individual had played, the sensitivity of this information may have influenced the way in which information was shared and with whom; and

87.5. The evidence of Dr Stephen Brearey is that, on reflection, there was an over-reliance on internal escalation and he regrets not being more open about the full nature of his concerns with those outside the Hospital.

Raising concerns in complex cases

88. NHS England, working with other partners including the National Freedom to Speak Up Guardian and the Care Quality Commission has considered whether further specific escalation routes are needed in complex cases, such as those involving a combination of potential criminal conduct and patient safety issues. A Task & Finish Group of subject matter experts was convened in November 2023 to explore this issue and specifically:

88.1. Whether the existing escalation routes for raising concerns are adequate;

88.2. Whether in specific cases there should be an additional route of, or a different approach to, escalation.

88.3. If so, to consider what the route would be, the criteria for escalation, responsibilities and immediate actions that would be taken; and

88.4. Agree the process to implement/operationalise such an approach.

89. The consensus of the Task & Finish Group was that no new escalation route or approach was needed. NHS England recognises this will likely be an issue that the Inquiry wishes to explore further and NHS England has suggested below at paragraph 150.3 where improvements could be made to enhance existing routes and ensure consistent application.

90. However, the Group did identify areas where further strengthening of the current system was warranted. These are:

90.1. Assurance: NHS England will use its regional assurance mechanisms to confirm adoption of the national Freedom to Speak Up policy by Integrated Care Board and Provider Boards and that Boards are using the Freedom to Speak Up Leaders Guide to assure themselves that speaking-up arrangements are effective.

90.2. Ways of working: NHS England and the CQC will refresh joint working arrangements to clarify (i) how the two bodies will work together on sharing intelligence and agreeing specific concerns raised with one or both and (ii) what issues/cases Boards would be expected to proactively escalate to NHS England and/or the CQC Strengthened self-certification requirements under the Oversight Framework will also be implemented. Where a provider can no longer meet its self-certification, Boards will be expected (by exception) to inform NHS England and their relevant Integrated Care Board immediately. This could include where a Board becomes aware of serious whistleblowing or speaking up concerns which, if verified, could impact its certification.

90.3. Communications and Engagement: a range of communications activity will be developed, in collaboration with the professional bodies, Royal Colleges, and other bodies, to re-socialise and

educate on Freedom to Speak Up routes. This will include targeted communications on escalation to national bodies.

90.4. Clinical Confidence and Awareness: this will complement the communications and engagement work described above, and will include a focus on health care trainees knowing how and where to raise concerns they have during training placements.

G. The Board, its role and skills *(Chair's Directions, 8e)*

91. The Inquiry has directed NHS England to address the following: (i) what was the Board's involvement in the way concerns about LL were raised by the hospital; (ii) what was the Board's oversight of clinical and corporate governance; and (iii) did the board members have the relevant skills effectively to oversee clinical and corporate governance?

The composition of the Board

92. The Hospital was (and remains) a Foundation Trust. The composition of its Board in the period 2015-2016 reflected the mandatory statutory executive roles[41] which ensure adequate clinical leadership and representation with a Medical Director[42] and Nursing Director[43] alongside a Chief Executive and Finance Director, and non-executive roles (Chair).

93. Foundation Trusts have additional governance in the form of Governors. The Governors, elected publicly, acting as the Council of Governors, are responsible for appointing (and removing) the Chair and non-executive directors. NHS England has no formal role in the appointment of members of a Foundation Trust Board, except in limited circumstances where a Foundation Trust is in receipt of regulatory intervention/support. Foundation Trusts also had (and continue to have) greater flexibility in terms of determining the overall composition of their board, although they would need to report annually against their compliance with the NHS Foundation Trust Code of Governance. Foundation Trusts were also expected to include in their annual reports a description of each director's skills, expertise and experience.[44]

94. The Hospital was authorised as a Foundation Trust in 2004, before changes were made to the authorisation process to reflect learnings from the Mid Staffordshire review and strengthen the checks carried out by Monitor/NHS Improvement in relation to an aspirant Foundation Trust's quality governance. However, Boards of Foundation Trusts authorised before this point, including the Hospital, would still have been required to self-certify that it met these strengthened quality governance requirements. The Well Led guidance recommended that an external developmental review was carried out every three years.

Well Led

95. Monitor's Well Led guidance[45] (updated 2014) describes the respective roles of Monitor and the CQC when assessing whether a Foundation Trust was Well Led. The CQC's inspections were intended to

[41] Schedule 7 of the National Health Service Act 2006
[42] This title is not used in Schedule 7; what is required is an executive director who is a "registered medical practitioner or registered dentist". Most Foundation Trusts use the term "Medical Director" for this role.
[43] This title is not used in Schedule 7; what is required is an executive director who is a registered nurse or registered midwife.
[44] NHS Foundation Trust Code of Governance Updated July 2014, B.1.a, B.1.4
[45] INQ0009237 page 8

provide an 'independent reality check' of patient experience at ward and service level; to assess the effectiveness of a Foundation Trust's arrangements. Monitor did not routinely inspect Foundation Trusts, reliance was placed on self certification or triggers that would otherwise suggest closer scrutiny was needed.

96. One of the ways that Foundation Trusts could assure the CQC as to the effectiveness of their governance arrangements was by providing information about any independent reviews carried out and how they had been acted on. The evidence disclosed to date does not describe any such review but it is clear that a number of changes were made to the Hospital's governance arrangements, including to the composition of the Board's committees, in the period from early 2013 on. One of the aims of these changes was to strengthen non-executive involvement in the Board's governance arrangements.[46]

97. The Well Led guidance describes the four domains of the well-led framework that were intended to inform governance reviews (whether carried out internally or with external support). All four of these domains are relevant, covering: (i) Strategy and planning; (ii) Capability and culture; (iii) Process and structures; and (iv) Measurement.

98. The Well Led guidance describes Foundation Trusts needing to be able to evidence an effective and comprehensive process in place to identify, understand, monitor and address current and future risks[47]. It was expected that the Board regularly reviewed and interrogated complaints and serious untoward incident data.

99. The importance of data received by the Board in being accurate, valid, reliable, timely and relevant was emphasised in the Well Led guidance. This included process expectations around clinical audit and clinical governance, as well as safeguards such as information being able to be traced to source and signed off by owners.

100. In the period prior to the early 2017, when NHS Improvement was made aware by the NHS England North Region Specialised Commissioning Team of concerns about the Hospital's transparency, there were no known regulatory concerns about the Hospital; indeed, it was considered a high-performing Foundation Trust, that was an early adopter of new models of care through its work to achieve 'vanguard' status.

The Countess of Chester Board in 2015-2016

101. The Hospital's Constitution[48] states that the Board will consist of the Chair, 5 non-executive directors, and 6 executive directors. In its Annual Reports for the period 2014-2017, the Hospital confirmed compliance with its Constitution.

<u>Did the board members have the relevant skills effectively to oversee clinical and corporate governance?</u>

102. Several witnesses have reflected on the fact that the Board in 2015 included a high number of new members. In its Annual Report for 2015/16, NHS England notes most of the board had been in place

[46] INQ0101081
[47] INQ0009237 page 27
[48] INQ0003011_0020

for the preceding two years and had the relevant skills and expertise.[49] Of the non-executive directors, however, the Chair was a highly experienced NHS leader and the Non Executive Director who held the Senior Independent Director role had joined the Hospital in November 2011. The other Non-Executive Directors had all been appointed to the Trust relatively recently.

103. Of the executive team, NHS England understands that the CEO, Medical Director and Nursing Director were all being performed by individuals who held these roles for the first time.

104. In their witness statement evidence, the non-executive directors described the training made available to them at induction and the mandatory annual training that all Board members had to do.[50]

105. The board, in composition, was ostensibly balanced. NHS England cannot yet say whether it conducted its meetings to ensure a balance of viewpoints were heard not least because the evidence of the Chair, the four former Executive Directors who have Core Participant status and the Director of Legal and Corporate Governance has either not yet been disclosed or disclosed shortly before the deadline for filing this statement.

What was the board's involvement in the way concerns about LL were raised by the hospital?

106. For this reason, NHS England does also not yet have a full understanding of what the Board's involvement was in the handling of the raising of concerns about LL and it does not, therefore, feel that it can provide a fully informed and final view on what the Board's involvement was at this point in time.

What was the board's oversight of clinical and corporate governance?

107. The arrangements that the Board had in place for clinical and corporate governance seem to have been broadly consistent with what the Code of Governance and Well Led guidance described.

108. The Board had ultimate responsibility for clinical and corporate governance at the Hospital. It had delegated certain responsibilities to committees of the Board, to support it in this role. This was normal and reflected the statutory framework, which enabled the Board's functions to be delegated to committees of its directors.[51]

109. Each committee had non-executive director membership and a non-executive chair. The key committee in terms of clinical governance was the Quality, Safety and Patient Experience Committee ("QSPEC"). There were three NEDs on QSPEC and the chair of this committee throughout the key period in question was also the Hospital's Senior Independent Director.[52]

110. Corporate governance appears to have been largely overseen by a Director of Corporate and Legal Services. In addition to QSPEC, the Audit Committee and the Finance & Governance Committee played a role in overseeing and assuring the Trust's governance arrangements. The Board had also established a Finance & Integrated Governance Committee.

111. The clinical governance and risk management arrangements described by those who supported the Board with these functions also appear to largely reflect the structures and processes that would have been expected. The Board utilised a Board Assurance Framework.

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[49] INQ0004570_0053
[50] INQ0101096, INQ0101323
[51] Schedule 7, The National Health Service Act 2006
[52] INQ0101081

112. Structures were in place for mortality reviews, with Ian Harvey the responsible executive for this. NHS England notes some witnesses have referenced concerns around capacity in relation to these reviews. As further evidence is disclosed, NHS England will be interested to understand more about how the Medical Director's responsibilities for mortality reviews worked alongside the broader quality responsibilities of the Director of Nursing and Quality.

113. There appear to have been challenges around the quality and availability of data. These would not have been unique to the Hospital at the time, although NHS England notes the related concerns some witnesses have expressed about poor version control in relation to key documents and the impact this may have had on review and scrutiny.

114. NHS England will keep its assessment of the Board's conduct under review as further evidence becomes available.

Subsequent appointments

115. NHS England's role in relation to subsequent appointments held by former members of the Hospital Board is described in NHSE/2 and in the witness statement evidence given by current and former Regional Directors. The role of two bodies accountable to NHS England, NHS Interim Management and Support and the NHS Leadership Academy, is also described in NHSE/2.[53]

116. Since the establishment of the first Foundation Trusts (which included, in 2004, the Hospital), appointments to their senior leadership teams have routinely been independent of any regulatory body (the exception being where a Foundation Trust was in 'special measures' or was subject to other regulatory intervention in relation to its leadership/governance arrangements). Instead, Governors (acting as the Council of Governors) play a crucial role in relation to appointments, particularly in relation to the Chair. This was the case in the period 2004-2022 when Monitor/NHS Improvement was the regulator and it remains the case today now that NHS England has the responsibilities previously held by Monitor.

117. The responsibilities of Foundation Trusts, as the appointing organisation, are set out in NHSE/2 but in summary now include carrying out reference checks and ensuring that it complied with the requirements of the fit and proper persons test. NHS England will often support this process, including through utilising Regional Director contacts to contribute to the appointments process, but it is not responsible for determining whether a candidate is appointable or not.

118. NHS England has described in its witness evidence its awareness in relation to subsequent appointments held by former Board members. The most substantive involvement that NHS England has had is in relation to the former Chief Executive Officer, Tony Chambers. It had also some awareness of the steps taken by Alison Kelly's current employer, the Northern Care Alliance. Having reflected on the subsequent appointments held, it is apparent to NHS England that the reference check and FPPT process was not as developed and effective as it could have been. This meant that there was insufficient consideration given to individuals' roles at the Hospital. NHS England has recognised this and strengthened the FPPT Framework to include a new Board Member reference template, which

[53] INQ0014552

requires greater consideration of all previous roles held (not just those within the immediate period prior to the appointment under consideration).

119. NHS England will keep its assessment of former Board member conduct under review as further evidence becomes available.

H. Management in the NHS and Regulation *(Chair's Directions, 8f)*

120. The Inquiry has asked that Core Participants consider the following:

120.1. Were senior managers held accountable for decisions made?

120.2. Was this good enough to keep babies safe?

120.3. What is the current position and could it be improved?

120.4. How should accountability of senior managers be strengthened?

120.5. Should they be regulated?

121. Taking these points in turn, NHS England submits as follows.

Were senior managers held accountable for decisions made?

122. NHS England takes "senior manager" to mean individuals holding a management role who would have been subject to the fit and proper person test. Regulation 5 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 is the applicable statutory framework for the fit and proper person test and, by virtue of Regulation 5(2), it applies to individuals who are directors or who perform the functions or, or equivalent or similar to, the functions of a director.

123. In NHS England's view, this in practice means that the primary focus of this question is on members of the Board and deputy directors. On this basis, NHS England's understanding is that no senior manager in post at the Hospital at time of offences and their immediate aftermath has been held formally accountable in relation to these events. NHS England understands that there are ongoing regulatory investigations in relation to the former Director of Nursing and Quality by her professional regulatory body, the Nursing and Midwifery Council. The former Medical Director retired and sought to voluntarily give up his professional registration in 2020. The General Medical Council investigated the concerns raised about him and the case was closed with no further action, although his professional registration has now been relinquished.

124. To the best of NHS England's knowledge, no other members of the Board were subject to professional regulation at the time, although NHS England is not clear when any professional registration held by Tony Chambers was relinquished.

125. Aside from referral to a professional regulatory body, and in the case of a Foundation Trust, there are two other key ways in which an individual holding a senior management role could have been held accountable: (i) through disciplinary action being taken by the individual's employer; and/or (ii) through a finding (by the employer) that the individual was no longer fit and proper for the purposes of Regulation 5.

Was this good enough to keep babies safe?

126. Individuals who have failed to meet the standards expected of them as senior managers should be held accountable. NHS England was assured at the time that steps had been taken to minimise risks to neonatal babies at the Hospital, including through the changing of the Hospital's designated level of neonatal care and enhanced scrutiny of the unit, overseen by the North Specialised Commissioning Regional team. Assurance was also taken from the commencement of the Police investigation and the subsequent inspection by the CQC (which resulted in regulatory action being taken by both the CQC and NHS England).

127. NHS England's limited knowledge of what had taken place at the Hospital meant that NHS England did not know about the concerns that have subsequently come to light around risk management, incident reporting and governance more broadly.

128. NHS England has also reflected on how information was shared between Regional and National teams and whether this meant that there were missed opportunities to contribute to earlier processes through which the accountability of individuals was considered. There are two particular issues that NHS England has identified in this context. The first is that briefings given to members of NHS England's National teams were often high-level and in many cases repeated the Hospital's position on, for instance, what the RCPCH review said. The other issue seems to have been a concern about compromising the Police investigation and a wariness as a result about sharing information on a need-to-know basis within NHS England. The impact of these concerns is illustrated particularly in the evidence of NHS England's Regional Directors.

129. While NHS England remains of the view that it was reasonable, pending a conclusion of the Police investigation, for any investigation/review of individual conduct to remain open, it has identified missed opportunities where assurance could have been sought in relation to senior managers. Key missed opportunities that NHS England has identified include:

    129.1. The acceptance of the explanation provided regarding Tony Chamber's departure from the Hospital.

    129.2. Not asking the Trust whether it had carried out a FPPT assessment, for those Board members in post in the period 2015-2017.

    129.3. Not asking the Trust whether it had reviewed whether any referrals were required in relation to any of the professionally regulated Board members to their professional regulatory bodies.

    129.4. Not 'joining the dots' when police and regulatory action was taken in 2018 with what that meant for historic events in the earlier period and the role of senior leaders at that time.

130. As part of its work to implement the recommendations made by Tom Kark KC in his 2019 review of the Fit and Proper Persons Test (and as described further below) NHS England has recognised that the systems and processes in place through which the FPPT was applied and relevant information retained and shared were not as robust as they could have been.

<u>What is the current position and could it be improved?</u>

131. The CQC remains the responsible statutory body in relation to the statutory framework for assessing whether an individual is fit and proper to hold a senior management role in the NHS.

132. NHS England has taken steps, however, to strengthen the Fit and Proper Persons Framework. In September 2023, as part of its work to implement the recommendations made by Tom Kark KC in his 2019 review of the Fit and Proper Persons Test, NHS England published the Fit and Proper Person Test Framework ("The FPPT Framework"). The FPPT Framework addressed the lack of a structured means through which information relating to the testing of the requirements of the FPPT could be retained and shared with prospective future NHS employers. It also included a set of standard competencies for all board directors and expanded the scope of the FPPT, to include NHS England, the CQC and Integrated Care Boards.

133. It is reasonable to assume that if the strengthened FPPT Framework had been in place at the time, those individuals who held senior management roles and who moved from the Hospital to new senior roles within the NHS would have been subject to greater scrutiny. However, there are complexities arising where there are ongoing police investigations that have a bearing on the events in question. NHS England notes, for instance, that the Facere Melius review was paused on request by the Police; no factual accuracy check process was therefore undertaken and the conclusions of the review were not shared in the way that they might otherwise have been. It does not follow, therefore, that the review findings would have been added to any Board member reference held by the Hospital in relation to an individual in post at the time and whose conduct was questioned by Facere Melius.

<u>How should accountability of senior managers be strengthened and should they be regulated?</u>

134. NHS England has addressed these two questions together. NHS England agrees that further regulation of NHS managers should be explored. However, any strengthened accountability measures, including regulation, need to be accompanied by the appropriate support, training and investment in NHS leaders, to make sure they are able to carry out these very complex scrutinised roles. NHS England continues to actively develop guidance and training for NHS leaders and it will be able to update the Inquiry in due course on these developments.

135. Any further regulation introduced will need to consider:

    135.1. duplication and differentiation: many NHS managers (including at least two of the Core Participants) are already regulated professionals by virtue of their clinical background;

    135.2. the entry level of regulation: the cohorts of managers in scope of regulation and to what standards needs to be determined.

    135.3. the identity of the regulator, how it will operate and its interaction with the existing professional regulatory bodies;

    135.4. the balance between accountability and development and improvement;

    135.5. fairness and proportionality to ensure that any system does not introduce unnecessary barriers for existing NHS staff or those moving into leadership roles from other industries.

Prevention of similar criminal conduct

136. The Inquiry has directed Core Participants to reflect on how the murders and injuries to babies that took place at the Hospital may have been prevented.

137. We note that Professor Dixon-Woods recommends, in paragraph 10 of her expert evidence, that transgressive behaviour is a distinct class of patient safety risk and that systems be designed and implemented to manage this. NHS England agrees, as set out at paragraph 3 above, that a greater willingness to openly plan for the possibility of this very rare behaviour may be needed.

138. There have been a number of measures introduced in the period since 2016 that NHS England considers provide further safeguards against criminality, as deterrent and/or detection. These measures include in particular:

    138.1. Enhanced external scrutiny through the implementation of the national Medical Examiners system and more active incident monitoring by Operational Delivery Networks, working to a formal specification which sets out NHS England's expectations about this role and relationship, addressing the lack of clarity around this aspect that existed in the 2015-2016 period;

    138.2. Strengthened internal assurance within each NHS Trust and NHS Foundation Trust, through the Maternity and Neonatal Champion role, which supports a more open culture of incident reporting and system-based review, risk-led action and improvement from ward to Board;

    138.3. Faster and more advanced signalling tools;

    138.4. Defined governance to support interpretation of signals through the Perinatal Quality Surveillance Model;

    138.5. A new way of responding to patient safety incidents, through the Patient Safety Incident Response Framework and associated changes to the reporting systems used.

139. There are further steps that could be taken to strengthen these safeguards, particularly in relation to early warning and signalling systems in a neonatal context. The importance of such systems has been recognised in many previous inquiries, investigations and reviews, including Shipman and Kirkup. No such system existed for neonatal care in 2015-2016. In the period since, data systems and tools have continued to develop, and this work remains ongoing. The Perinatal Quality Surveillance Model implemented by NHS England in 2020 is designed to provide for consistent and methodical oversight of all perinatal services, including neonatal services, and would provide the necessary governance to accompany the mandatory use of a signalling tool in neonatal services.

I. Previous Inquiries *(Chair's Directions, 8h)*

140. The publication of the Inquiry's Table of Previous Inquiries Recommendations highlights the number and scale of recommendations that have been made in the period since 1964 and attempts to assess their implementation. NHS England is aware of ongoing work being done by the Health Services Safety Investigations Body in this area and understands that it is intends to publish shortly a report on how to improve the effectiveness of quality and safety recommendations in healthcare.

141. Sir Robert Francis highlights in his expert evidence the difficulties of this kind of assessment, a 'formidable' task, and himself takes a broader approach to assess if meaningful change has been made. In his view, many of the recommendations are rolled up in policy approaches, frameworks and legislative restructures that address the intention of the recommendations.

142. The effectiveness of local implementation will inevitably be variable. Even in the few instances where recommendations identify a clear owner and require a specific and clear action to implement, such as the introduction of a new role, the effectiveness of the new role in practice depends on other factors, including the individual appointed to it; support and training made available to them; the culture within the organisation. Implementing a system to ensure all the various bodies in the NHS address their 'part' of a recommendation is often hampered by the very nature of the recommendation itself, lacking specificity of owner, scope and measurability.

143. However, recognising the public interest in the Table, NHS England with DHSC is now working to provide a more informative update on the state of implementation for each recommendation. An updated Table will be submitted to the Inquiry prior to the commencement of Part C of the Hearings.

J. Remedial Actions *(Chair's Directions, 10a)*

144. As described above, there have been a number of significant changes in the period since 2015-2016. Many of the remedial actions that the events at the Hospital might have raised as being needed were already underway, often as part of responding to the recommendations of previous inquiries.

145. It may, therefore, appear that there are only a small number of directly attributable remedial actions as a result of this specific case. However, NHS England has also reflected on whether actions already taken or underway are sufficient and in some cases, the events at the Hospital underscored the need for remedial action.

146. NHS England will continue to actively reflect and identify areas for further remedial action as the Inquiry progresses. A number of immediate new remedial actions have already been taken specifically in the wake of the August 2023 verdicts. These include:

    146.1. Facilitating targeted task and finish group discussions to determine what remedial actions might need to be taken. This included in particular:

        146.1.1. A task and finish group on External Freedom to Speak Up Routes in Very Serious Cases; and

        146.1.2. Regulation of managers.

    146.2. Supporting a Ministerial commission on the issue of insulin use on neonatal wards, current practice and what actions (if any) might need to be considered to address any safety concerns identified.

    146.3. Publication of the strengthened Fit and Proper Persons Framework.

    146.4. Ongoing implementation of the recommendations made in the Kark and Messenger reviews, including:

        146.4.1. the development of a new, multi-disciplinary NHS Management and Leadership Framework, which will be accompanied by a new Code of Practice for all managers and leaders, with clear standards and competencies for all levels of managers.

146.4.2. Co-production of the Insightful Board, guidance to support NHS boards on their effective operation, informed by concerns around the need for all boards to operate proportionately and with sufficient curiosity.

146.4.3. Continued work, in the context of the Maternity and Neonatal Three Year Delivery Plan to drive improvements in the safety and effectiveness of maternity and neonatal services.

147. NHS England also supported the Health and Care Act 2022, which includes the remedial structural changes discussed in this statement relating to the merging of provider regulation and commissioning, and the abolition of the duty of autonomy.

148. Finally, it is noted that the decision was taken prior to the verdict to expand the Maternity Programme to include the appointment of a Lead Neonatal Nurse and National Clinical Director role).

Recommendations (j)

149. NHS England has set out in its corporate evidence and this Opening Statement the areas in which it is currently working to improve patient safety. These include in particular:[54]

149.1. Better learning from incidents, which the Learn from Patient Safety Events Service has been designed to enhance.

149.2. Better reporting through the implementation of the Continued active implementation and evaluation of the Patient Safety Incident Response Framework, along with the work the National Clinical Director for Neonatology is doing with the British Association of Perinatal Medicine to develop a framework for the reporting of neonatal mortalities.

149.3. More effective and real time monitoring. The work arising from the Reading the Signals Report is ongoing and the Perinatal Quality Surveillance Model will provide mandated governance in relation to both the MBRRACE-UK real time monitoring tool and MOSS (which is still in the process of being developed for maternity care).[55] There is also ongoing work with the National Guardian's Office to enhance data reporting and monitoring.

150. In addition, NHS England recognises that there are some additional areas where the Inquiry may wish to consider making recommendations to address some of the missed opportunities discussed in this Opening Statement. These include:

150.1. A requirement for a minimum number of non-executive directors on the board of a Trust to have a clinical background, and for one of those directors to chair the Trust's Quality Committee.

150.2. Further guidance and training be provided to NHS staff to deal with concerns about unexplained clinical events resulting in patient harm and/or near misses, including a framework for reporting these concerns to the police. A new Memorandum of Understanding between the police and NHS may also assist in this regard.

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[54] INQ0017495_0385 paragraph 1018

[55] Dr Murdoch explains at paragraph 41 of her statement that the Maternity and Neonatal Outcomes Group considered whether to extend MOSS to include all neonatal deaths, but this was not deemed necessary as the MBRRACE-UK real time monitoring tool has this function. For this reason, both MOSS and the MBRRACE-UK real time monitoring tool will be used together, using the same guidelines and governance, to enhance safety signal system use and interpretation. See INQ0107010_0013

150.3. A new duty on providers to share invited clinical reviews with, and report suspected criminality or significant unexplained events where patient harm is identified to, other statutory bodies such as NHS England, ICBs and the CQC. NHS England notes in this regard that the Department of Health and Social Care is also currently considering the operation (including compliance and enforcement) of the statutory duty of candour for health and social care providers in England.

150.4. Existing social media, communication, and professional policies, including those of professional bodies such as the GMC and NMC, should be strengthened to ensure appropriate use and increase safeguards around the sharing of information.

151. NHS England will continue to reflect on these recommendations during the oral evidence provided during the Inquiry and will make any further suggestions for recommendations in its Closing Statement. This includes whether additional provision should be made to provide psychological support for families and members of staff in neonatal units.

Closing Remarks

152. At the heart of this Inquiry are the families whose babies were harmed or killed by LL at the Hospital. On behalf of the NHS, NHS England apologises to these parents and other family members that this occurred, and for the mistakes and system failures in the way that these incidents were reported and investigated. NHS England also apologises for the missed opportunities mentioned in this Opening Statement to detect and prevent the increase in unexpected and unexplained declines and deaths on the neonatal unit; the lack of compassion and candour in the way that information was shared and questions answered; and for the lack of support provided to families and all those affected by these awful events. NHS England is committed to listening, learning and implementing change where it is found to be needed as a result of this Inquiry.

NHS England
30 August 2024