



The Report of the Morecambe Bay Investigation

Dr Bill Kirkup CBE

March 2015

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An independent investigation into the management, delivery and outcomes of care provided by the maternity and neonatal services at the University Hospitals of Morecambe Bay NHS Foundation Trust from January 2004 to June 2013

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Introduction

For the great majority, pregnancy and childbirth should be a positive and happy experience that culminates in a healthy mother and baby. This means, however, that on those occasions when things do go wrong, the effects are even more devastating than in other areas of healthcare. Maternity care must reconcile these dual aspects in order to be safe, effective and responsive. When it does not, the consequences may be stark.

This Report details a distressing chain of events that began with serious failures of clinical care in the maternity unit at Furness General Hospital, part of what became the University Hospitals of Morecambe Bay NHS Foundation Trust. The result was avoidable harm to mothers and babies, including tragic and unnecessary deaths. What followed was a pattern of failure to recognise the nature and severity of the problem, with, in some cases, denial that any problem existed, and a series of missed opportunities to intervene that involved almost every level of the NHS. Had any of those opportunities been taken, the sequence of failures of care and unnecessary deaths could have been broken. As it is, they were still occurring after 2012, eight years after the initial warning event, and over four years after the dysfunctional nature of the unit should have become obvious.

This Report includes detailed and damning criticisms of the maternity unit, the Trust and the regulatory and supervisory system. In view of the progress that is now undoubtedly being made in all these areas, the necessity for this Investigation to lay bare all of this may perhaps be questioned, both by Trust staff (who undoubtedly feel beleaguered) and by others. There are two reasons to resist this view. First, although the signs of improvement are welcome, they are still at an early stage and there have been previous false dawns in the Trust; this emphasises the importance of understanding fully the extent and depth of the changes necessary. Second, there is a clear sense that neither the Trust nor the wider NHS has yet formally accepted the degree to which things went wrong in the past and admitted it to affected families; until this happens, there is little prospect of those families accepting that progress can be made.

These events have finally been brought to light thanks to the efforts of some diligent and courageous families, who persistently refused to accept what they were being told. Those families deserve great credit. That it needed their efforts over such a prolonged period reflects little credit on any of the NHS organisations concerned. Today, the name of Morecambe Bay has been added to a roll of dishonoured NHS names that stretches from Ely Hospital to Mid Staffordshire. This Report sets out why that is and how it could have been avoided. It is vital that the lessons, now plain to see, are learnt and acted upon, not least by other Trusts, which must not believe that 'it could not happen here'. If those lessons are not acted upon, we are destined sooner or later to add again to the roll of names.

BILL KIRKUP CBE

March 2015

Executive summary

- 1.** The Morecambe Bay Investigation was established by the Secretary of State for Health to examine concerns raised by the occurrence of serious incidents in maternity services provided by what became the University Hospitals of Morecambe Bay NHS Foundation Trust (the Trust), including the deaths of mothers and babies. Relatives of those harmed, and others, have expressed concern over the incidents themselves and why they happened, and over the responses to them by the Trust and by the wider National Health Service (NHS), including regulatory and other bodies.
- 2.** We have carried out a thorough and independent investigation of these events, covering the period from 1 January 2004 to 30 June 2013. The Investigation Panel included expert advisors in midwifery, obstetrics, paediatrics, nursing, management, governance and ethics. We reviewed 15,280 documents from 22 organisations, and we interviewed 118 individuals between May 2014 and February 2015. Family members of those harmed were invited to attend interviews and Panel meetings as observers.
- 3.** Our findings are stark, and catalogue a series of failures at almost every level – from the maternity unit to those responsible for regulating and monitoring the Trust. The nature of these problems is serious and shocking, and it is important for the lessons of these events to be learnt and acted upon, not only to improve the safety of maternity services, but also to reduce risk elsewhere in NHS systems.
- 4.** The origin of the problems we describe lay in the seriously dysfunctional nature of the maternity service at Furness General Hospital (FGH). Clinical competence was substandard, with deficient skills and knowledge; working relationships were extremely poor, particularly between different staff groups, such as obstetricians, paediatricians and midwives; there was a growing move amongst midwives to pursue normal childbirth ‘at any cost’; there were failures of risk assessment and care planning that resulted in inappropriate and unsafe care; and the response to adverse incidents was grossly deficient, with repeated failure to investigate properly and learn lessons.
- 5.** Together, these factors comprised a lethal mix that, we have no doubt, led to the unnecessary deaths of mothers and babies. We reviewed cases, including all the maternal deaths and deaths of babies in the period under investigation, using a validated method, and found 20 instances of significant or major failures of care at FGH, associated with three maternal deaths and the deaths of 16 babies at or shortly after birth. Different clinical care in these cases would have been expected to prevent the outcome in one maternal death and the deaths of 11 babies. This was almost four times the frequency of such failures of care at the Royal Lancaster Infirmary.
- 6.** These problems did not develop overnight, and the first sign of their presence occurred in 2004, when a baby died from the effects of shortage of oxygen, due to a mismanaged labour. Serious incidents happen in every health system because of the nature of healthcare, and no blame should be attached to staff who make mistakes. It is, however, vital that incidents are properly investigated, in order to identify problems and prevent a recurrence. The investigation in 2004 was rudimentary, over-protective of staff and failed to identify underlying problems.

7. Between 2004 and the end of 2008, there was a series of further missed opportunities to identify problems in the unit. Between 2006 and 2007, five more serious incidents occurred that showed evidence of problems similar in nature to the 2004 incident; investigations followed the same inadequate process and failed to identify problems. At this time, the failures of working relationships, approach and clinical competence affecting the maternity service must have been clear to senior and experienced unit staff, but we could find no attempt to escalate knowledge of this to the level of the Trust executives and Board.

8. A cluster of five serious incidents occurred in 2008: a baby damaged by the effects of shortage of oxygen in labour; a mother who died following untreated high blood pressure; a mother and baby who died from an amniotic fluid embolism; a baby who died in labour due to shortage of oxygen; and a baby who died from unrecognised infection. All showed evidence of the same problems of poor clinical competence, insufficient recognition of risk, inappropriate pursuit of normal childbirth and failures of team-working, as seen previously. Initial investigation was again deficient and failed to identify manifest problems.

9. The 2008 incidents, however, did signal unmistakably to the Trust executives and Board that all was not well with the unit. A letter from a consultant obstetrician set out concerns raised by one of the incidents to the clinical director and medical director, but failed to prompt any documented reaction. A complaint arising from another incident that was felt likely to generate adverse publicity was reported to the Board, and an external investigation was commissioned. Although this was based only on written statements and clinical records and therefore missed some important points, it did unequivocally identify systemic failings for the first time.

10. Many of the reactions of maternity unit staff at this stage were shaped by denial that there was a problem, their rejection of criticism of them that they felt was unjustified (and which, on occasion, turned to hostility) and a strong group mentality amongst midwives characterised as ‘the musketeers’. We found clear evidence of distortion of the truth in responses to investigation, including particularly the supposed universal lack of knowledge of the significance of hypothermia in a newborn baby, and in this context events such as the disappearance of records, although capable of innocent explanation, concerned us. We also found evidence of inappropriate distortion of the process of preparation for an inquest, with circulation of what we could only describe as ‘model answers’. Central to this was the conflict of roles of one individual who inappropriately combined the functions of senior midwife, maternity risk manager, supervisor of midwives and staff representative.

11. We make no criticism of staff for individual errors, which, for the most part, happen despite their best efforts and are found in all healthcare systems. Where individuals collude in concealing the truth of what has happened, however, their behaviour is inexcusable, as well as unprofessional. The failure to present a complete picture of how the maternity unit was operating was a missed opportunity that delayed both recognition and resolution of the problems and put further women and babies at risk. This followed the earlier missed opportunities to identify underlying problems in 2004 and 2006/07.

12. By the early part of 2009, there was clearly knowledge of the dysfunctional nature of the FGH maternity unit at Trust level, but the response was flawed, partly as a result of an inadequate flow of information through professional and managerial reporting lines. Clinical governance systems throughout the Trust were inadequate. The 2008 incidents were treated as individual unconnected events, and no link was made with previous incidents. Inappropriate reliance was placed on poor-quality internal investigations and, in one case, on a report on cause of death prepared for the coroner. Supervisor of midwives investigations were flawed, relying on poor-quality records that conflicted with patients’ and relatives’ accounts. An external review of the governance of the unit was carried out. Although tangential to the underlying issues, this identified the dysfunctional nature of professional relationships in the unit.

13. At the same time, in early 2009, the Trust was heavily focused on achieving Foundation Trust (FT) status, and this played a significant part in what transpired. As part of the application, the Trust listed its current serious untoward incidents, and declared 12, five in FGH maternity services. This alerted Monitor, which informed the North West Strategic Health Authority (NW SHA) and the newly formed Care Quality Commission (CQC). Monitor deferred the FT application, pending a response to its concerns about the Trust's maternity services.

14. A member of NW SHA staff questioned whether there was a gap in understanding of the five 2008 incidents, and whether they should be investigated. These were the right questions, but in implementing what became the Fielding review, the Trust not only shifted the emphasis away from what had happened and onto current systems, but also instructed Dame Pauline Fielding not to investigate the incidents. Despite stating that the review had not re-examined the incidents, the Fielding Report unwisely stated that they appeared "*coincidental rather than evidence of serious dysfunction*". This was easily misread as a finding of the review, and was widely misunderstood as a result.

15. The review report was produced in draft in March 2010, but what was described as minor redrafting took until August 2010 to finalise. It contained significant criticisms of the Trust's maternity care, including dysfunctional relationships, poor environment and a poor approach to clinical governance and effectiveness. The report was given very limited circulation within the Trust, and was not shared with the NW SHA until October 2010, or with the CQC and Monitor until April 2011. Although we heard different accounts, and it was clear that there was limited managerial capacity to deal with a demanding agenda, including the FT application, we found on the balance of probability that there was an element of conscious suppression of the report both internally and externally. This was a further significant missed opportunity.

16. The NW SHA adopted a developmental approach to Trusts in its region, and was significantly less effective at intervening when problems emerged. This shaped its dealings with the Trust, and it accepted assurances that there were no systemic problems and that action plans were in place following the governance review and the external investigation of the most high-profile 2008 case. Crucially, it also accepted the view that the 2008 incidents were 'coincidental' and it erroneously regarded the Fielding Report, when it finally received it, as confirming this view. This view formed the basis of the NW SHA's briefing, including to the Department of Health (DH). Had it adopted a more 'hands-on' approach, it is likely that both the implementation of action plans and the unconnected nature of the incidents would have been challenged. This was another missed opportunity.

17. When Monitor suspended the Trust's FT application in 2009, it looked to the CQC as the arbiter of clinical quality, including patient safety. The CQC, a new organisation at that point, adopted a generic approach to utilising its staff, many of whom were from a social care background, and its North West team had little experience of the NHS. It referred the Trust to the central CQC office for a potential investigation into the maternity incidents. The CQC investigation team declined the referral, principally on the grounds that the five incidents were deemed unconnected on the basis of superficial information on cause of death, but also because it was not thought that there were systemic problems. Had the investigation progressed to the next stage of information-gathering, it would have become clear that both assumptions were mistaken. This was a further missed opportunity.

18. Nevertheless the North West CQC team still had concerns about the Trust and gave it a 'Red' risk rating, which kept the FT application suspended, and Monitor told the Trust that the rating had to be 'Green' to restart the application.

19. At this point in 2009, the Parliamentary and Health Service Ombudsman (PHSO) was considering a complaint from James Titcombe, the father of Joshua, who had died in 2008 as a result of infection that was missed for almost 24 hours in FGH, despite clear signs. The Ombudsman formed the correct view that this constituted clear evidence of systemic problems in the maternity unit, and that the CQC was better placed to investigate this than the PHSO. What followed was a series of failed communications between the PHSO and the CQC – and, more significantly, within the CQC – which led the PHSO to believe that the CQC would take robust action and that a PHSO investigation of the complaint would add nothing significant. With hindsight, a CQC investigation would not have addressed Mr Titcombe's concerns, which calls into question the linking of the Ombudsman's decision not to investigate with the CQC's intentions. This was another missed opportunity.

20. Towards the end of 2009, it was clear that the North West CQC's concerns about the Trust were declining, and the Trust's risk rating was reduced from 'Red' to 'Amber' on the basis that the 2008 incidents were unconnected and that action plans were in place. In December 2009, the CQC was still signalling that it would use the registration process to ensure robust action by the Trust. All NHS providers were required to register with the CQC from April 2010, and where there were significant concerns, this was made conditional on further action and inspection, as happened with 22 Trusts out of a total of 378. By March 2010, however, there had been a striking change of approach, which coincided with the arrival of a new North West CQC head, and the Trust was put forward for registration with only minor concerns. Although this was challenged by the CQC's central registration panel on the grounds of the recent significant concerns, the regional team maintained that the problems were being addressed. On the basis of this poor appraisal of the position, the Trust was registered without conditions from April 2010, another missed opportunity.

21. The CQC reduced the Trust's risk rating to 'Green' in the following month, and the FT application process restarted. As the application had been deferred in 2009, rather than rejected, the Trust did not go through the quality assessment newly introduced by the DH in the aftermath of the Mid Staffordshire affair, and the DH received legal advice that it should not intervene, as the application had already received the Secretary of State's approval in 2009. Monitor approved the Trust for FT status in September 2010. This was another missed opportunity to ensure an effective assessment of service quality.

22. Four events in 2011, partly interrelated, changed this position and brought the significant problems in the Trust unmistakably to wider attention. First, the CQC and Monitor obtained the Fielding Report, which confirmed the existence of systemic problems. Second, the coroner's verdict in the inquest into the death of Joshua Titcombe was strongly critical not just of the failures of care, but also of the dysfunctional relationships between staff groups, of the collaboration between staff in preparing their evidence, and of the loss of a significant observation chart. Third, a police investigation was commenced, and subsequently widened, to examine other deaths. Fourth, other families came forward in response to the police investigation, revealing that many more families had been affected than had been thought.

23. The result was a significant upturn in the external level of concern in the Trust, and an intense period of intervention from 2011 into 2012. Monitor deemed the Trust to be in breach of its terms of authorisation as a Foundation Trust, and commissioned two major external reviews. One was critical of dysfunctional clinical working, the other of inadequate and ineffective clinical governance. The CQC also reviewed the Trust, and the NW SHA called a 'Gold Command'. The outcome, from mid-2012 onwards, was an almost entirely new senior management team in the Trust, and a new approach.

24. We found welcome signs of significant recent improvement in the Trust, including its maternity services and governance, and we believe that external systems are much better placed to detect failed services and to intervene, including particularly the CQC. Nevertheless, significant progress remains to be made in our view, and it is essential that change is sustained and built upon.

25. Our conclusion is that these events represent a major failure at almost every level. There were clinical failures, including failures of knowledge, team-working and approach to risk. There were investigatory failures, so that problems were not recognised and the same mistakes were needlessly repeated. There were failures, by both maternity unit staff and senior Trust staff, to escalate clear concerns that posed a threat to safety. There were repeated failures to be honest and open with patients, relatives and others raising concerns. The Trust was not honest and open with external bodies or the public. There was significant organisational failure on the part of the CQC, which left it unable to respond effectively to evidence of problems. The NW SHA and the PHSO failed to take opportunities that could have brought the problems to light sooner, and the DH was reliant on misleadingly optimistic assessments from the NW SHA. All of these organisations failed to work together effectively and to communicate effectively, and the result was mutual reassurance concerning the Trust that was based on no substance.

26. We found at least seven significant missed opportunities to intervene over the three years from 2008 (and two previously), across each level – from the FGH maternity unit upwards. Since 2008, there have been ten deaths in which there were significant or major failures of care; different clinical care in six would have been expected to prevent the outcome. We have made recommendations for both the Trust and the wider NHS that will, if implemented, ensure that the lessons that are clear are acted upon to reduce risk and improve the quality of maternity and other services.

CHAPTER ONE: Investigation findings

Dysfunctional maternity unit

1.1 The maternity department at Furness General Hospital (FGH) was a dysfunctional unit, to an extent that damaged its ability to provide safe and effective care. The problems fell in five principal areas.

1.2 First, the clinical competence of a proportion of staff fell significantly below the standard required for a safe, effective service. Essential knowledge was lacking in several important aspects, local and national guidelines were followed inconsistently, and we discovered repeated instances of failure to apply basic principles of maternity and paediatric care. We found clear instances of substandard clinical practice amongst midwives, obstetricians and paediatricians. This particularly included, but was not limited to, failures to recognise warning signs in pregnancy, in labour and in newborn babies that should clearly have signalled problems. On other occasions, warning signs were recognised but were not acted on appropriately. Some of the examples of failures of care that we saw in clinical records and heard about from staff were both shocking and saddening.

1.3 Second, the working relationships between different groups of staff were extremely poor. Maternity care requires close multidisciplinary working, particularly between midwives, obstetricians and paediatricians, to ensure a good outcome for both mother and baby. We found that none of these groups were able to work effectively together, with repeated instances of failure to communicate important clinical information about individual patients. We were told that there was a “*them and us*”¹ culture in the unit. There were instances when clinical care was compromised in this way by the handover of one staff member to another and by the move to another phase of care, such as following delivery. Clinical records were extremely poor and often written in retrospect (sometimes several days later), also jeopardising the necessary transfer of vital information. As well as individual care, poor working relationships hampered the development of the unit. Multidisciplinary meetings, whether to discuss clinical policies or to examine poor outcomes, were difficult to arrange, took place infrequently, and were often poorly attended by one or more staff groups. NHS staff have a professional duty to work together effectively for the benefit of those they are caring for, and we were dismayed to hear the extent to which obstetricians, midwives and paediatricians had allowed the breakdown of personal and interdisciplinary relationships to jeopardise care.

1.4 Third, midwifery care in the unit became strongly influenced by a small number of dominant individuals whose over-zealous pursuit of the natural childbirth approach led at times to inappropriate and unsafe care. One interviewee told us that “*there were a group of midwives who thought that normal childbirth was the... be all and end all... at any cost... yeah, it does sound awful, but I think it's true – you have a normal delivery at any cost*”.² Another interviewee “... was aware that there were certain midwives that would push past boundaries”.³ A third told us that there were “... a couple of senior people who believed that in all sincerity they were processing the agenda as dictated at the time... to uphold normality... there've been one or two influential figures who've

¹ Joan Moorby interview.

² Lindsey Biggs interview.

³ Joan Moorby interview.

perpetrated that... sort of approach and... there's nobody challenging...".⁴ Whilst natural childbirth is a beneficial and worthwhile objective in women at low risk of obstetric complications, we heard that midwives took over the risk assessment process without in many cases discussing intended care with obstetricians, and we found repeated instances of women inappropriately classified as being at low risk and managed incorrectly. We also heard distressing accounts of middle-grade obstetricians being strongly discouraged from intervening (or even assessing patients) when it was clear that problems had developed in labour that required obstetric care. We heard that some midwives would *"keep other people away, 'well, we don't need to tell the doctors, we don't need to tell our colleagues, we don't need to tell anybody else that this woman is in the unit, because she's normal'"*.⁵ Over time, we believe that these incorrect and damaging practices spread to other midwives in the unit, probably quite widely. Obstetricians working in the unit were well-placed to observe these lapses from proper standards, and it is clear that they did, but seemingly lacked the determination to challenge these practices. This in turn represents a failure to maintain professional standards on their part.

1.5 Fourth, advice to mothers that it was appropriate to consider delivery at FGH was significantly compromised by a failure to assess the risks properly. Neonatal paediatric services at FGH were staffed and equipped to provide a restricted range of neonatal care, but not to deal with more pre-term babies who needed more intensive forms of care. Whilst we recognise that there will be rare occasions when a mother arrives too advanced in labour to be safely transferred, it is clear that this was used as an excuse to deliver at FGH many other women whose babies were manifestly at too high a risk for this to be safe. Further, when babies were born who were very likely to need a high level of neonatal care, either as a result of this policy or through problems in labour or delivery, FGH paediatricians often adopted a 'wait and see' approach. Such babies may be relatively well during the first hours of life but then deteriorate rapidly to the point where highly intensive care is required: as a result of the 'wait and see' approach, this necessitated difficult emergency transfers of very sick babies which could have been prevented had transfer been arranged immediately and effected within the first few hours.

1.6 Fifth, the response from unit clinicians to serious incidents was grossly deficient. In maternity care, as in other areas of clinical practice, it is essential that incidents where something has gone wrong are properly looked at to determine what happened, what was the root cause and what can be done to prevent recurrence. This must be done across all relevant staff groups using a multidisciplinary approach, particularly when care depends on close team-working as in maternity services. The approach in the FGH unit fell far short of requirements. Investigations were almost always unidisciplinary, and were often carried out by the same senior midwife. Many reports that we saw were extremely brief, failed to identify key failures of care, and showed evidence of adopting an inappropriately protective approach to midwives. In those instances where other staff groups were involved, it seemed that defensive 'blame-shifting' behaviour predominated, and there was little visible dissemination of lessons learnt afterwards. Although some of the incidents involved outcomes that would be regarded seriously in any maternity unit, including maternal deaths, intrapartum stillbirths⁶ and neonatal deaths⁷ of apparently healthy term babies, the overall approach to investigating and learning lessons could only be described as rudimentary and flawed.

1.7 Any one of these serious problems would jeopardise the ability of a maternity unit to offer safe and effective care. Together, they constituted a lethal mix that we have no doubt led to the unnecessary deaths of mothers and babies, as we have set out in Chapter 3. We systematically reviewed care in 233 pregnancies, including all of the stillbirths, neonatal deaths and maternal deaths

⁴ Judith Kurutac interview.

⁵ Judith Kurutac interview.

⁶ Intrapartum stillbirth: delivery of a baby that has died during the course of labour, past 24 weeks of pregnancy.

⁷ Neonatal death: death of a baby within the first 28 days of life.

in the Trust over the period covered by the Investigation, together with other serious incidents drawn to our attention by families who contacted the Investigation. Of these, 63 showed features of concern prompting a full clinical review, as a result of which we found 20 instances of failures of care at FGH that were significant or major, associated with three maternal deaths, ten stillbirths and six neonatal deaths. In 13 of these we found, in the words of the validated investigation method, “*suboptimal care in which different management would reasonably have been expected to make a difference to the outcome*”,⁸ including one maternal death, five stillbirths and six neonatal deaths; the prevalence of these serious failures of care was four times that at Royal Lancaster Infirmary (RLI).

Delayed problem recognition

1.8 The FGH maternity unit did not become unsafe overnight: problems of this sort take time to develop. By the nature of maternity care, on the great majority of occasions the outcome is a healthy mother and baby without the need for significant intervention, because pregnancy and childbirth are inherently normal physiological processes. The safety of maternity units depends on their level of vigilance to detect risk and deviation from the norm, and on their taking effective action when it is found. Population trends in childbirth such as rising maternal age, obesity and diabetes mean that the inherent risks have increased, but even so, tragic outcomes fortunately remain relatively uncommon. Nevertheless they are devastating when they do occur, emphasising the importance of scrutinising every occurrence to see what has gone wrong and to ensure that it is not a sign of underlying problems.

1.9 The first event that should have triggered concern was the death shortly after delivery of a normal, term baby, Eleanor Bennett, in 2004, after she was born in very poor condition due to severe shortage of oxygen in labour. However, the investigation that was carried out was rudimentary, protective of the midwife involved, and failed to identify the shortcomings in practice and approach that led to inadequate monitoring of a high-risk pregnancy and a lack of necessary obstetric assessment and intervention. Follow-up after this investigation recorded only that “*having examined the notes of this lady I do have some concerns about record keeping throughout her antenatal, intrapartum and postnatal period...*”.⁹ Had an effective multidisciplinary investigation been carried out, it is likely that the early stages of dysfunctional relationships and inappropriate risk assessment would have been identified and could have been addressed, as the case shows several of the features that would become familiar later, including poor assessment of risk and failure to monitor adequately. If this had been done in 2004, it would not only have reduced the likelihood of unnecessary loss of babies and mothers, it could have corrected the poor risk assessment and unsafe practice at an early stage, before inappropriate attitudes and behaviour had become more deeply embedded into day-to-day practice and influenced others on the unit.

1.10 This opportunity in 2004 was missed. There were, however, further signals that all was not well with the unit, had serious untoward incidents (SUIs) been examined in any depth. Five incidents in 2006 and 2007 showed significant features of concern, including a stillbirth and a neonatal death, and a case that was not reported as an SUI or investigated. Moreover, it must have been abundantly clear to all those working in the unit at that time that relationships between midwives, obstetricians and paediatricians were fractured, as several interviewees admitted to us frankly, and the experienced clinicians amongst them must have known that this was both unsatisfactory and dangerous. We were disappointed to find that there was no systematic attempt to warn those in more senior positions in the Trust, whether managers, nurses or doctors, and there was no documentary evidence of concerns being raised at this time.

⁸ Draper ES, Kurinczuk JJ, Lamming CR, Clarke M, James D, Field D. A confidential enquiry into cases of neonatal encephalopathy. *Arch Dis Child Fetal Neonatal Ed* 2002;87:F176-F180 doi:10.1136/fn.87.3.F176.

⁹ Letter from Denise Fish to Marie Ratcliffe, 8 March 2004.

1.11 Events in 2008 demonstrated unmistakably the effects of deficient clinical skills, dysfunctional relationships, poor risk assessment and failure to appreciate the significance of incidents involving disastrous outcomes for mothers and babies. Five serious incidents occurred in the FGH maternity unit, including two maternal deaths (following one of which the baby also died), an intrapartum stillbirth, a neonatal death from sepsis, and a baby damaged by the effects of shortage of oxygen (hypoxia) around the time of birth. The care in each case was seriously deficient, as was clearly evident from examination of the clinical records as well as from the accounts of clinicians involved. Investigation of the first four of these incidents was inadequate and flawed. The first, in which a baby survived the effects of perinatal hypoxia but with damage, does not seem to have been logged as an untoward incident or investigated. The second, a maternal death, was thought to have been unavoidable, although there was clear evidence of raised blood pressure during pregnancy that was inadequately followed up. The third, a pregnancy which ended in the deaths of both mother and baby, Nittaya and Chester Hendrickson, was again thought to be unavoidable due to its cause, an amniotic fluid embolism, but there were serious deficiencies in the preceding care likely to have contributed to both deaths. Following the fourth incident, poor investigation into the events surrounding the intrapartum stillbirth of Alex Davey-Brady failed to identify deficient assessment of risk, lack of action in response to slow progress in the first stage of labour, inadequate monitoring of the baby during labour and failure to manage evident problems in the second stage of labour. It was not until an external review of the death of Joshua Titcombe from sepsis following prolonged rupture of the membranes and maternal illness, prompted by James Titcombe's complaint in November 2008, that any investigation showed unequivocal evidence of clinical failure.¹⁰

1.12 Yet there had been unequivocal signs of clinical failure in cases going back to 2004, including the cluster of five that occurred in 2008, that were evident on any competent review of the records, as we found. The failure to discover these problems or to enquire into the poor interpersonal relationships that afflicted the unit raises serious questions about the diligence and conduct of the clinicians involved in those cases and of the professional leads who knew of the cases.

Response following 2008 events

1.13 By the end of 2008, it must have been obvious to experienced staff within the maternity unit that there were serious problems. Regrettably, however, the response remained shaped by the dysfunctional nature of the unit. The previous pattern of inadequate, defensive internal investigations was initially replicated, treating each incident in isolation, but two events should have made it clear that this approach was significantly flawed.

1.14 First, following the intrapartum stillbirth of Alex Davey-Brady in mid-2008, an obstetric consultant, Prabas Misra, wrote a letter identifying some of the deficiencies that had contributed to the disastrous outcome, drawing a parallel with the early neonatal death in 2004 of Eleanor Bennett and warning that in his view further tragedies would ensue unless action followed.¹¹ His letter was addressed to the Clinical Director, Ibrahim Hussein, and copied to the Trust's Medical Director, Peter Dyer, and others. He did not receive a reply, and we could find no evidence that his concerns were taken seriously, acted upon or investigated: a meeting did subsequently take place to discuss the midwifery report of the incident, but none of the matters that he had raised were alluded to in the record of the meeting. We heard two different versions of the origin of the letter: either Mr Misra wrote it in an attempt to bring problems to light, or he was prompted to do so by Mr Hussein, who wanted concerns about the unit's functioning placed on record. In light of the lack of any documented response or recorded action following the investigation meeting, it cannot be said to have been effective.

¹⁰ *External Investigation into Serious Untoward Incident At Furness General Hospital: Baby Joshua Titcombe* (Chandler, Hopps and Farrier), 2009.

¹¹ Letter from Prabas Misra to Ibrahim Hussein and others, 2008.

1.15 Eight months after the letter was sent, it was discovered in the clinical records during the Trust's preparations for the inquest into Alex's death, and the flawed 2004 investigation was unearthed. The Trust's director of nursing wrote at the time: *"I have it on good authority that the midwife concerned (who was also involved in the [2008] incident) was referred for fetal monitoring training as part of her developmental support and JP [Jeanette Parkinson, Maternity Risk Manager and Senior Midwife] is attempting to find the relevant documentation to evidence this."*¹² We found no evidence of referral for any training at this stage, and correspondence following the rudimentary investigation in 2004 mentions only a general need for improved record-keeping.¹³ Sadly, there were marked similarities in the failures of care in the 2004 and 2008 incidents, including particularly failure to monitor the fetal heart effectively.

1.16 Second, Mr Titcombe's complaint prompted concern by the Trust Chief Executive, Tony Halsall, who ordered an external review of the case. This review, by an obstetrician, a midwife and a paediatrician was based on the clinical records and the midwives' accounts to the internal investigation. The content of the report was shared with Mr Titcombe, who challenged several aspects, and it became clear that there were significant discrepancies between the accounts given by midwives and the record made by the Titcombe family shortly before Joshua died. When an inquest was eventually held, the coroner was critical that the midwives had collaborated on the accounts given in court and of the loss of the observation chart, as well as the clinical care.

1.17 Faced with the increased level of scrutiny resulting from external review and inquests, the unit and its staff had a significant opportunity to make a clean break with the previous pattern of defensiveness, denial and blame-shifting. That they did not do so is perhaps explicable in light of the dysfunctional relationships that predominated, but it is deeply regrettable. In fact the previous patterns of behaviour became more firmly entrenched, and led to some grossly inappropriate actions that, we believe, constituted inexcusable derelictions of professional duty.

1.18 First, staff considered that there had not been failures of care and that they were being unfairly criticised. This was most graphically illustrated by the comment made to us by an interviewee as she left the room that *"sometimes bad things happen in maternity – people just have to accept it"*.¹⁴ Another said, with reference to the subsequent Fielding Report on clinical governance of the unit, *"well, some of the things that were accused [in the Fielding Report] I didn't feel that was justified"*.¹⁵ When the Panel interviewed staff, some still remained unable to recognise that there could have been failures of care in the 2008 incidents: we were, for example, told that there were *"no specific practice issues"*¹⁶ on review of one maternal death and that the other had been *"unpredictable, unavoidable and we did not highlight any practice issues in that case"*.¹⁷ Our review readily picked up significant failings in both.

1.19 Based on what we heard, we believe that staff reinforced each other's view that the care they were providing was acceptable, not sub-optimal. The midwifery staff were already a close-knit group (we heard that off-duty midwives would drop into the unit just to chat), and it is clear that in response to this perceived external threat they developed a 'one for all' approach, and in fact described themselves as *"the musketeers"*.¹⁸ We were particularly concerned at the conflicts of interest surrounding the position of maternity risk manager, who was also a supervisor of midwives: we believe that she was part of the close-knit midwifery group of 'musketeers' and, as a former

¹² Email from Jackie Holt, 1 July 2009.

¹³ Letter from Denise Fish to Marie Ratcliffe, 8 March 2004.

¹⁴ Interviewee following cessation of interview.

¹⁵ Stella McDowell interview.

¹⁶ Jeanette Parkinson interview.

¹⁷ Jeanette Parkinson interview.

¹⁸ Email from Jeanette Parkinson to Angela Peil, 19 April 2009.

Royal College of Midwives union official had continued to act in a staff representative role supporting individual midwives. She was central to deciding whether and how incidents would be investigated, often by herself: *"If there was any sort of serious incident or an incident where staff needed support or I needed to start an investigation I would go to that site as soon as possible."*¹⁹ This inherent blurring of roles was graphically illustrated in a letter following a medication error in 2007 to the midwife concerned: *"Jeanette Parkinson [Maternity Risk Manager] was present at the meeting yesterday evening (10/1/07) and explained that she was there as your representative."*²⁰

1.20 We do not believe that it is possible to combine roles in this way without a significant loss of objectivity. Given the central role of the maternity risk manager in following up incidents and providing assurance to the head of midwifery of safe and effective practice, in our view the remarkable conflicts of interest inherent in a single individual combining the roles of risk manager, supervisor of midwives, senior midwife and staff-side representative were unacceptable. We believe that this was significant in the events that developed, not only in encouraging the group think amongst midwives that all was well but also in promoting a view at more senior levels that there were no systemic problems in the unit.

1.21 Second, the strong view amongst staff that they were being unfairly criticised on occasions became overt hostility to those challenging this view. This underlying feeling was evident at times from the approach taken by interviewees in responding to our questions, and was sometimes apparent in email correspondence. The most notable example is an email from one midwife to another concerning a Nursing and Midwifery Council (NMC) investigation that was entitled *"NMC Shit"*.²¹ There is no excuse for committing such views to the record, but more important is the underlying attitude it illustrates.

1.22 Third, we believe that this strong desire to protect the group led to instances of distortion of the truth. The strongest evidence of this relates to the failure to recognise the significance of Joshua Titcombe's low temperature and to act on it. Any clinically qualified member of staff looking after neonates should be aware that a failure to maintain temperature is a cardinal sign of infection in a neonate, and Joshua was under observation for potential infection following his mother's illness and spontaneous rupture of the membranes. The account subsequently given by every midwife involved, including to the inquest into Joshua's death, was that none of them knew that hypothermia in a neonate could signify infection or should have resulted in an urgent paediatric assessment. It is on the face of it extraordinary that not a single one knew this basic fact, and many experienced interviewees expressed varying degrees of surprise and disbelief (one local supervising authority (LSA) midwife said to us that a unit in which no midwife knew this would have been unique in her experience²²). Moreover, this was not the account initially given to the internal investigation, which was that Joshua's temperature had not been significantly low, and one midwife said at that stage that she did understand that a low temperature would necessitate a medical assessment.²³ Only when Mr and Mrs Titcombe presented a convincing account that Joshua had been significantly hypothermic on two occasions, an account that was accepted by the midwives, did their version of events change to a universal lack of awareness of the significance of neonatal hypothermia. This represents a significant and regrettable attempt to conceal an evident truth, that a cardinal sign of infection in a newborn baby was wrongly ignored.

1.23 Fourth, the strong reaction of those who felt themselves under wrongful criticism was allowed to distort some of the processes of investigation that ensued. Again, the clearest evidence related

¹⁹ Jeanette Parkinson interview.

²⁰ Letter from Denise Fish to Geraldine Robinson, 11 January 2007.

²¹ Email from Lindsey Biggs to Holly Parkinson, 9 August 2009.

²² Judith Kurutac interview.

²³ Joanne Watts statement to supervisory investigation.

to Joshua Titcombe, in this case the preparations for the inquest into his death. A meeting took place to prepare the midwives who had been asked to give evidence. This would be entirely in order, and appropriate, given that most would not previously have been involved in such a process, and information on what would happen and what would be expected of them would be helpful both to them and to the process. As part of that meeting, a solicitor working for the Trust's legal advisors presented a series of 'difficult questions' that she felt witnesses were likely to be asked. This would be more controversial, but not in itself improper, provided that there was no general discussion of how to respond, on which both documentary evidence and interviewees are silent. What happened next, however, was clearly wrong: Jeanette Parkinson, the Maternity Risk Manager and Senior Midwife, prepared a single set of what we can only regard as 'model answers' to the questions, and circulated them to all of the midwives involved. This distortion of the process underlying an inquest was picked up by the coroner, who commented on the similarity of the accounts that he heard from different witnesses and the concern that this caused him.

1.24 NHS staff have a duty to be open and honest in their dealings with the public, including particularly in responding to untoward incidents, complaints and other instances where things have gone wrong. This professional responsibility predated the legal duty of candour that has been placed on NHS staff following the events at Mid Staffordshire. It is clear that staff in the maternity unit at FGH failed to follow the duty of openness and honesty. There are reasons that may help to account for why this should be, in light of the pressure of scrutiny on the unit set out above, but that in no way excuses their failure to maintain the standards expected of all NHS staff and of registered professionals.

1.25 Seen within the context that some staff were prepared to compromise the professional standards expected of them and to conceal the truth, there were other disquieting events surrounding some of the untoward incidents that we looked at that raise concern, including the disappearance of key clinical records and the delayed completion of critical notes. Although we could not entirely discount the possibility that these instances were coincidental – and clinical records, particularly observation charts, frequently do go missing in hospitals – neither could we escape a significant suspicion that their occurrence was convenient to those involved, given the evidence of willingness to compromise standards of openness and honesty that we have set out above.

University Hospitals of Morecambe Bay NHS Foundation Trust response

1.26 Although there was evidence of systematic failings in the FGH maternity unit prior to 2008, it is clear that none of it reached senior levels in the Trust, particularly executive directors and the Board itself. Partly, this was due to poorly developed systems of clinical governance within the Trust which meant that there was little formal oversight of safety or other quality matters in clinical services. It is important to note, however, that in this the Trust was little different from many others at the time. Partly, this was due to the nature of the service itself, in which, because childbirth is physiologically normal in the great majority of cases, obvious markers of problems such as deaths remain rare even when quality is poor; hence, high-level figures such as the perinatal mortality rate failed to signal any problem.

1.27 Mostly, however, it was due to the lack of any discernible communication of problems by those best placed to see the operation of the maternity unit at close quarters and its dysfunctional nature. Critical in this were the positions of the relevant clinical directors covering obstetrics, maternity and paediatrics,²⁴ the head of midwifery and the maternity risk manager. The circumstances surrounding each of those positions varied: for example, the doctor responsible for oversight of paediatrics was mostly based at RLI and so was less well-placed to see problems at first hand, and the conflicts of interest inherent in the maternity risk manager position have been described above. Common to all

²⁴ The exact titles differed under different organisational arrangements.

three, however, was that they failed to communicate any concern about failing clinical standards in the maternity unit to those to whom they reported at Board level. The clinical director at the time told us that there was little he could do other than pass the message on: *“But if you work with another three consultants who will not undertake any responsibility [for tackling problems] then there is a limit to what you can do. You can sit down with them. You can mention it to the Medical Director. You can mention it to the Chief Executive.”*²⁵ There is no evidence to suggest that he (or anyone else) mentioned it to either at that time, let alone raised it formally: the medical director told us specifically that no concerns were raised with him. *“The clinical director had certainly been in post for a number of years. I didn’t particularly have any concerns about the way in which he managed that bit of what he was expected. I met him on a regular basis, every month, and there were no concerns specifically flagged up to me by him... I certainly didn’t get a sense that, although there were challenging relationships, that they were actually detrimental to the service. I didn’t sense that at all.”*²⁶

1.28 In late 2008, however, concerns certainly did surface to the level of Board executives. First, Mr Misra’s letter of October 2008 about the failures of care leading to the intrapartum stillbirth of Alex Brady-Davey was copied to the Medical Director, Mr Dyer. He told us that he had no recollection of the letter but would have expected it to be followed up by the Clinical Director, Mr Hussein. Second, Mr Titcombe’s complaint in November 2008 alerted the Chief Executive, Mr Halsall, who informed the Trust Board at its next meeting that it carried the potential for adverse publicity.

1.29 Although there is no documentary evidence of any systematic review of the cluster of SULs in 2008, and no record that they were notified to or discussed by the Board, interviewees told us that they had been considered, although by whom was unclear. The medical director was emphatic: *“Each of those incidents was fully investigated. I’ve got timelines here. Two of the incidents were certainly subject to external review by a senior obstetrician, and they subsequently went to inquest as well. They all, as far as I know, went through a mechanism called STEIS, which was the way in which incidents would be reported up to the SHA. I was absolutely satisfied that they were properly investigated, that we took external review when necessary, and that we acted upon those.”*²⁷ It was clear to us, however, that there were significant flaws in each investigation. The internal investigations followed the previous pattern of superficiality and protectiveness; one of the ‘external reviews’ was a medical report for the coroner on the cause of a maternal death (and we were concerned at the suggestion that the Trust would rely on either this or the subsequent inquest as a form of incident investigation); and the external review of the last incident was restricted to case notes and written statements. Even more significantly, however, it was clear to us that each of these incidents had been looked at separately, but they had not been properly considered together. The question of whether the incidents might be related and might signify underlying systemic problems in the unit’s functioning was to become pivotal in how events unfolded.

1.30 At first sight, looking only at the summary outcome of each incident, the differences seem clear: two maternal deaths from different causes, an intrapartum stillbirth, the death of a baby from sepsis, and a baby damaged by shortage of oxygen in labour. Yet on closer examination, the underlying factors show the same pattern: failure to monitor the condition of mothers and babies properly; failure to recognise signs of clinical deterioration; failure to take effective action in response to developing clinical problems; and failure to communicate effectively within and between clinical teams. It seems to us, however, that excessive reliance was placed on the superficial differences in outcome, and little or no consideration was given to the underlying human and behavioural factors that lay behind those outcomes. The chief executive’s view was that there was no link evident at the time: *“I was convinced that the circumstances were different, and there was a different reason for them. You know, when you look back, five, six years later you can say well, actually, you know, were*

²⁵ Ibrahim Hussein interview.

²⁶ Peter Dyer interview.

²⁷ Peter Dyer interview

they a symptom of the same type of – the same thing. But, at the time, I definitely believed that we – we had worked out what had gone wrong, or what hadn't gone wrong..."²⁸ We asked the maternity risk manager. *"Do you want the honest answer? Depends what day you ask me."*²⁹ On further questioning, it was clear that she continued to rely on the clinically different nature of the outcomes to emphasise the lack of connectedness between the incidents.

1.31 The response to the 2008 incidents,³⁰ then, was to take each one in isolation, based on an assumption that remained tacit at the time that they were all unconnected. As we have seen, individual investigations were patchy, and those carried out internally remained of poor quality, undisciplined and protective of midwives. In the case of Mrs Hendrickson, reliance was placed on an independent expert view given to the coroner that a maternal death was unpredictable and unavoidable based on documented records, but this opinion was specifically directed at identifying the cause of death, and even so highlighted deficiencies of care in labour; it was clear to us on looking further that there were significant shortcomings in care before the event occurred and that different management would reasonably be expected to have made a difference to the outcome, the death of both mother and baby. Both this and the external review following the death of Joshua Titcombe³¹ were hampered in relying on documents which, as we have seen, suffered significantly from problems of poor-quality record-keeping, retrospective completion, poor investigation processes and inaccurate and changing accounts; in one case an important part of the clinical record had gone missing.

Subsequent investigations

1.32 Nevertheless, some of the findings, even if only of the last-mentioned report,³² did confirm the impression of the chief executive that all was not well in the maternity unit. He commissioned a report into the management structures around the maternity unit³³ which, although slightly tangential to the underlying clinical problems, did point to some of the relationship issues affecting the unit. He also, we heard, took over dealing with some of the complainants and relatives personally: *"We had a problem when there was a lot of publicity about the unit. There was a major, major problem with publicity. The Chief Executive, I think, took charge. I think he did everything possible except sacking midwives. I think he was meeting relatives, compensating them, apologising... But he was in charge."*³⁴ We also heard that this left some maternity staff feeling let down that they had been unable to meet bereaved relatives to give their view of what had happened.

1.33 In addition to Trust-initiated reviews, the supervisor of midwives system should have provided further insight into the way that the maternity unit operated. This mechanism, intended to maintain standards and ensure safety in midwifery practice, dates from the time when most midwives were independent practitioners responsible for home deliveries, and as a result operated in isolation from other clinical governance and professional regulatory systems. This caused friction when the chief executive delayed the supervisory investigation pending completion of the Trust's external

²⁸ Tony Halsall interview.

²⁹ Jeanette Parkinson interview.

³⁰ It must be recognised that while four of the incidents are clear, there have been several different versions of what constituted the fifth incident. Mr Halsall believed that this was the neonatal death of a baby shortly after his mother had died in labour, taking this as two separate incidents. Some external bodies thought that it was another baby with infection shortly after delivery, although there were no untoward features in the care. Others thought it was the death of a young woman during laparoscopy, although this was not in the maternity unit. We have included a baby who was damaged from the effects of lack of oxygen in labour, although it is unclear if this was reported or investigated at the time. This confusion says something about the accuracy and completeness of incident-reporting systems.

³¹ *External Investigation into Serious Untoward Incident At Furness General Hospital: Baby Joshua Titcombe* (Chandler, Hopps and Farrier Report), 2009.

³² *External Investigation into Serious Untoward Incident At Furness General Hospital: Baby Joshua Titcombe* (Chandler, Hopps and Farrier Report), 2009.

³³ UHMB Review of Overall Management Arrangements Maternity Service (Flynn), 2009.

³⁴ Ibrahim Hussein interview.

investigation into the last 2008 incident, but when it did take place it failed to identify shortcomings that were evident from the external review. It was clear to us on the basis of what we heard that this system suffered from all of the shortcomings of the Trust's internal investigations (and was often carried out by the same small group of individuals), and the external scrutiny by the LSA midwifery officer that should have provided assurance that supervisory investigations were properly carried out failed to pick up their inadequate nature. An external review of the LSA response was equally ineffective at detecting the problems of investigation and response to problems.³⁵ We believe that the supervisory system as applied in Morecambe Bay was slipshod, lacked objectivity and failed repeatedly to identify the evident problems in the unit or alert others to them. Further, the LSA system of oversight failed to assure the quality of the supervisory process and did not identify the conflicts of interest that should have been apparent. We are aware that the LSA system has recently been subject to review and that significant changes have been proposed. Although we have not looked at the system except in the context of Morecambe Bay, this comes as no surprise to us given its shortcomings there.³⁶

1.34 Events in 2009 became complex, and it is difficult to set out the events without putting them in the context of the things that were occurring outside the Trust. Although the findings relevant to these will be considered subsequently in this report, they will be set out briefly now. First, the Trust was asked to submit relevant paperwork to Monitor in February 2009 in connection with its application for Foundation Trust status. This included a required statement on SULs, in which the Trust identified 12, including the five maternity SULs. Second, the Care Quality Commission (CQC), which had been operating in shadow form, was established formally from April 2009, and was consulted by Monitor on the potential significance of the cluster of SULs. Although the CQC rejected a proposal for an investigation of the maternity unit put forward by the regional CQC team, there was sufficient concern that Monitor put the Foundation Trust application 'on hold' in May 2009, and the CQC gave the Trust a 'red' risk rating the following month, indicating that it should have a high degree of attention and scrutiny.

1.35 This is the context within which the Fielding review into the Trust's maternity services was commissioned later in 2009. The exact genesis is unclear from the documentation, but the most detailed and convincing account we heard was from the former North West Strategic Health Authority (NW SHA) nurse responsible for clinical quality, Angela Brown. She told us that in mid-2009 she was aware of the cluster of SULs and that they had been investigated independently, but felt concerned that there was a gap in the investigations, that there may have been systemic problems, and *"that they haven't gone far enough to pick up what those systemic issues might be... This was around, 'Have you understood everything that has happened that is important? Are you certain of that?'"*³⁷ She discussed this with Trust executives and suggested a further external review specifically addressed to that question, proposing Dame Pauline Fielding, an experienced senior nurse and manager, to lead it. In our view Ms Brown had asked exactly the right question and proposed a sensible way to address it; that the Trust did not commission the Fielding review to do what she believed she had suggested to the Trust was another significant missed opportunity.

1.36 In discussions, the Trust Chief Executive, Mr Halsall, and Nurse Director, Jackie Holt, put forward the idea that the proposed review should shift its emphasis away from the previous incidents to what should be done for the maternity unit to move forward, and how the Trust could gain assurance that it was. Ms Holt's view was that there was no point in a further look at the cluster of incidents: *"I think there was a feeling that there had been an independent review, there had been a clinical governance review, there had been the inhouse root cause analysis of incidents and that the Board needed to*

³⁵ Independent Local Supervising Authority Midwifery Officer Report for North West Strategic Health Authority (Yvonne Bronsky), June 2010.

³⁶ King's Fund review of midwifery supervision.

³⁷ Angela Brown interview.

*move forward in terms of more developmental – you know, developing and moving forward rather than going through another independent review looking at very specific issues, I believe.”*³⁸ Mr Halsall was clear that he commissioned the review to look at governance structures and not the previous incidents: *“I commissioned the report from Pauline Fielding, which was around... trying to look at clinical governance and not to review the individual cases, but to come back and say, ‘Look, in terms of the governance across this patch, what could we do? What structure could we put in place to governance [sic], that would get us past this?’”*³⁹

1.37 This was a significantly different approach from that proposed by Ms Brown in three aspects. First, the answer to the original question which prompted her proposal had now been assumed by Trust officers to be that there was nothing further to be learnt from the cluster of incidents, either individually or collectively. Second, the initial suggestion to shift the emphasis to the clinical governance requirements going forward had now evolved into the exclusion of previous incidents from the review. Third – and the phrase *“would get us past this”*⁴⁰ is instructive – we believe that a feeling began to grow among Trust staff at all levels that this was something the Trust needed to fend off as unsound rather than something that could provide the opportunity to identify the root causes of evident problems.

1.38 Ms Brown was aware of the shift of emphasis that was emerging, but not that the terms of reference (which she did not see) excluded examination of the incidents themselves. The terms of reference were drafted by Dame Pauline following a meeting with the chief executive, at which, she said, he was very definite about excluding the previous incidents:

*“His view was that there had been these five serious untoward incidents, which he was very specific about the fact that this review was not to reinvestigate those incidents. That those incidents had been investigated and that part of the story was over and that what he wanted us to do was to look at the review – look at the service and identify ways in which the service could be improved. So the emphasis was on improvement, not investigating the things that had gone wrong, although he did make the reports that had been carried out into the incident, he made those available to us. The Trust were very specific about the fact that we were not to reinvestigate those.”*⁴¹

She described the investigation reports as “quite brief”.⁴² Trust officers nominated an obstetrician, Andrew Calder, and a midwife, Yana Richens, to join the review.

1.39 The Fielding Report was submitted to the chief executive in March 2010 and sent back twice for redrafting. All those we interviewed were clear that the changes made were minor, and Dame Pauline confirmed that they did not change any of the recommendations, but it took until August 2010 until the final draft was produced. She was clear that she did not see the production of the report as the end of her investigation: *“I expected to be able to discuss that report with the Trust Board; that didn’t happen. And I expected that there would be a process of engagement with staff following the report, to take it further in terms of how they were going to implement it and what would happen. None of that took place.”*⁴³ She believed that these expectations, and the assumption that she would be asked to review progress after six months (which also did not materialise), were shared by Mr Halsall before the review.

³⁸ Jackie Holt interview.

³⁹ Tony Halsall interview.

⁴⁰ Tony Halsall interview.

⁴¹ Dame Pauline Fielding interview.

⁴² Dame Pauline Fielding interview.

⁴³ Dame Pauline Fielding interview.

1.40 Unfortunately, despite the fact that the review group had access only to the “quite brief” investigation reports and otherwise excluded any investigation of the incidents in line with their instructions, and despite the clear statement in the report that “it was not the purpose of the review to reinvestigate these incidents”,⁴⁴ the report included the observation that “the apparent ‘cluster’ of these episodes appeared to the review team to have been coincidental rather than evidence of serious dysfunction.”⁴⁵ We believe that this was an extremely unwise assertion that could only have been based on the flawed and “quite brief” material relating to individual incidents. It certainly gave the impression to any less than meticulous reader that the review had examined the cluster of cases and therefore had a proper basis to come to the conclusion that they were “coincidental”. This conclusion, which we believe was certainly wrong, was to prove far-reaching.

1.41 Nevertheless, the report was far from reassuring, highlighting facilities “not entirely fit for purpose” (particularly theatre provision for maternity work at FGH); a poor approach to clinical governance and clinical effectiveness (“... there does not appear to any [sic] multidisciplinary or multisite involvement in this process”); and, perhaps most significantly, dysfunctional working: “It was clear from most of our interviews that team working is dysfunctional in some parts of the maternity service. Whilst this is apparent in all professional groups, it is particularly evident in relation to medical staff.”⁴⁶ Although the report did also state that the arrangements for incident-reporting, analysis and feedback were robust and commendable (which matched nothing that we saw or heard), it is difficult to see how the report could be read in any other way than as signalling significant problems.

1.42 We heard different accounts of how the Fielding Report was viewed within the Trust. What is clear is that it was not presented to the Board until almost a year later, in April 2011, and that most staff remained unaware of it before that time. The chief executive was clear that this was because he did not regard it as having done what he had wanted, and the report was in effect sidelined: “I don’t think we thought that the Fielding Report did what we asked it to do... if you’re going to say, ‘Well actually we’re not going to do anything with that, the Board need to do it’.”⁴⁷ Although he admitted that this was poor practice, he denied that it represented a cover-up: “[W]e handled the Fielding Report incorrectly. So, you know, even if we hadn’t liked the Fielding Report and didn’t think it was, you know, credible, or we didn’t like the information, it should have gone to a minuted meeting of the Board from a governance point of view, without any doubt. So, you know, I don’t believe for one second that that was done in terms of trying to cover up a report or to, you know, anything else.”⁴⁸

1.43 His chairman at the time, however, gave us a different account. In his view, the executive team had signalled that the report was to be taken seriously: “There was a clear steer from the Board and from the chief executive and the director of nursing and the medical director. I don’t think there’s any doubt.”⁴⁹ Implementation of recommendations was, he told us, “... by getting the executive directors to get on with delivering the action plan, transmitting what needed to be done to whoever needed to do it, whether it was nurses, clinical staff, midwifery staff, in the normal process”.⁵⁰

1.44 The director of nursing took an intermediate position: “I think it [the Fielding Report] was seen as a developmental report rather than a, you know, an independent investigation and review, of which there had been many. I have to say that I did spend time – you know, I know that I talked to the

⁴⁴ Review of Maternity Services in University Hospitals of Morecambe Bay NHS Trust: Final Report (Fielding Report), 2010.

⁴⁵ Review of Maternity Services in University Hospitals of Morecambe Bay NHS Trust: Final Report (Fielding Report), 2010.

⁴⁶ Review of Maternity Services in University Hospitals of Morecambe Bay NHS Trust: Final Report (Fielding Report), 2010.

⁴⁷ Tony Halsall interview.

⁴⁸ Tony Halsall interview.

⁴⁹ Eddie Kane interview.

⁵⁰ Eddie Kane interview.

clinical team and the head of midwifery about it... whether that report was embraced by the clinical team I don't know, and owned by the clinical team, I could not say."⁵¹

1.45 In April 2011, the Trust decided to audit progress with the implementation of an action plan in response to the Fielding Report; we believe that it was prompted to do so by the increased external interest likely to be generated by the forthcoming inquest into Joshua Titcombe's death. It is clear from documentary evidence that an action plan had not been produced at that point, eight months after the final report had been received and over 18 months after the need for the review had first been mooted. An email exchange from April 2011 exemplifies that lack of engagement of staff and the mixed signals. A maternity matron wrote to the director of nursing: "*Joyce and I are very concerned to hear today that we are going to be audited on the progress made to date on the Fielding action plan. We only saw the report a few weeks ago... Fortunately we have been working on a lot of the points raised... but... we need to undertake and update this piece of work prior to the audit.*"⁵² The reply was on the same day: "*I was surprised to hear this from Sue given there was a meeting... last year... and the Division were asked to work on an action plan... I also made it clear that it was the division to decide whether to adopt all the recommendations...*"⁵³

1.46 Whether or not the director of nursing expected the division to produce and implement an action plan in 2010 – and the comment that she did not know "*whether that report was embraced by the clinical team*"⁵⁴ would make this an optimistic assumption – it is clear that they did not, that there had been no follow-up in the interim to see if they had, and that it was the division's decision as to which recommendations to adopt. This fits much more convincingly with the view that the executive team had decided that "*... actually we're not going to do anything with that...*"⁵⁵ than that there had been "*... a clear steer from the Board and from the chief executive and the director of nursing...*"⁵⁶. The chief executive confirmed to us that the action plan had been put together later: "*That was done in retrospect.*"

1.47 The Trust was just as reticent in sharing the Fielding Report with external bodies as it was with its own staff. Ms Brown at the NW SHA had, we believe, originally prompted the review and had nominated Dame Pauline to lead it. She told us that around June 2010 she had spoken to both Mr Halsall and Ms Holt to enquire about the report, and had been told that it was progressing:

*"What Jackie also told me was, 'It hasn't really told us anything that we didn't know and we weren't working on. This is work in progress, but it is about taking us forward.' So, she sent to me a document that had some of the key recommendations or what I thought were the key recommendations, as well as what was the – she'd put on that as well the terms of reference, which was the first time I'd seen the terms of reference. And on the bottom of that was also confirmation that CQC had done a visit into the unit and that everything had gone well. And I made some assumptions from that that CQC were sighted and this was a very joined up piece of work..."*⁵⁷

At that point, the report was about to be redrafted for the second time, and would not be finalised until August 2010. Ms Brown was sent a copy of the report in late October 2010, after she had requested it again and well after the point at which she had been asked for a view on the FGH maternity unit in connection with the Trust's application to become a Foundation Trust.

⁵¹ Jackie Holt interview.

⁵² Email from Karen Weakley to Jackie Holt (and others), 14 April 2011.

⁵³ Email from Jackie Holt to Karen Weakley (and others), 14 April 2011.

⁵⁴ Jackie Holt interview.

⁵⁵ Tony Halsall interview.

⁵⁶ Eddie Kane interview.

⁵⁷ Angela Brown interview.

1.48 Nor was the report shared with the CQC until April 2011. Mr Titcombe had emailed the CQC Regional Director, Sue McMillan, in January 2011 asking if she had seen the Fielding Report, which he attached. Ms McMillan told us that within a matter of hours he had phoned back to ask her to delete the report at the request of his lawyer (it had been sent to Mr Titcombe as part of the papers for the forthcoming inquest into the death of Joshua). Ms McMillan confirmed that the Trust had not shared the report with the CQC, and formally requested all maternity documentation and reports, obtaining a copy from the Trust in April 2011: *“They didn’t respond straightaway, but we pushed it and – we did, and eventually we got it in April...”*⁵⁸ Nor had the report been sent to Monitor as part of the Foundation Trust application, although we were told that Monitor would have expected the Trust to do so.⁵⁹

1.49 In Mr Halsall’s view, the failure to share the report with external bodies was not deliberate but an oversight: *“That first came back in around about the time where the Care Quality Commission had downgraded our rating from red to green and Monitor then triggered the next part of the process, and so we were just being asked for, literally, you know, hundreds of documents. I don’t believe we purposely decided not to do anything... I think it got lost in between everything else that we were doing at the time, if I’m being honest.”*⁶⁰ The subsequent interim Trust Chair, Sir David Henshaw, was strongly critical in speaking to us. He described coming across the Fielding Report in a filing cabinet:

*“I was appalled, frankly. I mean, you know, any system like the NHS, you are reliant on senior people operating with a level of competence that – let us use the word competence – makes the system work and I just, you know, was very surprised. I mean, I was appalled... At the very least I would have expected a conversation between the Chief Executive of the SHA and the Chief Executive of the Trust on the landing of that report as a colleague, a partner, in the journey towards what we are trying to do with FT status. That would have triggered a conversation between the Chief Executive of the SHA and myself [as the then SHA Chair] and then we would have made a judgment and I suspect – as always, hindsight is easy – we would have said, ‘we need to look at this more deeply’. That is what we would have done.”*⁶¹

1.50 The events surrounding the Fielding Report represent, in our view, a depressing series of missed opportunities that stretches from the flawed decision to prevent investigation of the cluster of incidents, through the five-month delay before finalisation, the lack of appreciation that the report contained some significant messages and the failure to signal that its findings should be acted upon, as far as the failure to share the report with external bodies, particularly the CQC and Monitor, who did not receive it until eight months later. Whilst it is clear that this was a fairly small Trust with limited management capacity to deal with a complex and difficult agenda at the time, we do not agree that this is likely to be the sole explanation, as Mr Halsall would have us believe. The widely different versions of events given by key individuals, the failure to involve Dame Pauline in the aftermath as she was led to expect, the need to assemble a retrospective action plan in 2011 and the reluctance of the Trust to share the report even when being pressed for it (as identified by Ms Brown and Ms McMillan) all lead us to conclude on the balance of probability that there was an element of conscious suppression of the report, both within the Trust and externally, although we could not entirely exclude other possibilities.

⁵⁸ Sue McMillan interview.

⁵⁹ David Bennett interview.

⁶⁰ Tony Halsall interview.

⁶¹ Sir David Henshaw interview.

The role of external bodies

1.51 The external relationships of the Trust were quite complex and subject to change over the period in question. Services were mainly commissioned by Morecambe Bay Primary Care Trust (PCT) until 30 September 2006, after which North Lancashire PCT commissioned most of the services at RLI and Cumbria PCT most of the services at FGH. Cumbria PCT also had to commission challenging services in the north and west of the county, and we heard that neither PCT was willing to cede 'lead commissioner' status to the other. Oversight of the operation of NHS Trusts (that is, Trusts that were not Foundation Trusts) was initially the responsibility of SHAs, in this case the NW SHA, with a role in both strategic direction and monitoring. The SHA's responsibility for service quality was initially shared with the Healthcare Commission, which also carried out the second stage of the NHS complaints procedure when local resolution was unsuccessful. From 1 April 2009, the Healthcare Commission was replaced by a new body, the Care Quality Commission (also responsible for the quality and regulation of social care providers), which had operated in shadow form from the preceding autumn. Responsibility for the second stage of the NHS complaints procedure did not pass to the CQC, however, but to the Parliamentary and Health Service Ombudsman (PHSO), who had previously become involved only when the Healthcare Commission did not resolve a complaint. The regulator for Foundation Trusts, other than for the CQC's responsibilities, was Monitor, which also ran the application process by which NHS Trusts were judged suitable or not to become Foundation Trusts.

1.52 Central to all of these organisations was the Department of Health (DH), responsible for setting policy under the direction of ministers and for the overall operation of the NHS; from 2006 this latter duty was separate from policy-setting under the NHS Executive, and from 2012 became the responsibility of what was to become NHS England. The DH, however, retained responsibility for oversight of the operation of the CQC and Monitor on an arm's length basis.

1.53 Not only is this complex and changing picture difficult to follow on occasions, we believe as a result of what we heard from a range of interviewees that the organisational changes led to confusion of roles and responsibilities, loss of organisational memory as personnel changed and, in some cases, staff of new organisations struggling with responsibilities for which their previous experience had not equipped them.

1.54 It seems to us on the basis of what we heard that the SHA's style was to take a strong lead on the developmental aspects of improving quality, as demonstrated by some of the projects that they set up, but that their approach to monitoring the performance of Trusts was poorly developed, and weak in comparison. The NHS chief executive at the time outlined the positive aspect: *"It was more strategic than most. It was innovative. It had a whole set of things, it was done particularly around... the improving quality stuff, all of the things they did which really did – you know, they were really leaders nationally in terms of understanding and getting all of the stuff together. Mike [Farrar] was a particular advocate for improving quality."*⁶² The same interviewee also spelled out the weaknesses:

*"One of them was dealing with big problems, outliers, that we thought they had some problems in all of that because many of the things, when you were dealing with an organisation, which is in serious, serious trouble it is not like dealing with organisations that have got some problems. It is very different. We raised that as one issue, we were concerned about their ability to do that... [T]he second criticism was that they did not, they sometimes struggled with really tough decisions. When it became really difficult decisions, they did not want to stand by them because they put a lot of store by developing the relationships with individual organisations and some of the relationships were very productive."*⁶³

⁶² Sir David Nicholson interview.

⁶³ Sir David Nicholson interview.

This aspect was also confirmed to us by PCT chief executives, who told us that SHA performance management was poorly developed or “*did not exist*”.⁶⁴

1.55 Prior to 2008, there was no particular reason for the SHA to be concerned about clinical quality in the Trust. If reports were not getting to the Trust Board, they would be most unlikely to reach the SHA and, as we found, the overall headline statistics for maternity were unremarkable. It is possible that one or more of the PCTs may have heard concerns from GPs, but the GPs we spoke to had no reason for concern about the services. Again, this is not a surprise given the preponderance of good outcomes in maternity regardless of care: most GPs would not see an example of the sort of disastrous outcome that happens when poor care intersects with a high-risk pregnancy and something goes wrong.

1.56 After 2008, the SHA did have cause for concern, as it became aware of the cluster of incidents in maternity services. We heard from the person most closely involved, Ms Brown, a senior nurse working on quality in the nurse director's team, that she was concerned that the incidents might have signalled underlying systemic problems, and proposed the Fielding review as a result. As we have seen, the way that the review was commissioned by the Trust meant that it could not address the question, but this was not made very clear in the report. As a result, Ms Brown was left under the impression that the cluster of incidents had been examined as part of the review and considered to be unrelated. She also reported that the Trust director of nursing “*told me that the [Fielding] recommendations were work in progress, they were doing it and they were all rolled into the one action plan*”.⁶⁵ These assurances, that the incidents were coincidental and the Trust was implementing an action plan, were accepted by executives in the SHA, including the nurse director and chief executive, and underpinned the SHA view that there were not systemic clinical problems and that governance was being addressed. An SHA briefing note for the DH in 2011 set this out: “*The Trust commissioned a further independent review of the cluster of incidents in the maternity unit at Furness General and the Fielding Report completed in 2010 found that the incidents were coincidental but identified a number of clinical governance and cultural concerns and highlighted the risks and poor facilities in the theatre at FGH. The Trust implemented the action plans arising from the investigation.*”⁶⁶ We found it disappointing that, given how central the “*coincidental*” nature of the incidents had become, nobody at more senior level in the SHA thought to check the basis of this view.

1.57 As we have seen, the Fielding review was not in a position to come to any conclusion on the cluster of incidents, and the action plan in response to the review was put together retrospectively almost a year later. Had the SHA adopted a more ‘hands on’ approach, it is likely that either or both of the chief executive and nurse director would have challenged the Trust on these points in more detail, and would have received responses that were much less reassuring. This was another missed opportunity.

1.58 Monitor became involved with the Trust when it applied for Foundation Trust status, initially in February 2009. As is clear both from interviewees and from documentation, Monitor's focus was on financial sustainability, and reliance was placed on the relevant body to provide assurance of service quality, previously the Healthcare Commission but about to become the CQC. The current chief executive of Monitor set this out clearly for us: “*It was still the case that the presumption would be that the primary test of whether or not a Trust was providing good quality care would be the quality regulator, and this... had become the Care Quality Commission... it was their job primarily to establish that good quality care was being provided.*”⁶⁷

⁶⁴ Sue Page interview.

⁶⁵ Angela Brown interview.

⁶⁶ SHA briefing note, 8 September 2011.

⁶⁷ David Bennett interview.

1.59 Nevertheless, as part of the application the Trust was required to provide to Monitor a list of current SULs, and the response identified 12, including the cluster of five maternity-related incidents. Monitor's staff who were reviewing the application in May 2009 flagged these up as a cause for concern, creditably in light of their explicit reliance on others to assure quality, and sought further information from both the CQC and the SHA:

*"So we spoke to the SHA and my understanding is that they were aware of the five SULs, but I don't think the CQC were at the time. So when we spoke to the manager at the CQC, we said, 'Look, we've identified this, is it a concern?' And I think at the time they said, 'We hadn't picked up that they had that trend'... Oh, sorry, I have to correct myself... [the SHA] were not aware of all five SULs because some of them might be reported directly through to [the PCTs]."*⁶⁸

As the responses that they received were not immediately reassuring, and the information was partly new to the SHA and fully new to the CQC, Monitor decided to suspend the application in 2009.

1.60 In response, the Trust chief executive went to Monitor to ask what the Trust needed to do for the application to be reactivated: *"We went – myself and Eddie Kane the Chairman went to see Bill Moyes and Miranda Carter at Monitor to say, 'Right, okay, this is where we think we are, what is it – you know, what happens? What is it we need to do?'"*⁶⁹ The answer was that the CQC must report no more than 'minor concerns' about the Trust. It is clear on the basis of what we heard that achieving that assessment from the CQC became a major focus for the Trust.

1.61 The information from Monitor to the CQC about the cluster of SULs arrived in May 2009, at the same time as a letter from Mr Titcombe about his concerns. The CQC was a new organisation, formed in April 2009 from the merger of organisations formerly responsible separately for quality in social care and the NHS. In addition to its central organisation it had a regional tier, which in the case of the North West was staffed at senior level predominantly by people with a social care background who had, they told us, little familiarity with health services. Both the Regional Manager, Alan Jefferson, and the Area Manager, Julia Denham, had had little prior NHS experience, and a combination of that and their concern about the incidents led them to refer to the central CQC Investigations Team to consider an investigation of the Trust's maternity services. Ms Denham told us that *"... in its simplest terms I was referring it to the Investigations Team because that at the least I knew that I had been advised that that is the place it should go... I knew at some point around that time that systemic failure was an issue and whether it was before I suggested the referral or after I am not sure."*⁷⁰

1.62 The referral went to a CQC Investigations Manager, Sarah Seaholme, whose role was to look at all referrals for CQC investigation, however they arose, to judge if they required investigation. She told us that the criteria for deciding on an investigation included a risk to patient safety, outlying mortality rates, potentially serious failures in team-working, and patterns of incidents, but that in the case of Morecambe Bay her focus was on the potential pattern of incidents. In her view, the incidents did not comprise a pattern: *"When I looked at the five SULs... I didn't think that there was a pattern within that five. And two of them I thought were... unavoidable, and the maternity department wouldn't have been able to prevent those cases."*⁷¹ She was clear in telling us that the only information she had available was a high-level summary, basically comprising the cause of death. She had had clinical experience as a podiatrist but did not have available to her a source of more expert advice on obstetrics, midwifery or paediatrics. Her decision, signed off by the CQC's Investigations Committee, was not to investigate, because *"... there was action by the Trust in order*

⁶⁸ Miranda Carter interview.

⁶⁹ Tony Halsall interview.

⁷⁰ Julia Denham interview.

⁷¹ Sarah Seaholme interview.

*to address the issues, the parliamentary health ombudsman [sic] was reviewing the case, and that was... in progress. It didn't appear on the mortality outlier surveillance data... as an outlier, for women or the babies, and on review of the incidents I didn't feel that there was a pattern there."*⁷²

1.63 Ms Seaholme had had previous experience of investigations with the Healthcare Commission where, she told us, there had been around 600 referrals in five years, around half of which went to the second stage of consideration (which Morecambe Bay did not) with 19 progressing to full investigations. It is also relevant to note that the intention had already been expressed at that stage to wind up the CQC Investigations Team, although Ms Seaholme did not think that that had influenced her decision.

1.64 With the benefit of more complete information, which would have been provided had the recommendation been to progress to the second stage of consideration, it is clear that Morecambe Bay met three of the four criteria: there was a pattern to the incidents (based not on the clinical cause of death but on the underlying human factors), there were serious failures in team-working, and there was a manifest risk to patient safety. This was another significant missed opportunity.

1.65 The CQC regional team continued to regard the Trust as in need of close follow-up, however, and gave it a 'red' risk rating in June 2009. In August 2009, an assessment panel for the PHSO considered whether a complaint from Mr Titcombe should be investigated by the PHSO. Based on the documentary evidence and on what we heard, we believe that the preliminary conclusion reached at that meeting was that a PHSO investigation was unlikely to discover further information on the events surrounding the death of Mr Titcombe's son and unlikely to be able to offer any remedy beyond what had already been offered, but that the information available was sufficient to give cause for concern about the quality of maternity services in the Trust, and that that aspect should be taken up with the CQC.

1.66 This was initiated in a meeting between the PHSO, Ann Abraham, and the Chief Executive of the CQC, Cynthia Bower. The meeting itself was an informal follow-up to an earlier, more formal and difficult meeting about drawing up a memorandum of understanding between the two organisations about areas of common interest. The conversation about Morecambe Bay was, by all accounts, brief and unminuted, in line with its informal nature, and we heard rather different accounts of it.

1.67 Ms Abraham was clear that in raising the matter she had conveyed the nature of her concerns that there were systemic problems:

*"I gave Cynthia a flavour of the case, in the sense that here was something where... to me it was self-evident there were systemic issues. That... a lot of the injustice in Ombudsman's language had already been remedied but there were fundamental issues in terms of quality of care. Therefore, the question for us is: What can we do?... I am trying to give her some background so she knows what I am talking about and why. Then I am saying, well, we need... to understand what CQC's position is on this; who should Kathryn [Hudson] talk to?"*⁷³

1.68 Ms Bower's recollection was less clear, but she was definite that the matter of systemic problems was not raised with her:

"At no point, unless somebody can show me a memo that I – an email that I had or whatever, I can never ever remember having any conversation that ran 'This is not a' – you know, about – I can't remember having that conversation about any organisation because I would have directed them to talk to the regional teams or whatever. It was very much a devolved decision-making structure but I certainly have no recollection, I do not believe

⁷² Sarah Seaholme interview.

⁷³ Ann Abraham interview.

anybody ever said to me 'We have decided that in the case of FGH or UHMB as a whole these are systemic issues and we expect you to investigate them'."⁷⁴

1.69 Within the context of everything else that we heard from both PHSO and CQC interviewees, we believe that Ms Abraham's account is distinctly more convincing; we were also disconcerted by the proviso in Ms Bower's account ("*... unless somebody can show me a memo...*"⁷⁵). It is clear that there was no shared understanding of the conversation. Amanda Sherlock, the CQC Director of Operations, having been nominated as a contact point, emailed Ms Hudson: "*I understand from Cynthia Bower that you would find it useful to consider whether there are any lessons to be learned from the way this complaint was dealt with and subsequent actions and impacts on our organisations.*"⁷⁶ Ms Hudson replied:

*"I wonder whether there has been some misunderstanding about the conversation between Ann Abraham and Cynthia Bower... I had thought that Cynthia had suggested that there might be a better way to deal with the issues involved through other assessments of the quality of the Trust and the future of midwifery services in the North West. If this were the case then we could consider declining to investigate but would want to be able to assure the family that their concerns would be dealt with robustly in another way."*⁷⁷

Ms Sherlock replied, acknowledging that "*... the message has got lost in translation...*"⁷⁸ and directing Ms Hudson to the CQC Regional Director, Mr Jefferson, as a better contact point.

1.70 We did not find any evidence to suggest any attempt by either the Ombudsman or the CQC chief executive to exert any improper influence on the other: in our view, the discussion that took place was appropriate in the circumstances save only that it failed to result in a shared understanding between the two parties. We accept Ms Hudson's view that her previous recollection had been flawed in suggesting that the proposal that the CQC deal with the systemic issues had arisen from Ms Bower. Not only would that not fit with the verbal evidence we heard from both her and Ms Abraham, it is contradicted by the contemporaneous Ombudsman's note in preparation for the meeting, the final section of which deals with Morecambe Bay: "*It seems to us that, whilst we could investigate the specific events, the greater need is for a broader investigation of the quality of maternity and midwifery services at this Trust. Would CQC be receptive to that?*"⁷⁹ This note, written prior to the meeting, would be incompatible with a version of events in which Ms Bower took the initiative in suggesting a broader CQC investigation.

1.71 We also considered carefully an email from Mr Halsall, the Chief Executive of the Trust, to his Chair, Mr Kane, around this time, which included the following odd phrase in relation to Mr Titcombe's complaint: "*... if I am right then the CQC can cover off the Ombudsman*".⁸⁰ We received no satisfactory explanation of what this meant. In our view it is most likely to follow from the line expressed by Monitor that all that was needed to restart the Foundation Trust application was a CQC rating of 'green', implying that in Mr Halsall's opinion that would render irrelevant the PHSO decision whether to investigate or not. We do not accept that either the Ombudsman or the CQC chief executive would take any notice of his opinion on how matters should proceed, which would fly in the face of the relationship between the organisations concerned.

⁷⁴ Cynthia Bower interview.

⁷⁵ Cynthia Bower interview.

⁷⁶ Email from Amanda Sherlock to Kathryn Hudson, 4 September 2009.

⁷⁷ Email from Kathryn Hudson to Amanda Sherlock, 4 September 2009.

⁷⁸ Email from Amanda Sherlock to Kathryn Hudson, 4 September 2009.

⁷⁹ Preparatory note for meeting between the Ombudsman, the CQC chief executive and the PHSO, 12 August 2009.

⁸⁰ Email from Tony Halsall to Eddie Kane, 2 June 2009.

1.72 Ms Hudson spoke to Mr Jefferson by telephone on 4 September 2009:

*"Mr Jefferson was well aware of this case, which he felt provided evidence of systematic failure in maternity services across the Trust, not solely at Barrow Hospital [sic] but in other hospitals as well. The concerns raised are in relation to the operation of the Trust itself. While at an earlier stage CQC had considered that [the Ombudsman's] decision as to whether to investigate was of great importance to their actions, and that they should await the outcome of [the PHSO's] work, their thinking has since developed further. The Trust itself has accepted that 'things are not right' and CQC do not need, and indeed should not, to [sic] wait for an investigation before working with them to ensure that the situation improves."*⁸¹

1.73 This is in accord with Ms Abraham's view, as expressed clearly to us, that not only would a PHSO investigation be unlikely to add significantly to knowledge of the events surrounding Joshua Titcombe's death, it was already evident that there were underlying systemic problems in the Trust's maternity service:

*"Records are missing, people's recollections are becoming entrenched and actually what is more important here is that the regulator goes and does the job the regulator is there to do... We had a documented record of a conversation which was very clear that all the ground was covered. I had no reason to think that anyone other than Alan Jefferson was the person from whom we should get those assurances. Therefore, I did not feel that I needed to do anything more than that because it was the regulator's job to do the things that they were doing or telling us they were doing and the system of registration and success of an FT stage application all that was in the regulatory system and, therefore, in terms of what was the Ombudsman's responsibility, what was our job? I thought we had done our job. I thought I could rely on those assurances. I had no reason to believe I could not."*⁸²

1.74 As subsequent events unfolded, however, it is clear that this was not a safe assumption. That month, September 2009, the CQC downgraded the risk rating from 'red' to 'amber' on the basis, as Mr Jefferson told us, that the cluster of incidents had been deemed to be unconnected and that the Trust had written an action plan: *"So the factors that led to removing the 'Red' rating and moving to the 'Amber' rating were first of all the report that said the six [sic] serious untoward incidents were not a cluster of similar matters; and secondly, the production of an action plan to deal with the issues arising from the Titcombe case, via the Charles Flynn report."*⁸³ As we have seen, the judgment that the incidents were unconnected was based on very limited information that ignored the underlying factors, and the idea that changing management arrangements could rapidly eradicate deep-seated cultural problems seems optimistic to say the least.

1.75 Nevertheless, it is clear that Mr Jefferson retained significant reservations about the Trust's maternity services. In December 2009, he wrote to Mr Titcombe:

*"... we have a number of concerns about the operation of UHMBT... poor levels of multi-disciplinary work within maternity services... we will be carefully reviewing their application and deciding what, if any, conditions we intend to apply. The Ombudsman is, of course, aware of these powers and of our determination to use them to secure improvements in the operation of the Trust."*⁸⁴

⁸¹ Briefing of telephone conversation sent from Kathryn Hudson to Ann Abraham, 4 September 2009.

⁸² Ann Abraham interview.

⁸³ Alan Jefferson interview.

⁸⁴ Letter from Alan Jefferson to James Titcombe, 6 December 2009.

The application referred to was the forthcoming registration process applied to all NHS providers for April 2010, which the CQC had signalled quite widely would be applied rigorously to Morecambe Bay in light of the concerns about systemic problems.

1.76 Mr Jefferson was soon to retire, and his replacement as CQC Regional Manager, Ms McMillan, took up post from February 2010. She told us that she was briefed by Mr Jefferson during the handover period that the Trust had been a problem but was addressing the areas of concern. In her view the main maternity issue was staffing levels (the Trust had requested an external 'Birthrate Plus' review of staffing levels, which had shown some shortfalls). Again, the mistaken perception that the 2008 incidents were unrelated was significant: *"I was aware, as part of my briefing, that there had been five SULs in maternity during that period. I also knew that initial work at the Trust, as confirmed by the SHA and ourselves, was that those five SULs were not connected, that there were different causes."*⁸⁵

1.77 In contrast to the previous signals that the CQC would subject the Trust to significant scrutiny prior to registration and its *"determination to use [its powers] to secure improvements in the operation of the Trust"*,⁸⁶ the CQC registered the Trust without conditions in April 2010. From the evidence that we have seen and heard, it seems that the prime mover in this remarkable shift in the CQC's position was the regional team. Immediately before registration, the regional team reported only 'minor concerns' over the Trust; this was considered by the central registration committee who, we were told, questioned whether the concerns should not be recorded as 'moderate' in view of the previous history, which would have meant registration subject to conditions. We heard, however, that the regional team gave assurances that the minor concerns related to maternity staffing issues (apparently related to the previous Birthrate Plus review) that were being resolved, and registration proceeded without conditions.

1.78 In our view, this was both an error and another missed opportunity. There were clearly deeper problems than the rather modest shortfall of staffing, which could not be rectified in a few months, and the change from the position of significant concern expressed by Mr Jefferson four months previously could hardly be starker. It is true that the CQC was a new organisation, with many staff in senior positions who had little or no experience of the health service, particularly those in the North West, and that they had a large number of applications for NHS registration to consider in April 2010 (378). Nevertheless, these factors do not seem to us to account for the totality of this rapid change in assessment. What we heard, and saw in documentary evidence, was that there was a gross breakdown of process and communication on the part of the CQC. This included the failure to heed the messages given by the PHSO on repeated occasions about the systemic nature of problems in the unit; the failure to communicate accurately on the nature of risk and the assessment of corrective action between the regional and central parts of the CQC; and the failure to ensure continuity of approach and assessment of problems in the handover from one regional director to another.

1.79 The epitome of this series of failed communications and inadequate processes was the CQC's director of operations' view as expressed to us that the PHSO decision not to investigate Mr Titcombe's complaint was instrumental in changing the CQC's perception of the Trust:

"There was [an implication for the CQC from the PHSO decision not to investigate]. It added to our evidence base around consideration of Morecambe Bay's application for registration under the Health and Social Care Act, that the problems that had been evident in 2008, when Joshua had died, had been resolved or were actively being resolved... taking that

⁸⁵ Sue McMillan interview.

⁸⁶ Letter from Alan Jefferson to James Titcombe, 6 December 2009.

information from the PHSO's decision, together with assurances from the Trust itself and the SHA, was one of the determinants in not registering the organisation with conditions."⁸⁷

As we have seen, the PHSO's decision was based at least in part on the point that the CQC was the right organisation to deal with the systemic problems they believed correctly were evident, and this had been explained previously to the same CQC director: *"If this were the case [that the CQC was a better way to investigate systemic problems] then we could consider declining to investigate but would want to be able to assure the family that their concerns would be dealt with robustly in another way."*⁸⁸ Yet within a few months CQC officers were taking the PHSO decision not to investigate as evidence that problems had been, or were being, resolved.

1.80 These events over the course of 2009/10 reveal, in our view, a level of organisational chaos centred on the CQC, and affecting its external relationships, of very significant degree, which disrupted its ability to detect and diagnose the serious systemic problems at Morecambe Bay and to take a coherent corporate approach to the Trust. Indeed, such is the scale of organisational failure in this regard that the question may be thought to arise as to whether there may have been an element of deliberate suppression of unwelcome news regarding the registration of Trusts in April 2010 and the impression this may have given of the NHS at the time. We have considered this question carefully, and have painstakingly sought any evidence from interviewees and from documents that might suggest that it was a factor. With one exception, we found little that would support the idea that it was.

1.81 The exception was Kay Sheldon, a CQC non-executive director who had raised concerns internally within the CQC about the organisation's approach to detecting risk in Trusts, particularly around registration, and used Morecambe Bay as an example. Whilst we fully agree with her reservations about the organisation's lack of competence to identify problems, we found little evidence to corroborate her impression that there was a desire to minimise concerns. She told us that *"there was a sense that the last thing that – well, the last thing the health environment needed was another Mid Staffs, and it was – it would often say, 'Oh no, it's not another Mid Staffs; it's not another Mid Staffs'. And I know that others have raised the fact that concerns – they felt that concerns were sort of minimised or kept quiet because they didn't want – in 2010 there was an election and there was the Mid Staffs, and I think I have some sympathy with that, actually."*⁸⁹

1.82 It is clear, however, that by the early part of 2010 there was no evidence coming from the CQC regional team to suggest any problems of the scale or severity of 'a Mid Staffs'. In fact the messages from the regional team fully supported registration without conditions, and we believe that Ms Sheldon is incorrect in suggesting that *"... there was a strong feeling that Morecambe Bay should have been registered with conditions, but that was overruled, apparently"*.⁹⁰ We heard that the CQC central registration committee had indeed challenged the regional team's recommendation to register without conditions, but it was the regional team's belief that the sole outstanding issue for the Trust was maternity staffing levels, which were being addressed, that proved decisive.

1.83 We are well aware that all NHS organisations are motivated to a greater or lesser extent by a desire to manage the communication of information that would show themselves, or the wider NHS, in a bad light, and that this may on occasions stray into inappropriate behaviour; this motivation is typically stronger in the run-up to a general election, simply because this is a period of intense media scrutiny when any adverse event becomes a front-page story. We did not, however, find any supporting evidence that this had been a factor in the CQC's approach to Morecambe Bay, and we

⁸⁷ Amanda Sherlock interview

⁸⁸ Email from Kathryn Hudson to Amanda Sherlock, 4 September 2009.

⁸⁹ Kay Sheldon interview.

⁹⁰ Kay Sheldon interview.

found no evidence that there had been any instruction to the CQC to modify their approach at the time. The CQC chief executive had suggested to the DH that up to 10% of Trusts might be registered with conditions, and told us that “... we weren’t under any pressure to not register Trusts with conditions”.⁹¹ In the event, 22 Trusts were registered with conditions, around 5%, and it is difficult to conceive of a scenario in which the existence of a 23rd would have generated headlines that the previous 22 did not.

1.84 On the basis of all the evidence that we have seen and heard, we believe that the failure lay in the underlying lack of organisational competence in the CQC to detect, diagnose and respond to the sort of problems that were evident at the Trust, and that this was exacerbated by a desire to believe that the Trust had identified what needed to be done and were putting it right. As the CQC regional director at the time of registration put it to us, “... with the benefit of hindsight, I think the Trust was very good at telling us what we wanted to hear, but I don’t think at the time we acknowledged that that was happening. They were telling us how they were making progress. That was what we wanted to hear...”⁹²

1.85 Had the CQC heeded the warning made clearly by the PHSO in September 2009 that there were evident systemic problems, they could have investigated the true nature of the problems much sooner than they became evident. Indeed this was the rationale behind the PHSO decision not to investigate Mr Titcombe’s complaint, as expressed to us:

*“The decision that I took at the time was to say this – this was too important for the Ombudsman to spend, you know, one or two years, yes, doing a forensic investigation when actually there were serious risks that other people were going to encounter in some of the failings. That was my judgment call. Actually it turned out to be that I had assurances from CQC that were worth absolutely nothing and fell apart, you know, within a matter of weeks. But that was my judgment call.”*⁹³

1.86 As it turned out, there would have been a great deal to be said for initiating a proper investigation at that stage, because there was a great deal more that could have been established about the events surrounding the FGH maternity unit and the Trust. It is understandable that the Ombudsman considered that the CQC was better placed to investigate and follow up on the systemic issues that had been identified. However, with the benefit of hindsight, it is clear to us that a CQC investigation would not have addressed all the concerns that Mr Titcombe had raised, which calls into question the linking of the decision not to investigate with the CQC’s intentions. Given that that was the decision and its basis, however, we were disappointed to learn that the PHSO’s role did not include a remit to follow this up with the CQC to confirm that the “robust action” had occurred.

1.87 On 12 April 2010, shortly after registration, the CQC reduced their risk assessment of the Trust again, from ‘amber’ to ‘green’, and four days later wrote to Monitor assuring them that they had only ‘minor concerns’ about the Trust. Taken together with the registration without conditions, these steps had a significant effect on the other organisations involved, the SHA and Monitor, who took the steps as evidence that effective action was eradicating the underlying problems, and Monitor reactivated the Foundation Trust process. The Trust itself also took reassurance from the CQC actions that they were regarded as having addressed the problems.

1.88 On 20 May 2009 the DH had been made aware by the SHA of “... a small number of Serious Untoward Incidents in relation to maternity services... [but that] the SHA has provided further reassurance that these are isolated incidents that are not indicative of any wider quality concerns at the Trust, and crucially all the information has been made available to inform any discussion on

⁹¹ Cynthia Bower interview.

⁹² Sue McMillan interview.

⁹³ Ann Abraham interview.

the Trust".⁹⁴ Recording also the complaint to the PHSO, this briefing recommended that it was not necessary to qualify support for the application, as Monitor was specifically checking with the CQC on maternity and would not consider the Trust for Foundation Trust authorisation if the Ombudsman intended to investigate the complaint. This was in line with the procedure to brief ministers to inform their support for a Foundation Trust application at that time. As we have seen, however, Monitor did defer the application in 2009. When it was resumed the following year, a revised and strengthened approach was in place in the DH following the Mid Staffs recommendations, but as this application had been deferred by Monitor rather than rejected, it seems that the DH were advised that they had no basis on which to qualify support in 2010.⁹⁵ Even if they had not, we doubt that the outcome would have been different given that the SHA Medical Director, Mike Cheshire, who would have reported any quality concerns to the NHS medical director under the new system, was newly in post and had not become involved in quality assessment at the SHA: *"As my role developed and as I got to understand it, which took me quite a few months, I was involved in all the subsequent FT applications and would go with the Quality Team to the hospitals, or the Mental Health Trusts, that were putting themselves forward for FT. We would go through their plans with a toothcomb. So I was deeply involved in those."*⁹⁶ In fact, as we have seen, there had been no scrutiny and none of the SHA directors had personally read the Fielding Report, which was wrongly believed to have confirmed that the incidents were not connected.

1.89 Prior to that, however, the SHA chief executive was clear that the CQC had overall responsibility for regulating the Trust on quality, and the SHA's responsibility was to pass its available information on the Trust to the CQC:

"The assurance process had to be that we gave all the information we could about that Trust to CQC. CQC decided whether that information met their own. They had the opportunity to go into the Trust. They had the opportunity to test our assumptions against anybody else's assumptions. They had powers that we didn't. We were not an inspectorate. You know, what I expect of the people in the SHA, and I've no reason to believe they didn't do this, was to give CQC all the information that they had, hard and soft about the Trust. And then CQC legally had the responsibility to take action."

Given that the CQC had just reduced their risk rating of the Trust to 'green' and reported only 'minor concerns' to Monitor, it seems to us unlikely that the SHA would have taken a different stance in relation to the Trust.

1.90 The DH had a clearly defined role at the start of the Trust's Foundation Trust application process, at which time the information they had was dependent on the SHA's perception of the situation. As we have seen, this was heavily influenced by the view that, although some governance issues had been identified and were subject to an action plan, the 2008 incidents were unconnected and not the results of systemic problems. The SHA chief executive was explicit on this point: *"I think it's absolutely critical in the context of this investigation that the grouping or the number of serious untoward incidents relating to children and childbirth and maternal deaths were scrutinised and seen as disconnected incidents. They weren't described as a cluster with a systemic underpinning..."*⁹⁷ We were careful to search for any evidence, either amongst documents or from interviewees, that might suggest that the DH became aware of any other signs of concern, either from the SHA or elsewhere. We found that almost all of the relevant information came from the SHA and followed the same line. Given that this was the information presented, we were not at all surprised to find that it was not considered necessary to brief senior DH officials, including the NHS medical director

⁹⁴ Briefing for Minister of State for Health by John Holden, NHS Finance Performance and Operations.

⁹⁵ Memo from Helen Hamilton to John Holden, July 2009.

⁹⁶ Mike Cheshire interview.

⁹⁷ Michael Farrar interview.

and chief nursing officer, or ministers. We are aware of a single briefing note for a meeting between the Secretary of State for Health and a local MP which was almost entirely focused on the subject of the meeting (cancer services at Westmorland General Hospital), but included a brief reference to maternity untoward incidents at FGH; again, given the content of the SHA's briefing, we were not at all surprised to find that the note was reassuring that these were being addressed, and did not signal any wider concerns.⁹⁸

1.91 In June 2010 the CQC carried out an inspection to follow up their 'improvement letter', issued in connection with the identification of staffing needs in maternity services, and found the Trust compliant with the required standards. It is clear to us that this inspection, carried out by generic CQC inspectors who were not necessarily experienced in assessing acute hospital services, was neither directed at, nor capable of, identifying the sort of systemic problems there were within the FGH unit. In August 2010 the Fielding Report was available to the Trust in final form, but as we have seen they did not share this with any external body at this stage. On 1 October 2010 the Trust was approved as a Foundation Trust. Later in October, Ms Brown at the SHA was given a copy of the Fielding Report after asking repeatedly (the CQC did not receive a copy from the Trust until April 2011). Given that the Trust had been left in no doubt that if the CQC reported more than 'minor concerns' the application would not proceed, it is difficult to avoid the conclusion that, however the delay in sharing the Fielding Report had arisen, it suited the Trust very well in the context of its Foundation Trust application.

1.92 In June 2011, HM Coroner for South and East Cumbria opened an inquest into the death of Joshua Titcombe in November 2008. The delay was caused by what seems to us an idiosyncrasy of the coronial system. The death occurred in Newcastle, where Joshua had been transferred for highly specialised treatment in a last-ditch attempt to sustain him long enough for his infection to be treated, and therefore fell under the jurisdiction of the coroner for Newcastle, but in view of the extremely poor condition of Joshua when he arrived in Newcastle the coroner was inclined to regard the death as expected and explicable, and therefore not requiring an inquest. It was not until persistent representations were made by Joshua's father that he was made aware of the events preceding Joshua's transfer and asked his counterpart in South and East Cumbria to take over.

1.93 The coroner made strong criticisms of both the clinical practice and conduct of Trust staff, including collusion in preparation for the inquest and possible destruction of evidence already discussed. Following a Rule 43 letter from the coroner expressing these concerns, Cumbria Constabulary launched a police investigation in September 2011. By its nature, this investigation was bound to be protracted, and the bar of establishing proof 'beyond reasonable doubt' for a criminal prosecution is a high one. Although it clearly falls outside our remit and expertise, we were struck by the thoroughness and persistence of this investigation, but not surprised that it ended with no prosecution. Nor are we convinced that a police investigation is the best way to uncover the truth in these circumstances, which is, we believe, what the families concerned wanted, although we can quite understand their frustration with the inability of previous NHS mechanisms to deliver it. Police interviews of FGH staff almost all ended with solicitors advising their clients to say nothing in addition to their written statement and answer no questions. This is in no way a criticism of the Cumbria Constabulary officers involved; it is a feature of the legal process. Although the majority of present and former staff were helpful and informative when interviewed, some appeared to us much more constrained in answering and stuck doggedly to previous lines even when these were difficult to sustain under challenge. We could not help but detect echoes of both the inquests and the police investigation in this approach.

1.94 The inquest and the onset of the police investigation prompted a significant escalation in the levels of concern surrounding the Trust. In addition, a further two SUIs occurred in the FGH

⁹⁸ Secretary of State briefing, 6 January 2010.

unit in September 2011, both resulting in stillbirths, that bore some unmistakable similarities to the earlier incidents. The picture changed rapidly and significantly from one generally characterised by under-involvement of external bodies and lack of familiarity with the Trust to one of multiple visits, inspections and reviews. This did finally lead to some more decisive action that began at last to identify the shortfalls in capacity and capability within the Trust to address the serious underlying problems in its maternity services. Initially, however, it seems to us that the Trust's focus remained on emphasising any positive statements in reviews and reports and undermining the more significant negative findings. The chief executive told us that, although he was by now aware of significant shortcomings in maternity services, it was important that the service continued and *"we were trying... to keep public confidence"*.⁹⁹ This was, in our view, a flawed approach. Not only was it misleading and falsely reassuring, in the long run undermining public confidence rather than maintaining it, it also surely increased the frustration and alienation of patients who had been harmed and their relatives.

1.95 On 3 October 2011 the SHA, which had continued to regard the supposedly coincidental nature of the previous incidents as evidence that there was no systemic problem up to 10 September 2011,¹⁰⁰ called a 'Gold Command'. The intention appears to have been to offer support to the Trust in responding and accessing additional staffing, but the evidence we heard suggested that it served as much to distract senior staff in the Trust, who had to brief twice-weekly Gold Command meetings. We could find no evidence of defined exit criteria to underpin the closing down of Gold Command by Cumbria PCT, and it was not clear exactly what had been achieved when this was done. Overall, we were unconvinced that this represented the best way to address the situation.

1.96 On 11 October 2011, Monitor found the Trust to be in breach of its terms of authorisation as a Foundation Trust, and subsequently used its statutory powers of intervention to commission a clinical review of services by a team from the Central Manchester University Hospitals NHS Foundation Trust, which in November 2011 reported serious service weaknesses. In December 2011 the Trust chair resigned and an interim chair was appointed, Sir David Henshaw. His view of the Trust was that *"the Board was not in control... there was no clear vision, no clear strategy, the quality of the Board in its debates and the agendas and the papers was very poor..."*¹⁰¹ He took early steps to improve the leadership in key areas: *"... Tony Halsall and I on the very second week had a conversation, and, I think, I made it clear I didn't see him as being the Chief Executive who would lead recovery on the basis of what I had seen in the previous 10 days... I [had a] conversation with [the medical director] and he agreed he would stand aside once I found somebody that we could bring into the role."*¹⁰²

1.97 In January 2012 the CQC carried out a Section 48 review of the emergency care pathway in the Trust, and governance arrangements. We were unable to discover a convincing reason why this review did not include maternity services, given the confluence of signs of significant problems at the time. A review of governance arrangements in the Trust, required by Monitor, was carried out by PricewaterhouseCoopers, and reported on 2 February 2012. This review also found serious weaknesses and was unable to provide assurance that the Trust's systems were adequate to identify problems and ensure improvement.

1.98 In February 2012 the Trust chief executive vacated his post, in line with the interim chair's appraisal, initially on a fixed-term secondment, and further Board changes followed. In mid-2012 a new chief executive was appointed substantively, and began a process of repairing the Trust's management arrangements, governance systems and clinical services. Our appraisal of the cumulative effect of this process is elsewhere.

⁹⁹ Tony Halsall interview.

¹⁰⁰ SHA briefing, 10 September 2011.

¹⁰¹ Sir David Henshaw interview.

¹⁰² Sir David Henshaw interview.

CHAPTER TWO: Background

Note on abbreviations

2.1 A glossary of abbreviations referred to in this Report is provided at Appendix 1, and an acknowledgement to those involved in the drafting and production of the Investigation Report is included as Appendix 2.

Background to the Investigation

2.2 The University Hospitals of Morecambe Bay NHS Foundation Trust (the Trust) had been the subject of scrutiny for a number of years, following the high number of serious untoward incidents in its maternity and neonatal services. The families of those who were harmed or died under the care of the Trust sought a full and independent investigation into the circumstances surrounding these deaths.

2.3 On 12 September 2013, the Rt Hon. Jeremy Hunt MP, Secretary of State for Health, announced to the House of Commons, by way of a written ministerial statement, the terms of reference for an independent investigation into the management, delivery and outcomes of care provided by the maternity and neonatal services of the Trust from 1 January 2004 to 30 June 2013.

2.4 The Investigation's terms of reference were:

1. *"To review the outcomes for mothers and babies that occurred during this time, including maternal and neonatal deaths that occurred in the Trust and in any other institutions to which patients were transferred;*
2. *To review the Trust Board's actions and governance procedures in response to untoward incidents such as the deaths of mothers and babies, including:*
 - a) *the Board's processes for responding to serious untoward incidents (SUIs);*
 - b) *the relationship and communication between the Trust and:*
 - *patients and families*
 - *GPs and community ante-natal midwifery services*
 - *commissioners, predominantly in the two local Primary Care Trusts (PCTs), Cumbria PCT and North Lancashire PCT, their predecessor PCTs, and successor Clinical Commissioning Groups (CCGs)*
 - *the North West Strategic Health Authority*
 - *regulators – including Monitor, the Care Quality Commission (CQC) and the Healthcare Commission*
 - *public health services*
 - *other Trusts where mothers and babies were transferred*
 - *any other relevant organisations; and*
 - c) *relevant investigations published by the Parliamentary and Health Service Ombudsman;*

3. *To review the Trust Board's responses to, and any subsequent actions taken following receipt of, the following reports:*
 - *Monitor's review of the Trust's application for Foundation Trust status (April 2010), October 2010*
 - *Fielding Report, August 2010*
 - *Central Manchester University Hospital Diagnostic Review, December 2011*
 - *PricewaterhouseCoopers Governance Review, February 2012*
 - *Gold Command Stocktake, April 2012*
 - *CQC Investigation Report, July 2012*
 - *Nursing and Midwifery Council (NMC) Review, July 2012*
 - *NHS Litigation Authority's Clinical Negligence Scheme for Trusts (CNST) reports.*
4. *To make findings as to the adequacy of the actions taken at the time by the Trust to mitigate concerns over safety;*
5. *In light of this, to assess and make findings as to the Trust's ability to discharge its duties in delivering maternity services; and*
6. *To make recommendations on the lessons to be learned for both the Trust and the wider NHS to secure the delivery of high quality care.”¹*

2.5 The Secretary of State announced that I had been asked to chair the Investigation. I had been a former associate medical director at the Department of Health and had served on the Hillsborough Independent Panel.

2.6 A copy of the Secretary of State's written ministerial statement regarding the establishment of the Morecambe Bay Investigation can be found at Appendix 3.

Establishing the Investigation

2.7 Prior to the Secretary of State's announcement on 12 September 2013, I had a meeting in Barrow with the group of families that was instrumental in campaigning for an independent investigation.

2.8 At that meeting I discussed the proposed terms of reference with the families, to ensure that the Investigation could commence its work in the knowledge that they were fully informed about the scope of the Investigation.

2.9 Having stated my intention that the Investigation should identify a base in the North West to enable families to attend the oral evidence sessions without them having to travel a significant distance, I was able to announce that accommodation had been secured at Park Hotel, East Cliff, Preston, PR1 3EA. The accommodation is managed by Lancashire County Council and the part that the Investigation uses is temporarily surplus to its requirements.

2.10 The Morecambe Bay Investigation held its first public meeting on 1 November 2013 at its offices at Park Hotel. The families, representatives from interested organisations, local Members of Parliament and members of the media were invited to hear me set out the methods I would use to undertake the Investigation, and the principles I would adopt.

2.11 I explained that the Investigation would be entirely independent. It would carry out a complete and thorough examination of the evidence, and it would operate as transparently as possible. I undertook to continue liaising directly with the families that had been immediately affected by the

¹ The Morecambe Bay Investigation: Terms of reference.

events at the Trust, as I hoped that this would enable families to put their views directly to me. These views I would take into account as far as possible, while remaining strictly impartial and objective.

2.12 I appointed a small, independent secretariat to support the work of the Investigation. All its members were based full time at the Investigation's premises in Preston.

2.13 The Investigation engaged the services of a data analyst to assist us in assessing the significant volume of data collected via the evidence-gathering process. Hannah Knight was seconded to the Investigation on a part-time basis from the Royal College of Obstetricians and Gynaecologists.

Selection and appointment of a Panel of expert advisors

2.14 An immediate priority was to select and appoint an independent Panel of expert advisors.

2.15 To ensure that the Investigation benefited from the expert advice of clinicians with up-to-date operational knowledge and experience and of individuals who had held senior leadership roles in the NHS – including those in those categories of organisations whose actions the Investigation would be reviewing, yet who were entirely independent of the provision or management of health services in the North West region – the Investigation secretary asked NHS England to provide the CVs of suitable clinical candidates. I then considered the nominations, determined what would constitute an appropriate Panel to address the Investigation's terms of reference, and appointed the following experts to form an advisory Panel:

- Professor Jonathan Montgomery, Chair of the Health Research Authority and Professor of Health Care Law at University College London, to be the Investigation's expert advisor on ethics;
- Dr Geraldine Walters, Director of Nursing at King's College Hospital in London, to be the Investigation's expert advisor on nursing and management;
- Mr Julian Brookes, Deputy Chief Operating Officer at Public Health England, to be the Investigation's expert advisor on governance;
- Ms Anne Thomas, Head of Midwifery and Gynaecology at Northampton General Hospital NHS Trust, to be the Investigation's expert advisor on midwifery;
- Dr Catherine Calderwood, an experienced senior obstetrician practising in Scotland, who advises the Scottish Government and is the National Clinical Director for Maternity and Women's Health at NHS England, to be the Investigation's expert advisor on obstetrics; and
- Professor Stewart Forsyth, former Chair of the Scottish Government Neonatal Expert Advisory Group and former Medical Director of NHS Tayside, to be the Investigation's expert advisor on paediatrics.

2.16 Due to unforeseen circumstances, Ms Thomas had to step down from the Investigation Panel prior to the first Panel meeting and was replaced by Mrs Jacqui Featherstone, Associate Director of Nursing and Midwifery at Princess Alexandra Hospital, Harlow.

2.17 When the number of individual cases to be reviewed and the volume of evidence requiring the scrutiny of the Panel's expert obstetrics advisor was confirmed, I invited Professor James Walker, Professor of Obstetrics and Gynaecology at St James's University Hospital in Leeds, to join the Panel in March 2014 to provide additional expert advice on obstetrics.

2.18 Further information regarding the Investigation's Panel of expert advisors is provided at Appendix 4.

2.19 During the course of the Investigation's work, and specifically during the interview programme, there were a small number of occasions when an individual interviewee was already known to me or to a fellow Panel member. On these occasions, and to ensure that the Investigation operated as transparently as possible, the Panel member concerned made known the professional capacity in which they were acquainted with an interviewee, and this was duly recorded.

2.20 Panel meetings were held monthly, and the families were invited to attend and observe all the sessions. A schedule of the Panel meeting dates and the venue for each meeting is listed at Appendix 5. The agenda and a brief summary of each Panel meeting were posted on the Investigation's website.

2.21 Whilst the early Panel meetings provided us with an appropriate forum in which to discuss and agree how the detailed work of the Investigation should proceed, in particular regarding the collection and analysis of data to help shape the evidence-gathering process, the first two Panel meetings, in November and December 2013, provided an opportunity for the entire Panel to hear directly from a number of the families that had been affected by events at the Trust about their experiences.

2.22 From the Panel, we established three sub-groups to progress the work of the Investigation. The clinical sub-group was chaired by Professor Forsyth; the Trust response and governance sub-group was chaired by Dr Walters; and Professor Montgomery chaired the external response and governance sub-group. Membership of the Investigation Panel's sub-groups is provided at Appendix 6. As their work progressed, the three sub-group leads provided colleagues with regular updates at Panel meetings.

2.23 Panel meetings were structured to ensure that we received updates from the Investigation's secretariat on progress with the evidence-gathering process, the Investigation's interview programme and how the Investigation was addressing the Investigation's terms of reference. Exceptionally, at the Panel meeting in March 2014, colleagues from NHS England were invited to give a presentation on the commissioning of health services in the Trust catchment area during the period under review by the Investigation.

Communication with the families

2.24 Prior to the establishment of the Investigation in September 2013, I was provided with the details of a group of known families. This enabled me to make contact with the families affected by the events at the Trust.

2.25 Following the establishment of the Investigation and the announcement of the Method Statement, with details of the Investigation's website, we were contacted by more families.

2.26 Over a period of several weeks in January 2014, the Investigation placed notices in the print and online editions of a number of local newspapers in the Trust catchment area (the *Westmorland Gazette*, the *North West Evening Mail*, the *Lancaster Guardian* and the *Morecambe Visitor*). A copy of the notice is attached at Appendix 7. The purpose of the notice was to provide families affected by the events at the Trust with details of the Investigation and to invite them to contact us if they wished to share their personal experiences about maternity and neonatal care provided by the Trust.

2.27 This exercise provided an important opportunity for many more families to make contact with us, and for the Investigation subsequently to ensure that it communicated directly with as many families as possible. In light of the need to respect families' privacy and our wish to avoid the possibility of unwittingly causing unwelcome and unwanted reminders to those who did not wish contact, we have not approached anyone directly without prior contact from them. We have, however, sought to spread information widely about the Investigation and have made it as easy as possible for anyone who wishes to contact us.

2.28 Throughout the course of the Investigation, I invited the families to meet me, so that I could provide progress updates and answer any questions they had regarding the Investigation process. These meetings took place on 1 November 2013 (prior to the announcement of the Method Statement) in Preston, and on 24 March 2014, 26 November 2014 and 6 February 2015 in Barrow.

Methodology and analysis of the evidence

2.29 On 1 November 2013, I set out how I proposed to undertake the evidence-gathering process.

2.30 Having reviewed the Investigation's terms of reference, the Panel developed a set of detailed questions it should ask in order to address each of them fully. The families were invited to submit any questions they had; where these were generic and within the terms of reference, they were included.

2.31 We then determined which interested organisations (including the legacy body in respect of any organisations that had been merged or abolished during the period of review set out in the Investigation's terms of reference) we should request evidence from, in order to get answers to the detailed questions.

2.32 Once material was submitted to the Investigation, we were in a position to review it and begin to draw up an initial list of potential interviewees – i.e. those individual post holders in each of the interested organisations, referred to in the evidence, who we considered were best placed to respond to the Investigation's questions. This list was not definitive and we added, and removed, names of interviewees as the review of the evidence became more complete.

2.33 Individuals were contacted in order to advise them that they may be invited to interview. Subsequently the Investigation developed an interview list, and individuals from a number of organisations, as well as individuals who had independently approached us, were invited to interview.

2.34 Information regarding the practical arrangements for evidence-gathering processes – evidence recovery and the interview programme – is set out below.

2.35 The Investigation's data analyst carried out a series of independent analyses using several sources of national and local Trust data. The aim of these analyses was to assess the extent to which the sources of data could be used to address the Investigation's terms of reference.

2.36 In particular, the analyses helped us to develop the list of key questions to be addressed under terms of reference 1 and 2, and provided context for the next phases of evidence gathering. We used the data in preparation for the case note review, and in order to compile a list of specific questions to direct to particular interviewees.

2.37 The sources of data examined were as follows:

- a. We were granted permission by the Secretary of State to access Hospital Episode Statistics (HES) data linked to the Office for National Statistics death register for the period under investigation. This dataset was used to address the following questions:
 - Is there evidence that the standard of care in the Trust's maternity and neonatal services was different from other NHS Trusts during the review period on indicators derived from routine data?
 - Is there evidence of change in the standard of maternity and neonatal services at the Trust during the review period?
 - To what extent were the outcomes of maternity and neonatal care within the Trust explained by the characteristics of the population served?

Rates of various clinical practices and outcomes derivable from HES data were calculated in order to compare the performance of the Trust's maternity and neonatal services with those of other NHS Trusts, and to compare changes over time. The metrics examined included the hospital standardised mortality ratios (HSMR), as well as rates of caesarean section, instrumental delivery, severe maternal morbidity, unplanned maternal readmission to hospital within 30 days of delivery, stillbirth, neonatal death, severe neonatal morbidity and unplanned neonatal readmission to hospital within 28 days of birth. All rates were adjusted for maternal and clinical risk factors that are beyond a provider's control: for example, maternal age, ethnicity and parity.² In addition, the quality of the data submitted to HES by the Trust was examined.

- b. We also commissioned data held by the Trust in the form of a data extract from its electronic maternity information system (Evolution) covering the period January 2005 to June 2013.³ This dataset contained additional information which was not available in HES, which is primarily an administrative dataset and therefore does not contain the level of clinical detail needed to examine some important outcomes. This data was used to cross-check the data in HES to ascertain its reliability. The data was also used to calculate rates of low Apgar score⁴ at the Trust; this information was then benchmarked against a similar regional dataset from the South West of England.
- c. The Health & Social Care Information Centre provided the Investigation with an extract of workforce data from the electronic staff record covering the period 2008 to 2013. This extract included data from the Trust and 16 other Trusts that were comparable in terms of the size of the maternity service. The data extract allowed the analyst to derive Trust-level information in maternity workforce numbers, pay bands, birth:midwife ratio; overtime expenditure; bank expenditure; stability index; and sickness absence. This data was analysed in order to identify any notable trends at the Trust compared with other Trusts of a similar size. However, the analyst was not able to examine differences in these measures between the Trust sites, due to issues of disclosure control: the small numbers involved meant that there was a risk of identifying individuals.
- d. The analyst also sought comparative data on the performance of the Trust that was published by various organisations in the public domain and to which the Trust could therefore reasonably have been expected to have access:
 - Care Quality Commission maternity experiences survey (2007; 2010; 2013), which measures the experience of women receiving maternity care
 - NHS staff survey, which measures staff engagement
 - Patient safety incident reporting figures, which show whether incidents are actively being reported.
- e. Finally, the Investigation requested copies of the Centre for Maternal and Child Enquiries (CMACE) Trust-level perinatal death reports covering the period 2004 to 2009. CMACE was decommissioned in 2011, and data from 2009 to 2013 was

² Logistic regression models built to predict the probability of each outcome at the patient level according to individual characteristics. These probabilities were summed at the hospital level to give the hospital's predicted rate of the outcome of interest. Risk-adjusted rates for each hospital were produced by dividing the hospital's unadjusted rate by its predicted rate, and multiplying this ratio by the national rate. Where appropriate, funnel plots were used to illustrate the level of national variation and to ascertain whether the hospital had a higher or lower rate of specific outcomes than expected, based on its size and population characteristics. For the neonatal outcomes, information was presented using sequential probability ratio test (SPRT) charts.

³ Evolution Dataset – January 2005 to June 2013.

⁴ Apgar score is a measure that ranges between 0 and 10 and summarily assesses the health of the newborn baby immediately after birth. Low Apgar score is defined as a score of less than 7 at five minutes among term, singleton live born infants, excluding those delivered by elective caesarean section.

therefore unavailable. However, a statistical review of perinatal mortality in Cumbria was commissioned by NHS Cumbria, covering deaths that occurred in 2009 and 2010.⁵

2.38 We considered the potential complexities, given the Trust's size and the nature of maternity care, of relying too heavily on statistical data to produce recommendations. These points are considered in more detail subsequently.

2.39 A further reason for our concern about relying on the analytical work carried out was the variable quality of national comparative data available. Complete and accurate data is essential for providing accurate information about the performance of organisations that can be used to improve the quality of care. However, a number of data quality issues limit the extent to which HES can be used to construct clinically meaningful and technically robust quality indicators for maternity care:

- HES is primarily an administrative database and therefore does not capture all relevant clinical information about patients. For example, certain maternal risk factors – such as body mass index, smoking and alcohol consumption – are not recorded, meaning that these factors cannot be taken into account. Furthermore, HES does not contain data on the time of birth, which meant that plans to examine patterns of maternal and neonatal outcomes at the Trust according to the timing of delivery could not be carried out.
- A national data warehouse like HES raises important issues around the standardisation of data definitions among units. Divergent coding practices can undermine meaningful comparisons, and some commentators have raised concerns about the accuracy and completeness of diagnosis and procedure coding in HES.
- There remains a persistent problem with the completeness of HES maternity data. Although the situation has improved slightly in recent years, the position is still that almost 30% of delivery records are missing at least one key piece of information about the delivery episode, such as gestational age or birth outcome. Regrettably, a number of Trusts still fail to submit maternity information for any deliveries.

2.40 These issues meant that it was not possible to reliably derive all of the outcomes that were of interest to us. We were also mindful of over-interpreting some of the data due to the small numbers involved. Finally, we considered what the Trust could reasonably have been expected to be aware of, given the information and the analytical assessments it had access to in the period under investigation.

The Investigation's evidence-gathering process

Document recovery

2.41 The Investigation secretary is registered with the Information Commissioner's Office to enable the Investigation to hold personal and sensitive data that we needed to review. This was a fundamental governance arrangement to ensure that there could be a safe release and transfer of material from interested organisations, most significantly from the Trust, which was asked to supply individual patients' records.

2.42 Appropriate protocols were developed regarding the storage, management, retention and return of material submitted to us (or in some cases the destruction of evidence that need not be returned), and these were shared with interested organisations and individuals.

2.43 Material was submitted to the Investigation in a variety of electronic file formats and hard copy.

2.44 Every document submitted to the Investigation was assigned a unique reference number, and a central log of evidence was maintained by the Investigation's Documents and Evidence Team.

⁵ *Review of Perinatal Mortality in Cumbria*. Solutions for Public Health, on behalf of NHS Cumbria, February 2013.

All evidence was scanned and placed on our evidence database. To enable the review of evidence remotely, the Investigation secretariat stored evidence on Huddle (a database that uses cloud-based collaboration software), which facilitated the secure storage and sharing of information between the secretariat and the Panel.

2.45 From 3 January 2014 onwards, we began making requests from a number of interested organisations for material relevant to our terms of reference. This process was significantly more protracted than anyone in the Investigation had initially anticipated – particularly, but not only, in respect of the material that was requested from organisations that had been subject to significant reorganisation or that had been abolished during the period that we were reviewing. The final evidence requested by the Investigation was received on 11 January 2015. Some late evidence was submitted on 16 February 2015; however, that material could not reasonably be included in any findings we would make.

2.46 During the course of the evidence-gathering process, we sought material from the following organisations:

- University Hospitals of Morecambe Bay NHS Foundation Trust
- Department of Health (both in respect of its policy responsibilities and as the legacy body holding the records of the former North West Strategic Health Authority and the former South Cumbria and North Lancashire PCTs)
- NHS England
- Monitor
- NHS Litigation Authority
- HM Coroner for South and East Cumbria
- Health and Safety Executive
- NHS Cumbria Clinical Commissioning Group (for the period 1 April 2013 – 30 June 2013 and in respect of functions transferred to it from South Cumbria PCT)
- NHS Lancashire North Clinical Commissioning Group (for the period 1 April 2013 – 30 June 2013 and in respect of functions transferred to it from North Lancashire PCT)
- Public Health England
- Nursing and Midwifery Council
- General Medical Council
- Parliamentary and Health Services Ombudsman
- Care Quality Commission
- Healthwatch Lancashire
- National Institute for Health and Care Excellence
- Lancaster Medical School (part of Liverpool University)
- University of Cumbria
- North Western Deanery
- People First Cumbria (Healthwatch Cumbria)
- Royal College of Surgeons
- Health & Social Care Information Centre.

2.47 In addition, the local Members of Parliament were asked to submit any material that they considered would assist the Investigation, and significant evidence was also provided to the

Investigation by the families and by interested members of the public. Cumbria Constabulary provided us with invaluable background information.

2.48 In total 15,280 documents were submitted to the Investigation as evidence.

The interview programme

2.49 It is explained earlier how we identified potential interviewees and those individuals we subsequently invited to interview.

2.50 Interested organisations were consulted on a draft interview protocol, and this was provided to all interviewees and potential interviewees. A copy of the interview protocol is attached at Appendix 8.

2.51 We conducted interviews at Park Hotel in Preston and the Trinity Enterprise Centre in Barrow.

2.52 Our first interview took place on 2 May 2014 and we concluded the interview programme on 9 February 2015.

2.53 The Investigation interviewed 118 individuals.

2.54 Brief summaries of all the interviews that were not held in a closed session are available on the Investigation's website.

2.55 We were able to interview a very high proportion of those that we set out to invite to attend. Many interviews involved difficult and stressful recollections, sometimes over a period of several hours, and we are grateful to all those who assisted us in this way. The benefits that I hope and believe will spring from this report would not be possible without their input.

2.56 In a few cases, either we could not contact individuals who had changed jobs and locations, or we were unable to interview them if deemed medically unfit. Given the small number concerned and the availability of alternative sources of evidence in each case, we are confident that these exceptions made no material difference to the Investigation or its findings.

2.57 We were disappointed that some interviewees sought to dispute the need to attend, for example on the grounds that the events took place some time ago or that others were better placed to provide information. Investigations such as this have a clear purpose in improving the NHS, and we believe that current and former public servants have a responsibility to assist. We do not believe that it is the job of an investigation to persuade interviewees of the need to attend. In the end, though, we were almost universally successful in obtaining interviews, but this required significant and sometimes protracted efforts, and we remain concerned at the example that this lack of cooperation sets for more junior staff.

2.58 A list of interviewees is attached at Appendix 9.

Communications

2.59 The Department of Health facilitated the establishment of an Investigation website: www.gov.uk/government/organisations/morecambe-bay-investigation

2.60 I explained on 1 November 2013 that, in order to establish the website as swiftly as possible, and in accordance with guidance issued by the Government Digital Service, the Investigation's website would be hosted by the Department of Health. In addition, the wording of the website's introductory page had to be written to meet government standards for accessibility. But these were matters of technical convenience only. The management of content was to be solely the responsibility of the Investigation's secretariat, and updates from the Investigation would be loaded as 'publications' onto its website.

2.61 During the course of its work, the Investigation faced challenge via the Information Commissioner's Office about its independence, on the basis of the standard wording on its website regarding Freedom of Information requests. This wording is a standard requirement for all Gov.uk websites, but was not accurate or appropriate for an independent investigation such as the Morecambe Bay Investigation, and the wording was amended accordingly.

2.62 Information regarding our progress was communicated directly to families, interviewees, interested organisations and the public when appropriate, and relevant information was placed on the Investigation's website.

The Investigation timeline

2.63 I was initially asked to report to the Secretary of State in July 2014.

2.64 Due to the complexity of our work, the volume of material submitted and the time required to arrange and conduct interviews, I asked the Secretary of State for two separate extensions to the Investigation timeline. The Secretary of State agreed the initial extension, to November 2014, and the second extension to February 2015.

CHAPTER THREE: Clinical services

Background

3.1 University Hospitals of Morecambe Bay NHS Foundation Trust (the Trust) provides a comprehensive range of acute and support hospital services for around 350,000 people across North Lancashire and South Cumbria.

3.2 With over 740 beds, the Trust operates from three main hospital sites: Furness General Hospital (FGH) in Barrow, the Royal Lancaster Infirmary (RLI) in Lancaster and Westmorland General Hospital (WGH) in Kendal. It also runs two centres: Queen Victoria Hospital in Morecambe and Ulverston Community Health Centre.

3.3 FGH and RLI have a range of general hospital services, with full emergency departments, critical/coronary care units and consultant-led beds. WGH provides a range of general hospital services, together with a primary care assessment service and general practice-led inpatient beds, operated by Cumbria Partnership NHS Foundation Trust.

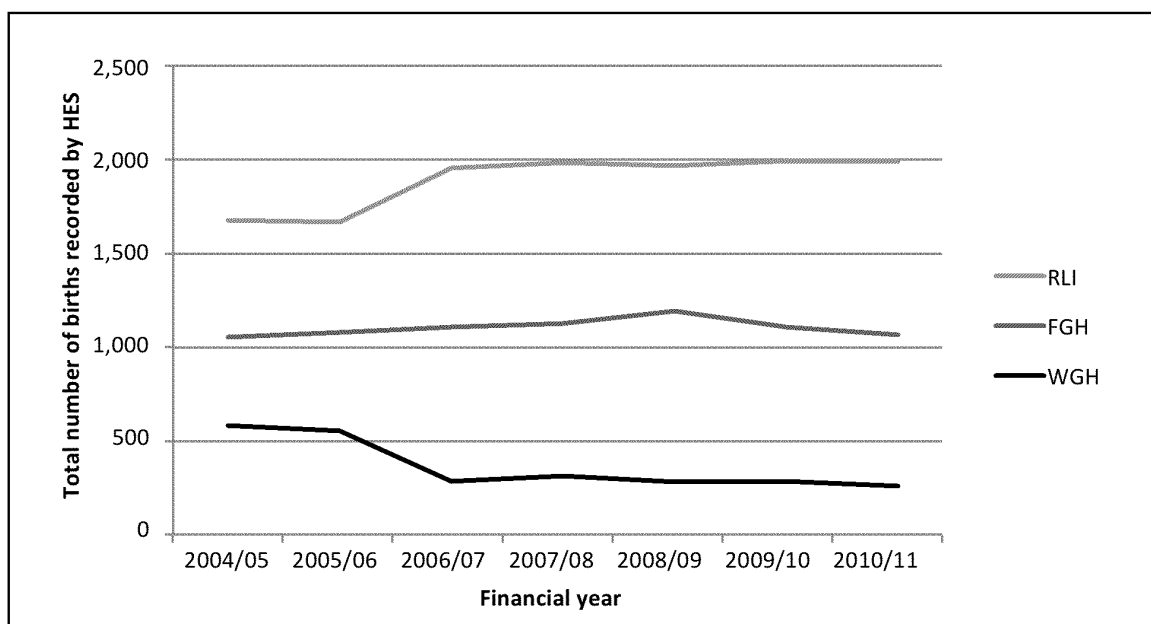
Maternity and neonatal services

3.4 Maternity services are provided on three hospital sites across the Trust. The maternity services at RLI consist of a central delivery suite and an antenatal/postnatal ward, and offer midwife-led and obstetric consultant-led care for high-risk and low-risk women. There is a level 2 neonatal unit, which may provide high dependency care and some short-term intensive care as agreed within the maternity and neonatal network. The maternity services at FGH consist of a labour ward and an antenatal/postnatal maternity ward, and offer midwife-led and obstetric consultant-led care for high-risk and low-risk women. There is a level 1 special care baby unit, which should not provide care for infants requiring high dependency or intensive care (British Association of Perinatal Paediatrics, 2001). However, in 2010 the British Association of Perinatal Paediatrics made some modifications to the categories of neonatal units: special care units can now also provide, by agreement with their neonatal network, some short-term high dependency services; and high dependency units, which have been redefined as local neonatal units, can provide special care and high dependency care and a restricted volume of intensive care (as agreed locally). However, it is expected that babies who require complex or longer-term intensive care will be transferred to a regional neonatal intensive care unit. Helme Chase is a midwife-led unit based in WGH which can provide care to women who have been assessed as low risk and not requiring consultant care. South Cumbria is part of the Lancashire and South Cumbria Neonatal Network, meaning that mothers or babies requiring tertiary-level care are usually transferred to the Royal Preston Hospital in Lancashire.

3.5 Apart from 2005/06, when the WGH obstetric-led unit was changed to a midwife-led unit, the trends in the total number of births at the three maternity sites within the Trust have remained relatively constant, with there being approximately twice as many deliveries at RLI as at FGH.

Geography and demography

3.6 The challenge for maternity service providers has been to ensure that there is safe and sustainable care provided across a rural area with a large geographic spread. For example, for those living in Barrow it is 52 miles to the nearest level 2 neonatal unit.



National comparative data

3.7 A maternal death is defined as the death of a woman while pregnant or within 42 days of the end of the pregnancy from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes.¹ Perinatal mortality is defined as the death of a fetus or newborn in the perinatal period that commences at 24 completed weeks' gestation and ends at seven completed days after birth. Perinatal mortality therefore encompasses both stillbirth, which is defined as a baby delivered without signs of life after 23+6 weeks of pregnancy, and early neonatal death, which is defined as the death of a live born baby occurring before seven completed days.

3.8 The World Health Organisation recommends the use of perinatal mortality as an indicator of maternity and newborn care, as it provides information required to improve the health of pregnant women, new mothers and newborn infants. It also allows decision-makers to identify issues, monitor trends and inequalities and consider changes to public health policy and practice.

3.9 In Cumbria during the years 2004–08, the five-year average perinatal mortality rate was 5.9 per 1,000 total births. A five-year average rate is used where deaths of babies in the perinatal period are relatively rare and may vary widely on an annual basis, especially in a relatively small geographical area such as Cumbria. The perinatal mortality rate in England and Wales for 2006 was 7.9 per 1,000 births.

3.10 In Cumbria, there appeared to be a decline in the perinatal mortality rate, from 7.3 per 1,000 total births in 2005 to 6.7 per 1,000 total births in 2009. However, this fall was not statistically significant. The stillbirth rate also decreased from 4.8 to 4.5 per 1,000 total births over the same period. The decline in early neonatal deaths exceeded that of stillbirths and the lack of a reduction in stillbirths meant that the proportion of perinatal mortality attributable to stillbirth rose from 50% to 66%.

3.11 A recent national report shows that there has been an overall fall in maternal deaths, from 11 per 100,000 deliveries in 2006–08, to 10 per 100,000 deliveries in 2010–12, primarily due to a reduction in the direct causes attributable to pregnancy.² Two-thirds of the mothers who died did so due to indirect causes of death (those due to co-existing medical and psychiatric conditions), and

¹ World Health Organisation, 2010

² *Saving Lives, Improving Mothers' Care*. MBRRACE-UK, 2014.

this figure has remained stable for the last ten years. Translating this data to the Trust, more than one maternal death in a three-year period would be unexpected.

3.12 It is important to recognise that perinatal outcomes are influenced by socio-economic, lifestyle and health factors, including maternal age, social deprivation, ethnicity, maternal obesity, smoking and alcohol consumption and, as these non-clinical factors can influence perinatal mortality rates, it cannot be assumed that the local perinatal mortality rate truly reflects the quality of clinical care. The overall perinatal mortality rate in the Trust is lower than the national and regional rate, but this may reflect the ethnicity and positive health and socio-economic status of the population. It is therefore important for each geographical area to try to determine the local causes of and risk factors for maternal death, stillbirth and neonatal death, and the contexts in which they occur. Therefore high-level metrics may not be sensitive to the underlying risks.³ For that reason, it is important to understand what is happening in clinical services themselves.

3.13 The teenage pregnancy rate within the Trust's catchment area is slightly higher than the national average, with more teenage deliveries taking place at FGH. Within the Trust there is a smaller proportion of mothers aged 35 or over than there is nationally (18% compared with 20% nationally). Overall there is less deprivation across the Trust compared with national levels, with 60% of the local population being in the top three least deprived categories, compared with 50% nationally. However, women delivering at FGH are considerably more deprived than those at RLI, with 59% in the two most deprived categories, compared with 38% at RLI (national mean = 50%). These are groups that are at greatest risk of maternal and perinatal mortality. There are also differences in ethnicity, with 97% of women delivering at the Trust being of white ethnicity, compared with 78% nationally. Women of non-white ethnicity are at greatest risk of maternal and perinatal mortality.

Review of clinical practice in maternity and neonatal services, University Hospitals of Morecambe Bay NHS Foundation Trust

3.14 The aims of the clinical practice review were:

1. to assess the quality of maternity and neonatal care provision for identified cases;
2. to identify areas of practice judged to be substandard;
3. to review whether the Trust was following national and network guidelines and pathways in relation to the cases selected for review;
4. to identify recurring themes for potential improvement to maternity and neonatal care provided by the Trust.

Sources of evidence

3.15 There are three sources of evidence that underpin this review of clinical practice:

1. the comparative analysis of data from the Trust with national data;
2. data from an extensive review of medical records from the Trust;
3. evidence from interviews with clinicians and clinical managers from the Trust.

National comparative analysis

3.16 In January 2014 the Clinical Effectiveness Unit at the Royal College of Surgeons of England was commissioned to undertake an analysis of Hospital Episode Statistics (HES) data for the Morecambe Bay Investigation.

³ *A promise to learn – a commitment to act: Improving the Safety of Patients in England* (Berwick review). National Advisory Group on the Safety of Patients in England, 2013.

3.17 The purpose of the analysis was to determine whether the reported statistics suggested that the standard of care in the Trust's maternity and neonatal services was different from that in other NHS Trusts during the review period (1 January 2004 to 1 June 2013).

3.18 The maternal outcomes proposed for the analysis were mode of delivery, severe maternal morbidity and unplanned maternal readmission to hospital within 30 days of delivery.

3.19 The neonatal outcomes were stillbirth, neonatal death, severe neonatal morbidity and unplanned neonatal readmission to hospital within 28 days of birth. In addition, the quality of the data submitted to HES by the Trust was also to be examined.

3.20 Some salient findings emerged from this analysis.

3.21 HES data completeness was only 20% in 2006/07. From 2008/09 to 2011/12, HES had a record of only one stillbirth, whereas the Trust's electronic maternity system had information on 52 stillbirths during the same period.

3.22 Hospital standardised mortality ratios (HSMRs) at the Trust were higher than expected in 2010/11, but this was associated with the move to a new information system that proved to be recording data on comorbidity and palliative care incompletely, which affected both FGH and RLI; HSMRs for previous and subsequent years were not significantly raised.

3.23 The analysis identified variation in clinical practice between the two obstetric-led maternity units in RLI and FGH. Instrumental deliveries were twice as common in RLI as in FGH, and the incidence of caesarean sections was also higher in RLI in the early part of the study period (2004/05 to 2006/07). However, there has been a steady increase in caesarean sections in FGH and by 2011/12 the rate was 5% higher than in RLI and above the national average. In parallel with this trend there was a reduction in the incidence of spontaneous vaginal deliveries in FGH.

3.24 Analysis of neonatal outcome data was also limited by the quality of the available data, but there was evidence of a relatively high incidence of resuscitation of infants born at the Trust compared with national data; this suggests a higher number of babies born in poor condition.

3.25 The variability in the quality of the local and national data made it difficult to draw firm conclusions from the analyses; however, the trends in practice were explored further in the case reviews and interviews with clinical staff.

Case records review

3.26 We carried out a systematic review of:

- the records of all maternal deaths, stillbirths and neonatal deaths between January 2004 and June 2013, the period covered by the Investigation;
- the records of all families known to the Investigation who had expressed concerns about the standard of care they had received in the maternity unit between January 2004 and June 2013;
- the records of all families who responded to a public announcement in local newspapers inviting anyone who had concerns about maternity or neonatal care between January 2004 and June 2013 to contact the Investigation.

The review process

3.27 Copies of the case records were provided by the Trust and were loaded onto a secure knowledge management system (Huddle). All case notes were initially reviewed by a clinically qualified member of the Investigation Panel.

3.28 This initial review recorded any notable factors in the care provided using a recording system previously designed and tested by the University of Leicester in previous confidential inquiries into stillbirths and neonatal deaths.⁴

3.29 The objective of this initial review was to identify cases that would require a more comprehensive review by a minimum of two clinical members of the Panel.

3.30 Following the comprehensive review, the standard of care provided for each case was graded according to the categories developed by the University of Leicester and used in the MBRRACE report⁵ and the UK report into perinatal deaths to be published in summer 2015.

Overall grading of sub-optimal care and relevance to the outcome for the infant

Grade of sub-optimal care	Definition
0 – None	No sub-optimal care
1 – Minor	Sub-optimal care, but different management would have made no difference to the outcome
2 – Significant	Sub-optimal care in which different management might have made a difference to the outcome
3 – Major	Sub-optimal care in which different management would reasonably be expected to have made a difference to the outcome

3.31 Emergent themes were identified and the findings were then considered by the full Investigation Panel.

References for standards of care

3.32 The obstetric, midwifery and neonatal benchmarks for standards of care that were relevant during the period of the review include the following:

Antenatal and postnatal mental health: clinical management and service guidance. National Institute for Health and Care Excellence (NICE), 2007.

Antenatal care: routine care for the healthy pregnant woman. NICE, 2003.

Caring for Vulnerable Babies: The reorganisation of neonatal services in England. National Audit Office, 2007.

Clinical Negligence Scheme for Trusts: Maternity Clinical Risk Management Standards. NHS Litigation Authority, 2005.

Diabetes in pregnancy: are we providing the best care? Findings of a national enquiry. CEMACH, 2007.

Guidelines for Maternity Services Liaison Committees (MSLCs). Department of Health, 2006.

Intrapartum Care: Care of healthy women and their babies during childbirth. National Collaborating Centre for Women's and Children's Health, 2007.

⁴ Draper ES, Kurinczuk JJ, Lamming CR, Clarke M, James D, Field D. A confidential enquiry into cases of neonatal encephalopathy. *Archives of Disease in Childhood: Fetal & Neonatal edition* 87 (2002), F176–F180. doi:10.1136/fn.87.3.F176.

⁵ *Saving Lives, Improving Mothers' Care.* MBRRACE-UK, 2014.

National Service Framework for Children, Young People and Maternity Services. Department for Education and Skills and Department of Health, 2004.

Postnatal care: Routine postnatal care of women and their babies. NICE, 2006.

Safer childbirth: minimum standards for the organisation and delivery of care in labour. Royal College of Anaesthetists, Royal College of Midwives (RCM), RCOG and Royal College of Paediatrics and Child Health (RCPCH), 2007.

Saving Mothers' Lives 2003–05. CEMACH, 2007.

Service Standards for Hospitals Providing Neonatal Care (Second Edition 2001; Third Edition 2010). British Association of Perinatal Medicine.

Standards for hospitals providing neonatal intensive and high dependency care (Second Edition). British Association of Perinatal Medicine, 2001.

Standards for Maternity Care. RCOG, RCM and RCPCH, 2008.

Toolkit for high quality neonatal services. Department of Health, 2009.

Why Mothers Die 2000–2002. CEMACH, 2005.

Findings from the review

3.33 The Investigation requested a list of all cases of maternal death, stillbirth and neonatal death that occurred at the Trust from 1 January 2004 to 30 June 2013. The Trust, through a thorough search and rigorous validation of records, identified 226 cases. The Investigation identified a further 13 cases, which were not all maternal, stillbirth or neonatal deaths but fell within the context of serious untoward incidents. This brought the total number of cases for review to 239. The Trust was unable to locate case notes for 6 of these cases, and the Investigation has therefore reviewed, in total, 233 cases. From the cases reviewed, 145 were from RLI, 84 from FGH and 4 from WGH.

3.34 From the initial review of the 233 cases, there were notable factors in 63 pregnancies that merited a comprehensive review. Within the 63 cases there were 2 twin pregnancies and therefore a total of 65 fetuses. Of the 63 selected pregnancies there were 9 maternal deaths, 22 stillbirths, 25 neonatal deaths and 18 live births. Of the live births, 10 suffered a clinical complication, 2 were healthy infants whose mother experienced a clinical care complication (mother given epidural infusion intravenously, and mother who had a severe reaction to epidural insertion), and 6 were healthy infants of late maternal deaths. In the other 3 maternal deaths the infant outcome was a stillbirth, a neonatal death and a premature live birth.

3.35 When the comprehensive review was completed, the standard of care was then graded according to the method devised by Draper and colleagues at the University of Leicester.⁶ The findings from this analysis were that, out of the 63 pregnancies, there was no evidence of sub-optimal care in 16 cases; there were 11 cases where there was evidence of sub-optimal care but different management would have made no difference to the outcome of these cases; there was sub-optimal care in 17 cases in which different management might have made a difference to the outcome; and there was sub-optimal care in 19 cases in which different management would reasonably be expected to have made a difference to the outcome.

3.36 When this data was allocated according to hospital, sub-optimal care was significantly more prevalent at FGH, compared with RLI. This is despite FGH being a low-risk unit and only delivering

⁶ Draper ES, Kurinczuk JJ, Lamming CR, Clarke M, James D, Field D. A confidential enquiry into cases of neonatal encephalopathy. *Archives of Disease in Childhood: Fetal & Neonatal* edition 87 (2002), F176–F180. doi:10.1136/fn.87.3.F176.

half the number of deliveries compared with RLI. Of the 36 cases where sub-optimal care might or would reasonably be expected to have adversely influenced the outcome (Grades 2 and 3), 20 (55.6%) cases occurred in FGH, 13 (36.1%) in RLI and 3 (8.3%) in WGH. When the number of cases categorised as Grade 2 or 3 sub-optimal care were related to the birth rate in each hospital, there were 0.8 cases per 1,000 births in RLI and 2.1 per 1,000 births in FGH (2.6 times the rate in RLI). For Grade 3 only, the number of cases per 1,000 births in which different management would reasonably be expected to have made a difference to the outcome was nearly four times higher in FGH (1.37 per 1,000 births in FGH and 0.37 per 1,000 births in RLI).

3.37 There were 9 maternal deaths identified during the period of the review (4 at FGH and 5 at RLI). Of these deaths, 3 were directly attributable to factors during the pregnancy and 6 were due to indirect causes of death (related to co-existing medical and psychiatric conditions). There was evidence of Grade 2 or 3 sub-optimal care in 62.5% of the cases from FGH we selected for review, and in 46.4% of the cases from RLI reviewed. It is also noted that there were 3 cases of Grade 2 sub-optimal care where delivery occurred in the midwife-led unit at WGH, which has an average of 270 deliveries per year. Of the 36 Grade 2 and 3 cases, 29 (80.5%) were reported as serious untoward incidents.

Leicester grade	FGH	RLI	WGH
3	13	6	
2	7	7	3
1	5	6	
0	7	9	
Total	32	28	3

3.38 It is important to emphasise that the cases reviewed were predominantly maternal deaths, stillbirths and neonatal deaths and, apart from a very few exceptions, the review did not include live births where there were maternal complications during pregnancy and delivery and/or where the infant developed perinatal-related morbidity.

Avoidable factors

3.39 Analysis of the avoidable factors found provides a more detailed investigation of clinical practice and service delivery. There were a number of significant avoidable factors that were identified during the review process and which contributed directly or indirectly to the adverse clinical outcomes, and most of these related to deficiencies in basic clinical care (see Table 3.1 overleaf).

3.40 It is evident that improvements in knowledge, skills, clinical assessment, investigation and management would have a significant impact on clinical outcomes.

Table 5.1: Examples of care provided and avoidable factors

Induction of labour: unrecognised hyperstimulation, maternal risk factors not acted on, non-compliance with protocol, very poor communication with family
Failed induction of labour, discharged home, no management plan
High-risk infant, no paediatrician at delivery, intubated at eight minutes
High body mass index, received 'low-risk' care, inadequate monitoring, poor communication between clinical staff, no fetal heart rate at birth
Failed forceps and ventouse extraction, emergency section, failed resuscitation
Two previous intrauterine growth restriction pregnancies, no growth scans this pregnancy, accepted for home delivery, undiagnosed footling breech and cord prolapse
No investigation of diabetes or previous history of raised blood pressure. Blood pressure increased during pregnancy not treated. Presented with cardiac arrest
Epidural given intravenously
Cardiotocography showed severe bradycardia, emergency section delayed one hour
Previous large baby, face presentation and shoulder dystocia, failure to diagnose poor progress in labour, delay in obstetric involvement in care
Maternal infection, failure to adequately monitor infant, fatal neonatal septicaemia
Presented with severe abdominal pain, junior doctor failed to recognise possible abruption, no senior involvement, poor communication, treated with analgesics
Presented at 33 weeks with vaginal bleeding and seen by a junior doctor and discharged
Extremely pre-term and high-risk infant continued to be cared for in a level 1 neonatal unit
Cardiotocography showed deep deceleration 90 minutes before delivery. Lost contact 20 minutes prior to delivery. Decision to deliver by ventouse. Cord tight round baby's neck
Failed intubation. Admitted to special care baby unit. Inadequate oxygenation. After eight hours called the retrieval team. On arrival baby in terminal condition
Body mass index 35. Blood pressure raised in early pregnancy. Evidence of pre-eclampsia, no treatment until 38 weeks
Retrospective notes written two days later after days off

Lack of clinical risk recognition and planning

3.41 An overarching emergent theme was insufficient awareness of potential and developing problems, demonstrated by a lack of clinical risk assessment, recognition and planning for high-risk obstetric patients. Despite its relative isolation, this was most prevalent in FGH. Clinical risk assessment and effective planning are crucial if patient harm is to be avoided. However, there were many examples of the presumption of normality, with failure to recognise or acknowledge high-risk obstetric patients or to recognise when risk status changed; failure to monitor, review and update clinical management plans for high-risk obstetric patients; failure to transfer high-risk mothers to tertiary-level units for delivery; and failure to transfer high-risk neonates to a regional intensive care unit before further clinical deterioration.

3.42 Clinical risk assessment begins with the first contact with the patient, and this may be at the antenatal clinic, the clinical assessment unit or the labour suite. The case records review identified that the first contact for the pregnant woman was with a midwife or junior doctor. There were several circumstances when the action taken at that first contact was inappropriate and in some cases had

serious consequences. Although this could have been partially mitigated by adherence to a robust escalation policy, recruitment of experienced middle-grade staff to FGH has been difficult, and those who rotate from the North West region are the more junior doctors on the rotation, meaning that the clinical risk will remain significant without the appropriate training and robust use of standard proformas. The lack of knowledge and experience contributed to the 'wait and see' approach prevalent in the labour suite and special care baby unit, and often the consequence of this inaction was further deterioration of the patient's condition. The consultants appeared not to recognise the relative inexperience of middle-grade staff as an additional risk, and there was no evidence of a consultant presence or of senior decision-making on the labour ward or in the neonatal unit except when an emergency situation arose. Earlier presence and better decision-making by senior medical staff would have helped to prevent these situations from occurring or escalating. Senior staff appear to see themselves as responders, but they need to be closer to the front line where they can be gatekeepers to their service and advise and support their junior doctors and midwifery colleagues.

3.43 Moreover, in FGH there is an obstetric service that provides antenatal, intrapartum and postnatal care for almost all women, regardless of the complexity of their condition and their level of risk, but the neonatal service is only staffed and equipped to care for minor neonatal conditions. This clinical model is clearly the source of considerable conflict between clinicians, and as a consequence places mothers and their babies at increased risk. Especially prior to the development of the neonatal network, there was no evidence of awareness that obstetric care or expert opinion should or could be sought from another larger unit, even when the condition was extremely rare, and a reluctance to accept that the small number of pregnancies cared for in FGH might mean that clinical experience would be limited for some cases. The service model and the clinical structures need to be aligned to ensure that patient safety is the priority.

Maternity unit response to serious untoward incidents and complaints

3.44 Until 2011 there was one person who undertook the role of governance. She was a risk manager (0.6 whole-time equivalent), who was appointed in 2004 to oversee patient safety in maternity services. The post holder worked cross-bay and had responsibility for undertaking all the pillars of governance and risk management, as well as supporting corporately the NHS Litigation Authority and Clinical Negligence Scheme for Trusts agenda. There was no practice development midwife or audit lead midwife, and there was not a whole-time dedicated risk manager or overall governance lead.

3.45 If a complaint was received in maternity services, it would be passed to the head of midwifery (HOM) or one of the matrons, who might ask a member of staff to investigate. The Trust acknowledges that, when clinical incidents occurred, they were not consistently triaged or reviewed. There may have been root cause analyses carried out, but these were generally not undertaken by a multidisciplinary team. They might have been reviewed by the clinical lead.

3.46 Supervisory investigations were undertaken by supervisors, who were frequently inexperienced and did not receive time or funding for training; in addition, they were often close colleagues and of a similar grade to the person they were investigating. There is evidence that the supervisory reports of staff involved in the more serious incidents were of poor quality and lacked insight. The supervisors of midwives had no formal link with governance and risk management. The risk manager was also a supervisor of midwives, which meant that the individual could be undertaking both management and supervisory investigations and therefore be subject to potential conflicts of interest.

3.47 There was an incident reporting system (Safeguard), which was mainly used by the matrons and the risk manager, but not by midwives as they had not received training.

Clinical leadership and multidisciplinary working

3.48 The clinical delivery of maternity and neonatal services is under the leadership of the clinical director and the HOM. During the period of the review there has been one clinical director/lead for obstetrics and gynaecology, two clinical directors of paediatrics and three HOMs.

3.49 In 2004 the HOM was Denise Fish, who continued in that post until her retirement in 2007. Although FGH and its maternity unit were now part of the Trust, there was little contact at that time between the FGH and RLI maternity units. The HOM, however, had some Trust-wide responsibilities. At that time the HOM was supported by seven matrons, with three at RLI, three at FGH and one at WGH.

3.50 At interview, the HOM indicated that the midwives took the lead in developing guidelines, with limited input from consultants. Similarly, the midwives were most active in reporting serious incidents, and this process was supported by the risk manager.

3.51 In 2006, financial pressures began to impact and the bereavement counsellor post was not replaced. There were also cost-cutting implications for midwifery staffing, which in FGH included two midwives on the antenatal and postnatal ward at night and three midwives on the delivery suite. It was agreed that one of the midwives would be on call from home. The midwives at FGH in particular objected to the staffing changes and the impact on morale within the unit was significant. It is notable that in the last three years there has been a significant increase in the number of midwives.

3.52 It was acknowledged by the HOM that there were cases that should have had more consultant obstetrician input, and she referred to the serious incident in 2004. It was also evident at this time that relations with the local paediatricians were difficult: *"some of the paediatricians I don't think had any respect for the obstetricians"*.⁷

3.53 In 2007 Miss Fish retired and was replaced by Angela Oxley. Eighteen months after being appointed HOM, she was given added responsibilities as service manager for gynaecology, inpatients and outpatients. Twelve months later that post was also subject to reorganisation and she was made lead manager for obstetrics and gynaecology (while continuing to act as HOM). She was subsequently asked to include governance in her portfolio. She was initially located in the Women's Health Directorate, then in the Surgery and Critical Care Directorate and finally in the Family Services Directorate. She initially had the support of eight matrons, but they were reduced to five, then to four. Her base was WGH, but most of the divisional meetings were at RLI and for most of her time she felt *"I was probably more of an outsider to Furness General Hospital than I was to Lancaster or Westmorland"*.⁸

3.54 For financial and service reasons she undertook a regrading process for Band 7 midwives. And she recalls the lead obstetrician at FGH saying to her: *"The Band 7s are not happy. They're not happy that you want to change things."*⁹ This reinforced her view that she did not have the support of colleagues in FGH.

3.55 She was aware that relations between obstetricians and paediatricians were poor and knew of examples of obstetricians proceeding to deliver high-risk mothers in FGH against paediatric advice. Similarly, she acknowledged that there was evidence of midwives overzealously guarding their patients from obstetric involvement. When the incidents emerged, she found that she was disciplining the midwives and putting them in supervised practice, but the response from the clinical director in relation to medical staff was that *"he would speak to the junior doctors"*.¹⁰

⁷ Denise Fish interview.

⁸ Angela Oxley interview.

⁹ Angela Oxley interview.

¹⁰ Angela Oxley interview.

3.56 At that time she felt that the executive team was fully focused on obtaining Foundation Trust status and discussions were dominated by *"We need to save £24 million, how're you going to get that money, you tell me..."*.¹¹ She also felt under particular pressure because the process towards Foundation Trust status had initially been halted because of the issues within maternity services. Unhappy in her role, Mrs Oxley left in March 2011.

3.57 Ibrahim Hussein became clinical director at the Trust from the time the Trust was established in 1998. Initially he had responsibility for obstetrics and gynaecology and paediatrics. Subsequently, paediatrics was separated and Mr Hussein remained clinical director for obstetrics and gynaecology until 2008. Following a restructuring of directorates the number of directorates was reduced to three, and he became a clinical lead for obstetrics and gynaecology. In 2010 he became an associate medical director for obstetrics, gynaecology and paediatrics and remained in this role until October 2011. Six months later he retired.

3.58 He felt that the midwives were generally excellent, but some had *"taken extra responsibilities which I think is very unwise"*.¹² He felt that the obstetricians needed to be more *"proactive"*¹³ with the midwives. When asked if he was proactive, he replied: *"Yes... but if you work with another three consultants who will not undertake any responsibility then there is a limit to what you can do. You can sit down with them. You can mention it to the medical director. You can mention it to the chief executive."*¹⁴

3.59 His involvement in the investigation and management of the incidents seems to have been limited. At interview he stated that the investigations were undertaken by the risk manager, who was reporting directly to the medical director. He had conversations with the chief executive but did not document any communication with the executive team.

3.60 In relation to the HOMs with whom he worked, he thought that Miss Fish had an *"old-fashioned style"*,¹⁵ but she didn't stand any nonsense. After she retired, *"things were not the same as far as managing midwives... Angela [Oxley] wasn't that experienced and some of the problems took place while she was in charge."*¹⁶

3.61 In relation to risk management of cases at FGH, he expressed the view that high-risk pregnancies should be allowed to be delivered in FGH, and specifically included triplet pregnancies.

3.62 Although Mr Hussein stated that he was very proud of what he had done as both a consultant obstetrician and a clinical director, from the evidence at interview and from the Trust documentation, it was difficult to identify evidence of strong and decisive leadership.

3.63 At interview he was challenged on his role as clinical director:

"You are a clinical director yet you don't ask questions of your consultants. You don't ask questions of the head of midwifery, even though you're accountable for the quality of the care in the Unit. You push things up to the chief executive and you don't follow up when things don't happen. I don't get what your professional role is as clinical director. Everything seems to flow through you. I don't understand what you do."

His response was:

¹¹ Angela Oxley interview.

¹² Ibrahim Hussein interview.

¹³ Ibrahim Hussein interview.

¹⁴ Ibrahim Hussein interview.

¹⁵ Ibrahim Hussein interview.

¹⁶ Ibrahim Hussein interview.

"Tell me, what do you expect more? If you have concern, you express your concern to your superiors. What more can you do?"¹⁷

3.64 Paul Gibson was clinical director for paediatrics from 2002 to 2007, when the Children's Directorate and the Obstetrics and Gynaecology Directorate were taken into the Surgical Directorate. From 2007 until 2009 he remained as the head of the children's department inside the enlarged Surgical Directorate. In 2010 he was appointed as the associate medical director for child health for Cumbria when consideration was being given to a Cumbria-wide child health service. He subsequently undertook a year working abroad and since his return to the Trust he has been a consultant paediatrician based at RLI.

3.65 In 2003 Mr Gibson's clinical directorate responsibilities included FGH, WGH and RLI. He described the paediatric service at FGH as *"exceedingly dysfunctional. I think it still is dysfunctional, but... it was exceedingly dysfunctional then."*¹⁸ This referred particularly to the medical staff, and he commented that there was an excellent matron in paediatrics. The merging of Lancaster and Kendal Trusts had been uneventful; however, the amalgamation with FGH was fraught.

3.66 As the clinical director, he wanted to spend a day a week in FGH because most of the clinical directors were based in RLI and would do a flying visit for half a day, which was not well received by colleagues in FGH. With Lyn Shannon, a senior paediatric nurse who had a cross-bay appointment, he wanted to develop greater integration between RLI and FGH. He decided to adopt an approach that he had used when working abroad, and joined consultant colleagues on their ward rounds. However, they found this intimidating and two of his colleagues from FGH wrote a letter to the chief executive complaining about the clinical director's *"bullying and intrusive management style"*.¹⁹ This led to a formal inquiry, and Mr Gibson was given management training that was funded by the Trust. At interview he was asked if during these visits to FGH he found anything that concerned him in terms of the way in which the hospital was operating, and he described it as a "mess":

*"There weren't enough consultant paediatricians, there just wasn't enough staff. There was a management camp and a clinical camp. There was a paediatrician camp and there was a children's nurse camp. The doctor/nurse relationship I would describe as a 1960s relationship, which was just in huge marked contrast to Lancaster."*²⁰

3.67 The clinical director had concerns about the quality of child health services across Cumbria, and his concerns still exist. He said that he believed there are issues at all levels, and made the point that if there are many reasons for the quality of service to be poor, no one individual feels responsible. *"And that's my feeling about child health in Cumbria, that actually the whole system is full of highly motivated, really well-intentioned people who don't realise that their actions are having a negative effect in other places."*²¹

3.68 In relation to the clinical incidents, the clinical director felt that the midwives became disproportionately the focus of attention, and that the paediatric team, himself included, was overlooked and bypassed. He also believed that the obstetricians were less in focus than they should have been, and describes the relationship between obstetrics and midwifery in FGH as *"a dysfunctional marriage where superficially it looked okay, but it was more like a marriage where people met in the same house but kind of had their own lives..."*²²

¹⁷ Ibrahim Hussein interview.

¹⁸ Ibrahim Hussein interview.

¹⁹ Paul Gibson interview.

²⁰ Paul Gibson interview.

²¹ Paul Gibson interview.

²² Paul Gibson interview.

3.69 Owen Galt was appointed a clinical lead in paediatrics in May 2010, and became clinical director for women and children's services in April 2012, when the Trust restructured. He joined the Trust in January 2007 as a general paediatrician working in both acute and community paediatrics. He is based at RLI, and when he was first appointed he had one clinic per week at WGH.

3.70 When he first joined the Trust, there were seven consultants in Lancaster working on a traditional three-tier rota system, with middle-grade trainees from the North Western Deanery and some staff grades on the middle-grade rota, and approximately seven GP trainees or junior trainees in paediatrics on the first tier of the rota. There were also four or five consultants working in the generic role, and two or three working completely for acute paediatrics. There was no full-time consultant community paediatrician at RLI.

3.71 FGH had four consultants, and a diminishing number of middle-grade staff. The North Western Deanery did not provide middle-grade paediatric trainees to FGH because of the size of the population and the low clinical activity levels. There are approximately five junior doctors, who are GP trainees.

3.72 The RLI neonatal unit has about 180 admissions per year, and those are babies who are born at 28 weeks' gestation and upwards. The policy is to transfer out *in utero* babies that are likely to be born at less than 28 weeks' gestation. It is commissioned for an average of one intensive care, two high dependency unit and seven special care cots. The unit in FGH has approximately 100 admissions per year, and the policy is that it looks after babies from 32 weeks upwards (this was reduced from 34 weeks as agreed with the neonatal network).

3.73 Because the number of consultant staff has been increased, the consultants in FGH are now working a shift system, with a back-up consultant on call at home, so the cover is now much more robust. The number of junior doctors does not allow for 24/7 cover of a rota, so at night time when activity is low, a consultant is on site as the paediatric doctor.

3.74 In terms of sustainability, the clinical director considers that, whilst there are currently sufficient trainees in paediatrics coming through the training system, and international recruitment is offering good-quality candidates, the model is sustainable and may be for the next decade. However, if (as predicted) the Royal College reduces the number of trainees in paediatrics to the point where it balances out the number of posts available with the number of trainees being trained, or perhaps is even flipped slightly the other way, then the current provision in smaller hospitals will not be sustainable and care will need to become centralised in larger centres.

3.75 Sascha Wells became HOM in May 2011. Her priority on taking up the post was staffing levels, because of pressures in the system and exceptional sickness rates. At interview she stated that by the time the Trust had recruited to the budgeted staffing level, there would be 43 new full-time equivalent midwives in the service. Moreover, it was recognised that the new recruits would bring with them a fresh view and outlook and a positive culture.

3.76 When she started in 2011, there was one person who undertook the role of governance (0.6 whole-time equivalent). Over the last three years, a strong governance team has been put in place. There is now closer working between the commissioners of the maternity services, with a joint specification and agreed key performance indicators.

Trust management of maternity and neonatal services

3.77 FGH originally had its own Trust status and was therefore managerially independent for several years. During that time it served a loyal community of patients and staff. The merging of Trusts in 1998 and the establishment of the University Hospitals Morecambe Bay Trust (UHMBT) shifted the balance of self-determination. Following the establishment of UHMBT, there have been several changes in the Trust organisational structure, with maternity and neonatal services being relocated on several occasions.

3.78 In 1998 there was a Directorate for Women and Children's Services, but in 2003 this was divided into a Directorate for Obstetrics and Gynaecology and a Directorate of Paediatrics. In 2007 both of these directorates were merged into a division with general surgery and critical care. Then in 2009, in response to recommendations contained within the Mitchell Report – which stated that the child health service should be integrated across hospitals and the community, working closely with other public services, and that this would not be achieved within the existing divisional structure – a separate Family Services Division was formed. At interview, Fraser Cant, former Assistant Director of Operations, stated that a consequence of the separation from surgery and critical care was that the new Family Services Division began operation with a financial deficit of £600,000.

3.79 Within one year, the Trust decided to merge the Family Services Division with core clinical services, the latter including outpatients and therapy services, radiology, pathology and clinical engineering. The explanation from the divisional manager for family services joining this disparate group of services in 2010 was that when they demerged from the Surgery and Critical Care Directorate, the majority of support services remained within that directorate, and this had presented considerable difficulties for the Family Services Division. It was presented to them that the Core Clinical Services Division had a substantial infrastructure, including a vacant divisional manager post. This was more generally viewed, however, as part of a cost-cutting exercise rather than an initiative to improve maternity and paediatric services, according to Mr Cant. Then, in December 2011, the Central Manchester Report recommended that family services demerge from core clinical services and that a Women and Children's Services Division be created. The establishment of this standalone Women and Children's Services Division took place in March 2012 and included the appointment of a new clinical director as the overall lead for the division. This was part of a Trust initiative to put clinicians in charge of clinical divisions with support from managers.

3.80 During the period around the time of the review, maternity and neonatal services were therefore located in six different management teams, and it is instructive that the current structure resembles the original directorate in 1998. The serial restructuring resulted in multiple changes in directorate and divisional managers, most of whom had no experience of managing maternity and neonatal services. Moreover, the divisional managers had other perceived priorities: the divisional manager for surgical and critical care services, who for a short time had responsibility for maternity and neonatal services, stated: *"What I found as divisional manager, though, it was a pressurised, acute trust environment and we were tending to focus on money, 18 weeks cancer targets and neglecting the clinical aspects of the role"*.²³

3.81 We heard clear evidence that, when the serious incidents in 2008/09 began to emerge, clinical leaders and managers within the division struggled to adequately address the underlying issues. The divisional clinical director, who would subsequently become Trust medical director, stated:

"I have to say that at the time my concern was that I didn't actually feel that I had the knowledge and the time to get sufficiently detailed involvement with this that I could adequately pick them up myself and we, both the divisional general manager at the time, Vanessa Harris, and myself had had conversations with... the chief operating officer,

²³ Vanessa Harris interview.

Stephen Bourne. I had certainly raised it with the medical director that I felt that the detailed involvement with all surgical, anaesthetic services and with paediatrics and obstetrics on the two sites, I did not have the insight or time to become as involved as we should be and to fully understand what all the issues were and we were probably too dependent on delegation of these to other people, and whether that was one of the prime movers in setting up a separate division for Women's and Children's Services in 2009 I don't know."²⁴

3.82 The division was aware of sub-optimal staffing levels in maternity and neonatal services at FGH; however, it was not only an issue of staff numbers but also of staff quality. At this time there were only four paediatric consultants at FGH, and two of those were subsequently suspended by the General Medical Council (GMC). There was also an associate specialist who was investigated by the GMC but who was not suspended. The situation at FGH was compounded by the resistance from the RLI clinicians to undertaking clinical duties at FGH. It is therefore evident that the repeated management restructuring within the Trust failed to adequately address this key issue of the staffing of maternity and neonatal services. The current Trust strategy is to increase the staffing levels in FGH, despite the difficulties in recruitment, the low clinical activity and the risk of deskilling staff, rather than achieve full clinical integration of these services across the Trust catchment area. The current clinical director for women and children's services told us that he thought the current model of care might not be sustainable in the future.²⁵

3.83 The evidence from the clinical case reviews and from the interviews indicates that healthcare workers with responsibility for maternity and neonatal services struggled to deliver safe services when support structures were changing or disappearing. Maternity and neonatal services had their management arrangements changed six times during the period covered by this review. As a result of this managerial instability, there is evidence that lines of responsibility and accountability were blurred, many posts were combined and in some cases became unworkable, individuals were given management posts in maternity and neonatal services without any knowledge or experience of these services, and the focus was on operational objectives such as finance and waiting times rather than governance and quality of service.

Workforce and working environment

3.84 Providing two small consultant-led maternity units 50 miles apart, and also one midwife-led unit, that meet national clinical and workforce standards is challenging. To maximise clinical skills and for the service to be cost-effective, a flexible and integrated workforce is required.

3.85 We heard consistently that recruitment and retention have been particular issues for the maternity unit in FGH. During the period covered by the review, the service has been dependent upon locum doctors and bank and agency midwives and neonatal nurses. Recruitment of good-quality medical staff has been difficult and there have been disciplinary issues, with conditions of clinical practice being placed on senior clinicians by the GMC. There is also evidence of failure to retain senior clinicians.

3.86 It is clear to us on the basis of what we heard that what has compounded an already difficult workforce issue has been the failure to establish good working relations between key health professionals. There appear to us to be geographical and professional divisions underpinning the animosity that has been present for many years and still exists, although possibly to a lesser extent.

3.87 We heard consistently that there has been a reluctance of staff at FGH to become involved in cross-bay planning and delivery of services. This attitude has probably been fuelled over the years by what may be perceived by those living in Barrow as preferential support for RLI and WGH. Moreover,

²⁴ George Nasymth interview.

²⁵ Owen Galt interview.

there has been reluctance from RLI clinicians to undertake clinical duties in FGH. This separation not only makes provision of a Trust-wide service more difficult, but reduces the opportunities for peer review and multidisciplinary working. At interview, several senior managers from the Trust and commissioning groups explained that there was no difficulty in recruiting to RLI, but FGH was a problem. As a consequence, services in RLI, including maternity and neonatal services, have been very well staffed compared with those in FGH. Moreover, the vast majority of the clinical leads are based in RLI, although interestingly the long-standing obstetric lead is based in FGH. If an objective of the merging of the Trusts in 1998 was to develop integrated, high-quality, sustainable services, this objective has not been met for maternity and neonatal services.

3.88 Interviews with clinical staff from both FGH and RLI confirmed that working relations between the two centres were difficult and this led to a lack of constructive discussion on service delivery. The issue of working relations, however, is not limited to geographical factors. Within FGH there are significant interpersonal issues. The obstetricians have poor working relations with the paediatricians and the paediatricians do not have good relations with each other. More than one paediatrician described the paediatric consultants as “*a dysfunctional team*”. The relationship between the obstetricians and the midwives is, we believe, more subtle and is reflected in their clinical practice, with evidence that the midwives sought to avoid involvement of the obstetricians in the care of their patients, while the obstetricians remained content to wait to be called (and sometimes then to be dismissed again as no longer needed). We heard that the origin of this way of working rested with one or two influential midwives, who pursued normal childbirth “*at any cost*”,²⁶ and that this deeply flawed approach became more widespread and embedded in the practice of the unit. It is evident that none of these manifestations of poor working relations are in the best interest of the patients, but there is a lack of awareness among staff of their responsibility to help solve these problems.

3.89 In addition to issues of quality of staff, there has also been continuing pressure to achieve safe staffing levels. There is evidence of low staffing numbers relative to births and low numbers of staff per shift, making it difficult to cope with simultaneous tasks (labouring women, postnatal women and post-Caesarean section women). This has led to poor morale amongst maternity unit staff. The process of regrading the Band 7 midwives had a significant impact on morale and working relationships, especially in FGH.

3.90 During the period of the review it is evident that at all points in the patient journey many clinical staff were failing to provide an acceptable quality of care in an environment of trust and respect.

Recent changes and developments

3.91 Staffing: There have been significant improvements in the staffing of maternity and neonatal services. In the last three years, the Trust reports that it has appointed an additional 27 whole-time equivalent midwives across the Trust. It has funded plans for an additional 16 community midwifery posts and 7 hospital midwife posts.

3.92 There has been an increase in the obstetric and paediatric consultant staffing level, which should allow for resident consultant cover in FGH.

3.93 Governance: Over the last three years, a stronger governance team has been developed, which now consists of a divisional governance lead who covers the Women and Children’s Services Division. This post is supported by a risk manager for maternity services at Band 7, and there is also a risk manager for paediatrics and neonates at the same grade. In maternity services, there is a Band 6 quality and safety midwife whose role is predominantly around triaging clinical incidents and making sure that they are managed appropriately through the governance process. There is also

²⁶ Lindsey Biggs interview.

an audit midwife at Band 6 and a practice development midwife at Band 7, whose responsibility is education and development of the entire midwifery and gynaecology nursing workforce.

3.94 In August 2012 an independent review of governance in the Women and Children's Services Division was undertaken by the head of governance at Liverpool Women's NHS Foundation Trust. The final report was published in April 2013. It stated that the governance arrangements were satisfactory and made nine recommendations.

3.95 Culture: Throughout 2012, culture workshops were held for all staff working within maternity services. The purpose of the workshops was *"to enable staff to understand how culture is created, agree on common values for the maternity service and what that means to them"*.²⁷ The key actions that came out of the culture workshops included developing a stronger governance structure, communicating lessons learnt across the teams, establishing visual information boards at each site, holding divisional away days and developing a staffing business case.

3.96 Leadership: The Women and Children's Services Division became a standalone division in March 2012. A new HOM (Ms Wells) took up post in May 2011 and has led the work on midwife staffing levels and governance structures across the division. Dr Galt, Clinical Director for Women and Children's Services, was appointed in April 2012 and has been closely involved in staffing structures for both obstetric and paediatric services. The current structure places clinicians in overall charge of the clinical divisions, with support from division managers.

3.97 Multidisciplinary team-working: It is reported by the Trust that there is collaborative multidisciplinary working and a greater level of respect for each profession, particularly at FGH. Members of the multidisciplinary team are coming together to discuss difficult cases and they are reported to be following the same guidance. At interview we were informed by several interviewees that working relations were much improved, but we also heard from some of the long-standing clinicians that relations with midwives had not improved and had possibly deteriorated over the last two to three years. Changes in both the consultant obstetric and paediatric staff have resulted in an improvement in relations between obstetricians and paediatricians, but there was no available evidence to determine if the underlying issue of the management of high-risk women and the need to transfer them to a regional neonatal unit had been resolved.

3.98 Clinical practice: The improved multidisciplinary working in the labour ward is evidenced by joint ward rounds with the consultant, registrar and labour suite coordinator two to three times per 12-hour shift. There is also improved communication between the maternity ward, labour suite and special care baby unit. This has apparently been aided by the relocation of the special care baby unit to be adjacent to the maternity ward. At interview, concern was expressed that there was still a risk that midwives observing newborn babies in the labour ward or the postnatal ward might not detect early signs of ill health. However, it is noted that practice educator midwives have been appointed, and that they work closely with medical colleagues. At interview the clinical lead for paediatrics acknowledged that there had been issues with compliance with guidelines and protocols; that relations with colleagues had been difficult; and that because of the limited numbers of consultants there had been an unacceptable dependence on inexperienced junior doctors. He emphasised, however, that in recent years there had been significant improvements in clinical staff numbers, the quality of clinical practice and the professional relationships between paediatricians, obstetricians and midwives.

²⁷ *Morecambe Bay: An approach to improvement.* University Hospitals of Morecambe Bay NHS Foundation Trust, 8 October 2014.

Chapter conclusions

1. Our overall impression is of a maternity unit that felt itself to be isolated, both geographically and professionally, and unsupported by the local healthcare system. This was exacerbated by a series of health service reorganisations. During this process there was a loss of ownership and understanding by local communities; healthcare workers struggled to deliver safe services when support structures were changing or disappearing; and, as elsewhere, financial imperatives dominated all aspects of the Trust.
2. Throughout this time there was no agreed vision, strategy or operational plan for maternity and neonatal services. Decision-making was reactive rather than proactive; short term rather than long term; and driven by finance rather than health needs.
3. The total number of case notes reviewed was 233, of which 145 were from RLI, 84 from FGH and 4 from WGH. From the initial review of the 233 case notes, there were notable factors in 63 pregnancies that merited a comprehensive review. Within these 63 cases, there were 2 twin pregnancies and therefore a total of 65 fetuses. Of the 63 selected pregnancies, there were 22 stillbirths, 25 neonatal deaths and 18 live births; 10 of these infants had clinical complications.
4. There were 9 maternal deaths identified during the period of the review (4 at FGH and 5 at RLI), which for relatively low-risk obstetric units is high when compared with national data. Of the 36 cases where sub-optimal care might or would be expected to have adversely influenced the outcome, 20 (55.6%) occurred in FGH, 13 (36.1%) in RLI and 3 (8.3%) in WGH. When the number of cases categorised as Grade 2 or 3 sub-optimal care was related to the birth rate in each hospital, there were 0.8 cases per 1,000 births in RLI and 2.1 cases per 1,000 births in FGH (2.6 times the rate in RLI). For Grade 3 only, the number of cases per 1,000 births in which different management would reasonably be expected to have made a difference to the outcome was nearly four times higher in FGH (0.37 per 1,000 births in RLI and 1.37 per 1,000 births in FGH). This data relates particularly to the selected group of maternal deaths, stillbirths and neonatal deaths, and there are only a few live births included in this analysis.
5. The identification of avoidable factors provided a more in-depth analysis of clinical practice and service delivery. There were numerous significant avoidable factors that were identified during the review process and which contributed directly or indirectly to the adverse clinical outcomes, and most of these related to deficiencies in basic clinical care. There was evidence of a lack of situation awareness, with a deficiency in understanding of basic observations, their clinical significance and how they should be managed. There were many instances where symptoms and signs, observations, progress in labour, and the concerns of patients, parents and families were recorded, but were not underpinned by a clinical plan or escalation of clinical decision-making.
6. There was evidence of a lack of basic understanding of the processes of labour by both midwifery and medical staff. There were frequent examples of staff ignoring the whole clinical picture of the woman (including pre-existing risk factors) and her baby, and only reacting to events in isolation. A lack of clinical risk assessment and planning for high-risk obstetric patients was an overarching theme. Despite its relative isolation, this was most prevalent in FGH. Clinical risk assessment and effective planning are crucial if patient harm is to be avoided. Clinical risk assessment begins with the first contact with the patient, and this may be at the antenatal clinic, the clinical assessment unit or the labour suite.
7. Although we did not investigate in detail aspects of hospital care outside the maternity and neonatal unit, there was evidence that the response of medical teams from other specialties when complications developed in pregnant women was inconsistent. There

- was evidence of non-involvement of appropriate multidisciplinary senior clinical staff, a lack of escalation and a failure to seek external advice for complex, extremely sick patients.
8. Arrangements for assessing pregnant women who present with concerns need to ensure that patients receive an opinion from experienced midwives or obstetricians. The consultants need to be closer to the front line, where they can be gatekeepers to their service and advise and support their junior doctors and midwifery colleagues. The staffing levels should ensure that this clinical opinion is available 24/7.
 9. The skills and knowledge of the clinicians should enable a prompt and effective response if the condition of a mother or her baby deviates from normal. This may require the patient to be transferred to a regional unit. A lack of knowledge and experience is probably responsible for the 'wait and see' approach that was prevalent in both the labour suite and the special care baby unit, and often led to further deterioration of the patient's condition and a poor outcome in the cases we reviewed.
 10. Clinical leadership in maternity and neonatal services was ineffective. This was partly due to the lack of vision and strategic planning of these services, but also due to the lack of managerial support and the increasingly defiant behaviour by clinical colleagues. High-quality leadership skills are required in those difficult circumstances, and these were not evident.
 11. Most importantly, there is evidence of poor interdisciplinary working relations and substandard care. The failure of obstetricians and paediatricians to communicate in a professional way on the planning and delivery of high-risk patients is unacceptable. Similarly, the reluctance of midwives and obstetricians to share responsibility for the care of high-risk pregnant women is denying patients their rights to the best care.
 12. As a consequence of the serial restructuring by the Trust, maternity and neonatal services had their management arrangements changed six times during the period covered by this Investigation. As a result of this managerial instability, there is evidence that lines of responsibility and accountability were blurred, many posts were combined and in some cases became unworkable, individuals were given management posts in maternity and neonatal services without any knowledge or experience of these services, and the focus was on operational objectives such as finance and waiting times rather than governance and quality of service.
 13. The clinical review has identified deficiencies at all levels within the organisation that impact on quality of clinical care: clinicians who place their personal clinical interest before the safety of their patients; failure of the FGH and RLI clinicians to work as an effective clinical team; weak clinical leadership and poor management at the directorate and division levels; and an executive team that was more focused on obtaining Foundation Trust status than on delivering high-quality care to the citizens of South Cumbria and North Lancashire.
 14. Finally, at interview, patients, parents and families indicated that they had not received adequate – or in some cases any – explanations of why something went wrong, and indeed still had basic questions about aspects of the care received. This has led to assumptions of a cover-up of poor care and has exacerbated their feelings of grief and loss. In addition, the Trust needs to reflect on how it managed the serious incidents, especially when the media and external agencies became involved. Many of the clinical staff wished they could have spoken directly with the families to apologise and express their deepest sympathies. They also felt that they had not had an opportunity to fully explain what they felt were the failings in the care that the patients received. Many still feel devastated and damaged by what happened. The Trust recognises that it has to rebuild trust and confidence in the service and in the community, and part of that process should be to consider what the Trust can do to repair the emotional damage experienced by its staff and the family members of its patients.

CHAPTER FOUR: Trust response

Background

4.1 This Investigation deals with events that took place at University Hospitals Morecambe Bay Trust (the Trust) between 2004 and 2014. For the purposes of the Investigation, the Trust response can be described in terms of four discrete time periods within these years:

- Between 2004 and 2007/08, for the majority of the time, the Trust was regarded by the North West Strategic Health Authority (NW SHA) and the Healthcare Commission (HCC) as one of the higher-performing English Hospital Trusts, one of the early aspirant Foundation Trusts. However, there were signs of financial difficulty and uncertainty over longer-term clinical service configuration within the locality from 2005 onwards.
- From 2008, concerns about the safety of maternity services at Furness General Hospital (FGH) began to emerge. Between 2008 and 2011, the Trust continued to pursue Foundation Trust status, although issues of clinical service configuration remained unresolved. However, the Trust was successfully authorised as a Foundation Trust in October 2010.
- From 2011 to 2012, maternity services continued to generate concern, and became the subject of increased external scrutiny. Other operational problems emerged, including a large backlog of outpatient appointments. The response of the organisation and the wider NHS to the situation did not generate confidence.
- Between 2012 and 2014, new leadership was put in place and efforts were made to improve services, and to demonstrate that services had been improved in order to restore confidence in the organisation.

4.2 During these periods there were a number of changes of personnel at Trust Board level, as well as associated changes in organisational structure and in structures and processes to support clinical governance. Below the level of the Trust Board there were relatively few changes in managerial and clinical staff, although the same people held different roles over time.

4.3 In order to understand the Trust response in each of these periods, we need to consider the systems that were in place in the Trust for clinical governance and responding to complaints.

Clinical governance and complaints

Clinical governance

4.4 Clinical governance was introduced formally to the NHS by the Department of Health White Paper *The New NHS: Modern, Dependable* in 1998. This was the first time that the demonstration of formal systems of assurance and scrutiny in relation to clinical quality and safety issues had been an explicit requirement of NHS Trust Boards. Effective clinical governance in organisations has a number of characteristics:

1. Organisational systems and processes consisting of policies, procedures and strategies to describe how staff are expected to: identify and report risks, ensure compliance with the most up-to-date and effective clinical treatments, participate in audits of the quality of

service provided to demonstrate continuous improvement, and engage in education and training activities in order to remain up to date in clinical knowledge.

2. Engagement and ownership of frontline staff to ensure compliance with the policies, procedures and strategies of the organisation, in order to generate robust and meaningful information to provide assurance about organisational quality and safety.
3. Effective committee and reporting structures which communicate this information from the front line to the Board.
4. Resource to provide the required expertise and administrative support to manage the governance system effectively at all levels in the organisation.

4.5 In 2004, many organisations within the NHS were still struggling with the introduction of clinical governance, often seeking to implement it through structural means, such as committee organisation, reporting lines and processes (elements 1 and 3 above). To be effective, however, these systems required administrative support and expertise in functions such as risk management and clinical audit (element 4). It was challenging to provide this at a time when Trusts had to reduce costs, particularly management costs.

4.6 It has become evident that clinical governance depends critically on the quality of information being communicated to the Board about clinical services and their outcomes, to enable informed assessments of the safety and effectiveness of services and, if necessary, action to improve them. The generation of meaningful clinical information is very reliant on clinical staff, who have not always been quick to see the need to engage with clinical governance. Without clinical engagement, clinical governance is bound to remain poorly informed and ineffective.

4.7 In addition, it is difficult to define the right level of detail that should be escalated to the level of the Trust Board: too little, and the Trust may discover significant risks only in hindsight, after a problem has become evident; too much, and the amount of detail swamps the Board's ability to detect what is significant. It seems to us, on the basis of the documents we have seen, that the Trust took a pragmatic approach to this dilemma at this time, taking a more detailed look only at externally defined priorities such as meticillin-resistant staphylococcus aureus (MRSA) reporting; we believe that it was far from alone in adopting this approach at this time.

Clinical governance at the Trust: structures and processes

4.8 We found evidence of a governance committee structure in the Trust from 2004 onwards. This took the form of a Trust-wide committee chaired by either an executive or a non-executive director. The committee structure changed over time as senior staff came and went, as we believe generally happened as Trusts sought to improve structures, as described above. We found that a range of appropriate policies and procedures were in place. There is evidence that policies were reviewed and updated regularly over the period. A maternity risk management strategy was in place in 2004 and was reviewed and updated between 2004 and 2014.

4.9 Between 2004 and 2006, the Trust medical director was responsible for clinical governance within the Trust, supported by a head of clinical governance and a head of legal services. The structure included clinical audit, clinical risk, clinical effectiveness and complaints and the patient advice and liaison service (PALS).¹ The Trust had a Governance Committee, chaired by either the chief executive or the medical director and had an appropriate membership across the organisation. Minutes of the meetings were shared with the Trust Board. On review of the papers, we found that, although the content of the meetings appeared appropriate, the committee operated at a high level, and received little detailed information related to actual clinical risks and outcomes in a systematic

¹ Evidence from the Trust Governance Framework.

way. Rather, it seemed to us to have focused on quality development and strategy, and on receiving minutes from other committees.

4.10 Following the arrival of a new chief executive in 2007 (Tony Halsall), new nursing and medical directors were appointed, and a Clinical Quality and Safety Committee was set up in place of the Governance Committee, chaired by a non-executive director. Further changes were made in 2007/08 with a move to an integrated risk management approach, which included governance.

Board assurance in relation to clinical governance structures and processes

4.11 At the time, the principal source of assurance about the robustness of structures and processes for clinical governance available to NHS Boards was accreditation by the Clinical Negligence Scheme for Trusts (CNST), operated by the NHS Litigation Authority (NHS LA). Although aimed at reducing medical negligence claims, CNST accreditation involved inspection of a range of clinical governance systems and processes against defined standards by external reviewers. The process was designed to assess the level of risk against which Trusts' NHS LA financial premium to cover negligence claims was set, with level 0 accreditation implying the highest risk from poor systems, and level 3 the lowest risk from the best systems. There were separate accreditation systems for general acute services and for maternity, recognising the higher number and cost of negligence claims in maternity services.

4.12 The requirements of the CNST accreditation process changed between 2004 and 2012, but a necessary element of the accreditation was to confirm that the Trust had a governance committee structure with appropriate membership, terms of reference and reporting lines in place, with a number of key policies and strategies, the content of which, although not prescribed by the CNST, reached the required standard. The Trust achieved level 1 rating in 2005 and level 2 for maternity services in 2008. The Trust's Serious Incident Investigation Policy was found to be compliant with the National Patient Safety Agency standard, including definition of a serious untoward incident, information on how to carry out an investigation, how the outcome of the investigation should be shared, and how staff should be trained in incident investigation.

4.13 We heard how the system operated, at least in high-profile cases that would be the subject of an inquest:

*"That would have been escalated to the chief executive's office or me very quickly. Who exactly picked it up would depend on who was around at the time. We would then, firstly, make sure everything was being done to render the situation safe. I'm thinking there of things like equipment failures, get it out of action, do you need a replacement, the immediate sort of stuff in order to make it safe and continue service. Then, at a more measured level, convene a group to have a look at it. Again that would entirely depend on exactly what the situation required. And then get some outcomes from it. The reason for that is, certainly with the deaths, that is going to go to the coroner's court and I firmly believed, not just for defensive reasons, because it's very important to be publicly reassuring about these things, by the time the thing came to inquest we should have the answers in place."*²

Whilst this was a clear and positive description, we found little confirmatory evidence that this is how it usually operated in practice, and it was clear that few of the incidents arising in maternity services at this time had generated this response.

How clinical governance worked in practice at the Trust: Board level

4.14 We heard from a range of executive-level interviewees that they were involved in clinical governance and were motivated to develop systems that would strengthen it. A review of agendas and

² David Telford interview.

meeting minutes indicates that much effort was focused on committee and reporting arrangements and gaining CNST accreditation, and we also heard that quality and governance had a low profile at the Board, with the predominant focus being on finance and performance targets.³

How clinical governance worked at the Trust: divisional and frontline level

4.15 In addition to the Board structures, each clinical division had its own governance arrangements. These were responsible for the review and management of governance within the directorates, with precise structures left to the divisions/clinical directorates to design and operate. It is unclear from the evidence we saw precisely what structures were in place for maternity services between 2004 and 2010, other than that they changed regularly as maternity services moved divisions. Responsibility for clinical governance lay with the clinical directors – also sometimes known as associate medical directors. They should therefore have been champions of clinical governance and the focal point for governance activity within the divisions. Through them, the medical director and the rest of the Board should have been made aware of problems, and they were responsible for ensuring that problems were solved.

4.16 In the Surgical and Critical & Family Services Division, this was not the case in practice. Evidence that we heard from staff identified the fact that governance structures functioned less well at divisional level.

4.17 Divisional middle managers said to us that they were not involved in the clinical governance process. They described a divisional management structure that was very stretched, with a top-down emphasis on financial balance and achievement of targets. We were told that patient safety at divisional level was the responsibility of the clinical director and head of midwifery, but that clinical governance was seen as separate from operational and financial management within the division.

4.18 Fraser Cant was the divisional manager for the Family Services Division. In 2011, the Family Services Division merged with other services to form the Family and Clinical Services Division. Although this resulted in a much bigger, dispersed division, Mr Cant said that he supported this move because the management and support infrastructure within the Family Services Division was very weak, and he believed that in a bigger directorate there would be economies of scale and therefore better support for quality, safety and governance activities across the division as a whole. For example, there were no risk managers within family services and no administrative support for audit or governance activities. Mr Cant also confirmed that he had little to do with clinical quality and safety within the division, and the priorities for his role at the time were predominantly financial and operational:

"I had a deputy general manager who was off sick, I had financial targets to meet. I had the performance targets to meet, which were all – you know, I can't describe how important those are. So I had those to ensure that we met, and I wanted to develop the governance because I was concerned..."

The first week in the Trust I was called to an extraordinary meeting with the exec team on the financial performance of women and children – of the family services. I'd only been there a week and it had only just been created. And it was £600,000 adrift. How that could be in a newly created division, I don't know, but clearly that was a pressure that I felt day one, week one..."

³ David Bennett interview.

... the governance, those issues were primarily down the director of nursing route through the nurses, or through the medical director at the – I had very few conversations I can recall with the director of ops on governance.”⁴

4.19 Other staff expressed a different view to us: that as part of a large Family and Clinical Services Division, family services, particularly maternity, became a “*small fish in a big pool*”, making it difficult for concerns to be heard.⁵

Clinical governance and quality in maternity services

4.20 Whilst there is evidence that the Board was mindful of the strategic and financial problems related to maternity services (which also affected other parts of the organisation), we found no evidence that it considered the quality of maternity services to be in question prior to late 2008. We believe there were several reasons. First, maternity services, by their nature, generate patient safety incidents relatively infrequently. In the great majority of cases childbirth is a normal physiological process, but on those occasions when something goes wrong the outcome can be tragic and devastating. Maintaining patient safety in these circumstances depends on being vigilant for signs of deviation from normal and being prepared to take effective and prompt action when they are detected. However, because of their relative rarity, it may be some time before obvious serious incidents occur even when care is suboptimal. Hence it was no surprise to us to find that patient satisfaction levels remained high, there were few complaints, GPs reported no apparent problems,⁶ and the Trust was not an outlier on perinatal deaths.⁷ We heard that the Trust Board took assurance from these findings, and we doubt that it would have been alone in doing so. Secondly, in the absence of any high-level information that could have signalled problems, the Board was crucially dependent on information from staff in the maternity unit; as we have seen, they failed to alert anyone outside the division at Board level prior to 2008.

Weaknesses at clinical unit level

4.21 As discussed in paragraph 4.6 above, the robustness of organisational quality and safety systems is heavily dependent on frontline clinical information to provide data that can be scrutinised to review outcomes and trends and to identify problems. A key weakness in clinical governance systems exists if the members of the clinical team do not recognise a poor outcome as a clinical incident that could potentially have been avoided, or do not report it, so that such cases go unnoticed outside the immediate clinical team.

4.22 Although some stillbirths in late pregnancy are neither predictable nor preventable, those that occur in labour (intrapartum) to previously normal babies are serious incidents that should be investigated. The review of all stillbirths in the Trust that is reported in Chapter 3 identified an intrapartum stillbirth in 2004 that was not reported as a serious incident. A review of records indicates that risks were not recognised, follow-up arrangements were not clear and fetal monitoring was inadequate. The investigation into this death failed to recognise both the root causes and the fact that there were lessons to be learnt. Five more serious incidents, including deaths, that occurred at the FGH unit between 2006 and 2007 were also considered by the Investigation to illustrate similar elements of concern but some were not reported as serious untoward incidents. The investigation of these cases within the unit failed to recognise root causes, and therefore the similar patterns of underlying causes were not recognised.

⁴ Fraser Cant interview.

⁵ Karen Weakley interview.

⁶ Dr Geoff Jolliffe interview.

⁷ Confidential Enquiry into Maternal and Child Health.

4.23 There are a number of reasons why this might have been the case: clinicians knowingly wishing to obscure poor outcomes to avoid loss of reputation and blame; clinicians not having the knowledge and skills to recognise that problems could have been avoided; or poor engagement and awareness of incidents across the full range of multidisciplinary staff in the unit, and therefore less discussion and challenge about incidents and causes, which might have resulted in the development of greater insight and recognition of problems.

4.24 Jennifer Bowns was a senior midwife and supervisor of midwives at the Trust. She no longer works at the Trust, but was asked whether multidisciplinary meetings took place in response to incidents:

*"I can't answer for everybody... I just haven't an awareness of sitting in a room with everybody discussing it. I am aware that, you know, the risk team, the head of midwifery and clinical governance, they were meeting but it just didn't seem to involve [others]."*⁸

4.25 If information on the underlying causes of the serious incidents had been known outside the unit, or if any of the other indicators of service quality had been less favourable, the possibility that this might have been sufficient to prompt a more detailed investigation of the service by Trust management cannot be excluded. But in the absence of any indicators of poor outcome, and in the presence of more reassuring information, the clinical quality of the service was not highlighted as an issue of concern and was not identified by the Executive or the Trust Board as an item that needed to be explored in detail at that time.

Complaints

NHS complaints

4.26 The effective management of complaints within an organisation is key to good governance. The proper management of complaints can reduce the distress of patients, their families and friends. It can provide an explanation for what went wrong, where appropriate offer an apology, and provide reassurance that lessons have been learnt and that the chances of something similar happening again have been reduced. Where complaints are handled badly, they can exacerbate the situation, reduce confidence in the service and reduce the chances that lessons are learnt. They also increase the risk of litigation and cost to the Trust.

4.27 Since 2000, there has been an increasing focus on improving the way in which the NHS responds to complaints. This was, in part, a response to events such as Shipman, but was also due to a growing understanding that effective healthcare requires a more open and inclusive approach to patient care.

4.28 In April 2003, *NHS Complaints Reform: Making Things Right* was published. It outlined a new approach to complaints and stated that the process would be:

- **open and easy to access** – by being flexible about the ways in which people can complain and by providing effective support for people wishing to do so;
- **fair and independent** – with the emphasis on early and effective resolution, so minimising the strain and distress for all those involved;
- **responsive** – providing appropriate and proportionate responses and redress; and
- **learning and developing** – ensuring complaints are viewed as a positive opportunity to listen and learn from patients' views to drive continual improvement in services.⁹

⁸ Jennifer Bowns interview.

⁹ *NHS Complaints Reform: Making Things Right*. Department of Health, 2003.

4.29 The new complaints procedures were set down in Regulations in July 2004.¹⁰ This remained the system in the NHS until 2009.

4.30 The process had three stages: complaint to the relevant Trust, referral if not satisfied to the Healthcare Commission and then referral to the Parliamentary and Health Service Ombudsman (PHSO) if the complainant was not satisfied with the Healthcare Commission's decision. However, where there was evidence that the individual intended to take legal action, the case was excluded. Time limits were set on individuals to complain (six months) and on the organisations to respond. These were to be encapsulated in each organisation's policies and procedures, and regular monitoring by the Board was required, as was an annual return to the Department of Health. There were no provisions for Primary Care Trusts (PCTs) to receive information about complaints, although many agreed arrangements by which the summaries would be shared.

4.31 In 2009, the system was streamlined, removing the second stage – referral to the Healthcare Commission. In 2012, the NHS Constitution enshrined the rights and expectations of patients and their families. The NHS Constitution sets this out as follows:

***"You have the right** to have any complaint you make about NHS services acknowledged within three working days and to have it properly investigated.*

***You have the right** to discuss the manner in which the complaint is to be handled, and to know the period within which the investigation is likely to be completed and the response sent.*

***You have the right** to be kept informed of progress and to know the outcome of any investigation into your complaint, including an explanation of the conclusions and confirmation that any action needed in consequence of the complaint has been taken or is proposed to be taken.*

***You have the right** to take your complaint to the independent Parliamentary and Health Service Ombudsman or Local Government Ombudsman, if you are not satisfied with the way your complaint has been dealt with by the NHS.*

***You have the right** to make a claim for judicial review if you think you have been directly affected by an unlawful act or decision of an NHS body or local authority.*

***You have the right** to compensation where you have been harmed by negligent treatment."¹¹*

4.32 Throughout this time and throughout the changes to the complaints system, one aspect remained constant: the responsibility for the NHS organisation to deal with complaints effectively and fairly in as short a time as possible. The redress systems for complaints changed, but this fundamental responsibility remained with a Trust or other NHS body to investigate, respond to and take appropriate action based on the findings of the complaint.

Complaints in the Trust

4.33 We have looked at the documents provided and have concluded that there were policies in place within the Trust, although changes to, and operation of, the policies is not clear at times. There was a policy in place in 2004.¹² A further policy was introduced in 2012. We could find no clear indication of whether the policies of the Trust were updated routinely in the period under

¹⁰ National Health Service (Complaints) Regulations, 2004.

¹¹ *The NHS Constitution: The NHS belongs to us all*. NHS, 2013.

¹² Morecambe Bay Hospitals NHS Trust Complaints Procedure, 2004.

investigation. A revision would have been necessary in 2009 to change the referral of complaints from the Healthcare Commission to the PHSO, but no documentation has been seen to confirm this.

4.34 The Trust Board received quarterly summaries of complaints, and there was a review through the Risk Management Advisory Group,¹³ and then through subsequent governance groups as the governance framework within the Trust changed between 2004 and 2012.

4.35 In 2004, reporting to the Board was minimal, focusing on numbers and completion rates within specified days. Reports gave very little indication of what was being complained about, and nothing about actions being taken to rectify issues raised. Within the information provided, it is apparent that a significant number of complaints (30%) were not being resolved within the specified period of 20 working days. Only 75% were being completed within 30 working days.¹⁴

4.36 In 2005, performance became even poorer, with approximately 50% of cases being completed within four weeks. Workload, complexity of cases, staff sickness and medical record delays were cited as reasons for the drop in performance. Reference is made to one complaint being reviewed by the Healthcare Commission. The report has little information about the complaints and any themes, but it does have a short section on lessons learnt.¹⁵

4.37 A similar pattern was seen in 2006 and again in 2007.¹⁶ Reporting in 2007 improved,¹⁷ with additional information for the Board about the issues being raised by patients. The most significant reason for complaint was inadequate care/treatment. The Women's Health Directorate, and the Surgical and Critical & Family Services Division that succeeded it in 2007, recorded complaints about care and treatment, administration, staff attitudes, (medical) adverse outcomes, diagnosis problems and waiting times.

4.38 No quarterly reports for 2008 were seen by the Investigation. An annual report for 2007/08 was within the evidence. It showed a consistent pattern of poor response rates, increasing referrals to the Healthcare Commission and very little information on the actions taken to deal with the issues raised by the complainants. Papers from 2009 referred to changes made to the complaints procedures. The complaints reporting to the Board remained consistently poor in approach and content for the remainder of the time period under investigation – although new formats were introduced in 2012.

4.39 Throughout the period under investigation, information was provided to the governance committees and, through them, to the Board. The focus is not on the lessons learnt or the issues arising from the complaints, but predominantly on the time taken to process an investigation. Information of a valuable nature that might have identified trends, clinical issues or consistent service failures appears to be absent in any meaningful way. Minutes from the meetings do not provide any additional insight, as they tend to be very limited in nature.

4.40 In conclusion, we found that there were within the Trust processes and procedures for handling complaints. The Trust's governance around assessing and reviewing procedures seems, on the basis of the evidence we have seen, to have been poor. The quality of the information shared with the Board was poor, focusing on numbers and rates of completion within specified times, rather than identifying issues and learning. But even within these limited parameters, there are signs of poor performance. We found evidence of significant numbers of complaints taking well over four weeks to be responded to, and, if anything, a pattern of declining levels of performance. No evidence has been seen of action to address this, such as ensuring that there was sufficient resource available. We

¹³ Morecambe Bay Hospitals NHS Trust Complaints Procedure, 2004.

¹⁴ Trust Board paper, 1 April 2004: Complaints and medical claims.

¹⁵ Trust Board paper, 30 March 2005: Complaints.

¹⁶ Trust Board paper, 7 June 2006.

¹⁷ Trust Board paper, 27 June 2007: Complaints.

heard from a manager involved in complaint handling that “[there were] three key members of staff [who] either went part time or left, which left us extremely short-handed”.¹⁸

4.41 We found evidence of pressure among the staff managing complaints, and questions about whether resourcing was sufficient to manage the process within the Trust’s policies. However, given the consistently poor levels of performance by the Trust and the apparent lack of action, it seems to us reasonable to conclude that this was not seen as a priority by the Trust.

4.42 The experiences of some of those who have come forward and been interviewed by the Investigation would support this conclusion. In one instance, we were told that a complaint received by the Trust within a couple of days of the incident was stopped by the Trust after six weeks with no resolution, because, the family believed, the Trust was investigating another case. The complaint review did not start again for another six months.¹⁹ Within this time period, there were meetings, evidence was sought and there was correspondence between the complainant and the Trust, but no conclusion to the process until over six months had passed. Then there was no satisfactory conclusion to the complaint from the family’s point of view.

4.43 On reviewing the way that this complaint was handled, we found the process to be chaotic and poorly coordinated. Initial contact was rapid, but then the issues were not followed up and it did not follow an acceptable process. Delays grew longer and, if the family had not been proactive, the complaint might have continued to drift. In this and other cases, procedures were not followed appropriately, and whilst this may have been intended to help resolution, it did not lead to effective management of the complaint.

4.44 We formed the view, on the basis of what we heard and saw, that complaints were seen as an administrative chore by the Trust, to be completed as quickly as possible before addressing the next case. Opportunities for learning were missed, and it is hard to see how complaints were being used by the Trust to improve the care it offered patients.

4.45 We believe that the Trust needs to consider carefully how it interacts with patients and families through complaints. It cannot see them as administrative tasks, but rather as insights into the working of the organisation. Complaints can be an essential route to tackling systemic and individual failings within an organisation. The approach during the period of the Investigation does not demonstrate that anything changed as a result of the lessons learnt by the failures in service. The Board needs to be vigilant and to challenge its officers about the complaints it receives, and not be satisfied with number-based reports.

Trust profile, 2004–08

4.46 Between 2004 and 2006, it is clear from what we heard that the major priorities for the organisation were: the clinical service configuration affecting North Lancashire and Cumbria, within which the Trust was a major service provider; the clinical strategy within the three site organisations; the Trust’s ability to achieve financial balance; and achievement of operational targets. All of these were key to a successful Foundation Trust application. Reviewing the external indicators of Trust performance which applied to all NHS Trusts at that time, it seems to us that the overall impression that would have been gained was of an organisation performing relatively well in comparison with other similar Trusts. These indicators would have contributed to reassuring the Trust Board that all was well.

4.47 The Trust had been categorised by the Healthcare Commission in 2004 as a three-star Trust, the best classification on a scale of zero to three. We saw that it had received positive feedback

¹⁸ Graham Hall interview.

¹⁹ Reported by family member to Panel.

from the Department of Health regarding governance proposals and consultation documents in relation to its Foundation Trust application, and had been awarded level 1 CNST accreditation for maternity services in 2004 and level 2 in 2008. In 2005, the Trust was categorised as 'excellent' in a number of aspects of Healthcare Commission inspections. The Healthcare Commission Annual Health Check gave the organisation an overall rating of 'good' for general and paediatric services. The Trust performed above average in the national patient survey between 2004 and 2006, and above average in the maternity users' satisfaction survey in two-thirds of the measures (2007). The Patient Environment Action Team (PEAT) inspections, involving members of the public and external stakeholders, led to ratings of 'excellent' at every hospital site (2005). In relation to staff management and well-being, the Trust received 'Improving Working Lives Practice Plus' status in 2006. All of these achievements would have contributed, in our view, to reassuring the Trust Board and external bodies that the Trust was providing safe and effective services.

4.48 Application for Foundation Trust status was influenced mainly by performance in the NHS star ratings, and the star ratings were influenced by operational targets, finance, high-level quality assessments by the quality regulator (the Commission for Health Improvement or the Healthcare Commission) and some measurable clinical indicators (for example numbers of MRSA bloodstream infections). The Trust began working towards Foundation Trust status in 2004, relatively early in the life of the Foundation Trust policy. The first indication of the decline in fortunes of the Trust began with loss of star ratings between 2004 and 2006: it fell from three to two stars in 2004, at which point the chief executive informed the Board that, as a result, the plans to seek Foundation Trust status would be "*slowed down*";²⁰ and from two stars to one in 2005, which was explained to the Board as being "*financially related*".²¹ From 2007 to 2010, pursuing Foundation Trust status remained an aspiration of the organisation and the NW SHA, although Tony Halsall, Chief Executive from 2007, told us that in his view the organisation was "*a million miles away*" from being ready for Foundation Trust status.²² Nevertheless, efforts toward this continued in spite of the organisation being in a challenged position: it was financially stretched and was running small-scale, relatively expensive services across a number of geographically distant sites without a confirmed clinical strategy for either the sector or the organisation (a very contentious issue, with public protests taking place at the time in relation to the review of services). The Trust also had an equal pay claim to deal with, following its earlier merger, which is noted in the Trust Board papers as having a potential financial impact in the region of 10% of turnover,²³ and, as was the case for all Trusts, the Trust was required to meet operational targets and maintain service quality. In our view, this was a substantial and challenging agenda for a moderately sized Trust to deal with, even without the added demands on limited management capacity of the process of application for Foundation Trust status.

Maternity services, 2004–08

4.49 At this time, the key concerns for the Trust Board in relation to maternity services seem to us, on the basis of what we have seen and heard, to have been strategic and financial. Ian Cumming (Chief Executive 2004 to September 2006) described to us the process that had taken place to review maternity services across the Trust.²⁴ Maternity services then, as now, were provided from three sites: obstetric services at the Royal Lancaster Infirmary (RLI) and FGH, and a midwife-led service at Westmorland General Hospital (the Helme Chase unit). The review identified that the National Tariff did not cover the cost of the three services and left a funding gap of £5.4m, and there were future risks around being able to recruit adequate numbers of obstetricians and midwives to

²⁰ Trust Board minutes, July 2004.

²¹ Trust Board minutes, July 2005.

²² Tony Halsall interview.

²³ Trust Board minutes, February 2008.

²⁴ Maternity Services Review, 2006.

run the service. The conclusion was that it was either not possible to sustain all three services in their current format, or, if all three services were to be maintained, either costs would need to be reduced or the service cross-subsidised from other profitable Trust services.²⁵ Public opinion strongly opposed a reduction in services at FGH maternity unit, and the decision was taken to continue the existing service pattern by cross-subsidising costs from other income. We were told that the PCT was informed of this, but no response was received.²⁶

4.50 Given the financial constraints, actions to look at costs, efficiency, service planning and increasing user involvement were also identified. To this end, the head of midwifery was charged with implementing risk management training for midwives, and with involving midwives more in service strategy and planning. This suggests to us recognition of the need to encourage the midwives to think about safety, but also about the relationship between costs and types of services, and to be in a position to influence, with users, the type of service that it would be most fitting to provide in the different obstetric settings in the future. The review also looked at staffing levels using the Birthrate Plus tool. The recommended levels for FGH at the time were similar to the actual numbers of staff in place: 38.6 midwives and 16.6 support staff recommended, compared with the actual levels of 39.8 midwives and 10.6 support staff. It was therefore planned to undertake a skill-mix review and convert midwife posts to support-worker posts as posts became vacant.²⁷

4.51 It is clear, from the evidence that we saw and heard, that the Trust was considering its future strategy in relation to maternity services, based on concerns about financial viability, staffing and sustainability. We found no evidence that any concerns about the safety of the service or other aspects of its quality were raised at Trust Board level prior to 2008. David Telford, the Trust's medical director from 2001 to 2006, told us that maternity services in FGH were "*not on the radar*".²⁸ The Trust Board was aware that its maternity services required subsidy from other income, and of the risk that inadequate funding might compromise staffing cover. The review of midwifery staffing it had commissioned suggested adequate levels. However, many interviewees emphasised to us the difficulty of recruiting medical staff to obstetric and paediatric posts at FGH, particularly in light of the perceived remoteness of Barrow and the limited nature of the clinical workload. We heard that the Board was conscious of the diversion of limited resources to fund locums to cover vacancies, and was mindful of the need to strengthen recruitment to permanent posts.²⁹

Trust profile, 2008–10

Overview

4.52 From 2008 to 2010, the situation that the Trust found itself in changed significantly. All the evidence that we saw and heard underlined the fact that the Trust still saw achieving Foundation Trust status as its key priority, and it was supported in this by the NW SHA. We also heard that clinical service reconfiguration remained a concern: the clinical services strategy for the Trust had still not been agreed, and consequently finances remained a problem. Problems in maternity services first came to the Board's attention in November 2008, as a result of a complaint concerning the death of Joshua Titcombe from neonatal infection, which was notified to the Board in view of likely impending publicity. When five maternity-related serious untoward incidents (SUIs) were identified in a declaration on incidents to Monitor in February 2009, as part of the Foundation Trust application, this was a clear signal of potentially significant problems. The Trust initiated a number of external reviews. The first was an in-depth investigation into the care of Joshua Titcombe, which, although

²⁵ Ian Cumming interview.

²⁶ Ian Cumming interview.

²⁷ Annual Review 2004/2005 Maternity Services – Morecambe Bay Hospitals NHS Trust.

²⁸ David Telford interview.

²⁹ June Greenwell interview.

based only on written records and statements, identified failings in the care of mother and baby.³⁰ Subsequently, a further two reviews were commissioned: the Flynn review,³¹ completed in June 2009, looked at management arrangements related to maternity services; and the Fielding review, commissioned in 2009 and completed by August 2010, looked at clinical governance of maternity services.³² The Flynn Report identified some positive aspects of the management arrangements, but criticised the lack of multidisciplinary working. The Fielding Report highlighted more issues of significance. There is no evidence that the Trust responded to these reports robustly through the governance process at any level, and chances were missed to recognise and tackle the significant clinical issues.

4.53 These events and the Trust response are described in more detail in the following sections.

Clinical governance in the Trust, 2008–10

4.54 The governance arrangements continued unchanged until 2011, but the remit of the medical director increased to incorporate research and development (R&D), emergency planning, occupational health and safety and legal services, as well as clinical governance. These changes were mirrored by changes to the Board committee structure: the Clinical Quality and Safety Committee remained a sub-committee of the Board, but an Integrated Risk Committee was set up to report to it. The maternity risk sub-group reported to this Integrated Risk Committee.

4.55 We reviewed examples of committee reports, and found that these were reasonably detailed, identifying numbers and trends in incidents and complaints over time, which were discussed appropriately. We were, though, mindful that the usefulness of this discussion and the subsequent reporting upwards to the Board were critically dependent on the completeness and quality of the incident reporting and on the detail provided on complaints. As has been set out elsewhere, both were significantly deficient.

4.56 An integrated performance report was a regular item at the Board from 2009 onwards. This report gave a high-level review of performance in the areas of finance, efficiency (which largely consisted of progress against cost improvement targets), activity, performance against national targets, quality and safety, and workforce. The report was presented graphically to show Trust-wide trends, with some divisional breakdown and explanatory text. The workforce section contained charts showing trends in vacancies, sickness absence, turnover, maternity leave, grievances and disciplinary cases, suspensions and whistleblowing. The quality and safety section dealt with performance against MRSA and *Clostridium difficile* targets, trends in terms of total incidents reported, with numbers of incidents per service for the previous month, trends in complaint numbers and response times, and numbers of complaints that had been reopened or referred outside the Trust.

4.57 In our view, the intention of these arrangements was sound, and the content of the reports is not dissimilar to what we would have expected to see elsewhere. However, it is notable that the integrated performance reports were entirely focused on those issues that required close monitoring and attention in order to meet Foundation Trust requirements. The obvious flaw is that items that were not a priority for achieving Foundation Trust status received no systematic review, unless identified by exception by the relevant sub-committee. Otherwise, the minutes of the Clinical Quality and Safety Committee were presented as ‘information only’ items, and there is no evidence that these items were ever discussed.

³⁰ *External Investigation into Serious Untoward Incident at Furness General Hospital: Baby Joshua Titcombe* (Chandler, Hopps and Farrier Report).

³¹ University Hospitals of Morecambe Bay NHS Trust, internal audit report 2010–11, serious untoward incident – maternity (Flynn Report).

³² *Review of Maternity Services in University Hospitals of Morecambe Bay NHS Trust: Final Report* (Fielding Report), 2010.

4.58 The Trust-level clinical governance structure seems to us to have been operated by delegation of consideration of problems by the Board to the Clinical Quality and Safety Committee, which in turn delegated them to the divisions to handle. We heard, however, that this did not work in practice. We heard, for example, that the main task of a service manager in the Family Services Division was to “*keep the numbers right*” on referral to treatment times and outpatient follow-ups, and that as a service manager he had little to do with clinical risks.³³

4.59 Whilst we believe that the delegation of responsibility to divisions is likely to have been appropriate, given their central role in the delivery of services, we heard that there was no subsequent feedback to the Trust-level committee to provide assurance that issues actually had been dealt with operationally.³⁴ We believe that this was an inadequate approach, as was acknowledged in hindsight to us by the medical director at the time.³⁵

4.60 In summary, the Board did receive information on quality issues, including incidents and complaints, and important workforce issues. But not only was the initial reporting of both incidents and complaints deficient, but also the reporting systems from the Board sub-committees upwards were not detailed enough to detect either significant events or trends unless these had been recognised and highlighted by exception further down the governance structure. Problems in maternity were further obscured by the division being part of a larger group. This relied on the clinical staff within maternity recognising and highlighting their own problems; as we have seen, they singularly failed to do so.

The cluster of serious incidents

4.61 Between February and October 2008, a sequence of five serious incidents occurred in the maternity unit. A baby suffered complications shortly after pre-term delivery following poor risk assessment and paediatric management. A mother died in pregnancy due to the effect of high blood pressure that had been inadequately monitored during antenatal care. Another mother (Nittaya Hendrickson) died following a series of poor clinical decisions involving management of a high-risk pregnancy, induction of labour, monitoring of the baby in labour and recognition and response to the mother’s collapse. The baby, Chester, subsequently also died from the effects of shortage of oxygen. A further baby, Alex Davey-Brady, was stillborn due to shortage of oxygen in labour, following poor management of a high-risk pregnancy, inadequate monitoring of the baby during labour and lack of response to slow progress in labour. In October, a baby, Joshua Titcombe, died from infection following spontaneous rupture of the membranes; examination, monitoring and treatment of the baby were inadequate, given that the mother had become acutely unwell shortly following delivery and required intravenous antibiotics for a serious infection.

4.62 We found no evidence that the first event had been investigated as an incident; unit investigations were carried out in relation to another three events, and followed the same pattern as seen previously, with findings dominated by the need to keep better records and little emphasis placed on the failures of care that were evident. A consultant obstetrician, Prabas Misra, involved in the care of Alex Davey-Brady’s mother wrote to the clinical director, Ibrahim Hussein, and others including the Trust’s medical director, drawing attention to serious concerns and referring to the similarity to an intrapartum stillbirth in 2004. This was the death of Eleanor Bennett, but neither Mr Misra’s concerns nor the previous incident were reflected in the incident report or the investigation meeting.³⁶

³³ Julian Grieves interview.

³⁴ Peter Dyer interview.

³⁵ Peter Dyer interview.

³⁶ Letter from Prabas Misra to Ibrahim Hussein, Clinical Lead in Obstetrics, 17 October 2008.

The Joshua Titcombe case

4.63 Although this was not the first serious incident in maternity at Furness General Hospital in 2008, we were told by Tony Halsall, the Chief Executive, that he first became aware of a problem in maternity services when he received a letter from James Titcombe. He reported the complaint to the Board, adding that an investigation had been initiated “*as part of our clinical risk management procedures*”, and that the complaint may result in media interest.³⁷ The review of the care of Mrs Titcombe and Joshua was carried out by an independent experienced midwife and obstetrician, based on review of the clinical records and staff statements.³⁸ An investigation by the supervisor of midwives also took place, but was delayed pending completion of the external report. The Chandler, Hopps and Farrier Report concluded that several opportunities had been missed to spot Joshua's infection and treat it before it had become life threatening. The authors highlighted in particular deficient monitoring of the baby by midwives, but the delayed supervisor of midwives investigation played down the importance of this factor and the possibility that better monitoring might have identified the problem before the baby became critically ill.

4.64 Mr Halsall was critical of the supervisor of midwives report, and subsequently wrote to the Local Supervising Authority Midwifery Officer (LSAMO) expressing concerns about the independence of the investigating midwife, the quality of the investigation and therefore the validity of its findings.³⁹ These concerns were later reflected in the review of the case by the Nursing and Midwifery Council (NMC).

4.65 The Trust formally accepted liability for the death of Joshua and, following referral to the NHS Litigation Authority, a settlement was made in February 2009. Mr Titcombe did not accept that the Trust had been fully open in responding to his complaint, and referred the matter to the PHSO.

4.66 An incident investigation was also undertaken subsequent to the external review, but did not identify a clear root cause. Action following this internal investigation included a review of all clinical incidents between April 2008 and March 2009, which was reported as showing “*no significant trends identified and no overall increase in level of cases reported*”.⁴⁰

4.67 Meanwhile, a Local Supervising Authority audit was undertaken of the midwifery supervisory arrangements at FGH, and the Trust commissioned a review of the management of maternity services: the Flynn Report.

Monitor governance submission

4.68 In February 2009, the Trust was required to submit paperwork to Monitor in support of its application for Foundation Trust (FT) status. This included a statement on SUIs: the Trust identified 12, 5 of which were maternity incidents that occurred in 2008. It does not appear to us, on the basis of written and interview evidence, that the Trust considered that these five incidents might constitute an unexpected cluster before it was required to complete the Monitor submission. However, the Trust's notification to Monitor resulted in its Foundation Trust application being put ‘on hold’ pending further assurance.

³⁷ Trust Board minutes, November 2008.

³⁸ *External Investigation into Serious Untoward Incident at Furness General Hospital: Baby Joshua Titcombe* (Chandler, Hopps and Farrier Report).

³⁹ Letter from Tony Halsall to Marian Drazek, 16 July 2009.

⁴⁰ University Hospitals of Morecambe Bay NHS Trust, internal audit report 2010–11, serious untoward incident – maternity (Flynn Report).

4.69 We were told that once Monitor had raised the issue of the apparent cluster of the five maternity SUIs, they were reviewed.⁴¹ Peter Dyer, Trust Medical Director at the time, told us that he thought all five had been investigated in accordance with standard policies: *“They were all, as far as I know, went [sic] through a mechanism called StEIS [Strategic Executive Information System], which was the way in which incidents would be reporting [sic] up to the SHA. I was absolutely satisfied that they were properly investigated, that we took external review when necessary, and that we acted upon those.”*⁴² The process for all maternity incidents involved the clinical director and the head of midwifery reviewing each case, although we heard from several interviewees that in practice the review was done by the maternity risk manager, and the clinical director was not routinely involved.⁴³ We saw consistent evidence that unit reviews carried out by the maternity risk manager were superficial, protective of midwives and failed to identify problems arising from a lack of multidisciplinary team work. External opinions were commissioned in relation to two of the cases. One was an independent opinion on the cause of a maternal death, commissioned by the coroner prior to an inquest. The second was a more detailed review of a neonatal death, although based only on clinical records and statements.⁴⁴ There was no external review of all five cases taken together, although we were told by the chief executive that after their declaration to Monitor they were discussed as a group on a number of occasions:

*“The SHA, as I recall, were aware of the cases. As I say, there was definitely one particular meeting where the SHAs handed over responsibility to the PCTs. Where we handed over case by case, and each of those cases were live cases that were discussed openly in the room. So I know that from the SHA – I know that we had the Board to Board, two occasions during the foundation trust process, where they were discussed. At the two Board to Boards that we had with Monitor the cases were discussed in detail. And I know they were discussed in detail with the CQC [Care Quality Commission].”*⁴⁵

4.70 Mr Halsall also told us that the incidents were discussed with the Board after the declaration to Monitor, and this is confirmed in the minutes of the Trust Board meeting of 22 July 2009. The minutes state that the chief executive updated the Board on the serious untoward incidents *“that the Board had been appraised of previously”*.⁴⁶ The cases were introduced to the Board one by one, identifying their current status.

The Flynn Report

4.71 The Flynn Report was commissioned by the chief executive following the review of the Joshua Titcombe case by Chandler, Hopps and Farrier, which had identified failings in care. The brief was to investigate the management arrangements in the Trust’s maternity services and to compare them with national best practice. Liverpool Women’s NHS Foundation Trust was identified as an example of national best practice against which to benchmark the Trust. The reviewer interviewed staff and looked at documentary evidence.

4.72 The report was produced in June 2009 and concluded that governance arrangements for midwifery were adequate and had improved significantly since the incident (there appears to have been no recognition by the review of the other incidents), that relationships with external stakeholders had improved in the last 18 months, and that, although interdisciplinary arrangements had improved

⁴¹ Peter Dyer interview; Tony Halsall interview.

⁴² Peter Dyer interview.

⁴³ Ibrahim Hussein interview; Jeanette Parkinson interview.

⁴⁴ *External Investigation into Serious Untoward Incident at Furness General Hospital: Baby Joshua Titcombe* (Chandler, Hopps and Farrier Report).

⁴⁵ Tony Halsall interview.

⁴⁶ Trust Board minutes, 22 July 2009.

since the incident, these were still problematic and there was still “*some way to go*” to match those in Liverpool.⁴⁷ The report found that management systems in maternity services had been improved since the incident, and suggested that the maternity strategy for 2009–12 should be commended and supported by the Trust.

4.73 In summary, although the report raised issues of multidisciplinary relationships, and the possibility of improving current governance arrangements by adopting some of the systems of Liverpool Women's Hospital, it fell short of suggesting that the shortcomings identified were critical issues that needed urgent attention. In light of subsequent events, we must regard this as a significant missed opportunity.

Trust response to the Flynn Report

4.74 At the time the Flynn Report was produced, in June 2009, the regional CQC gave the Trust a ‘Red’ risk rating, indicating that the CQC should give the Trust a high degree of attention and scrutiny, on the basis of the incidents and concern over the production of action plans in response. The NW SHA's lead on clinical risk, Angela Brown, produced a briefing which outlined the incidents and stated that the Flynn review had reported that management arrangements in the maternity unit were fit for purpose and the unit had made considerable progress over the previous 18 months, but that there was a need for improvement in interdisciplinary working.⁴⁸ The CQC was also reassured that the local PCTs would in future provide oversight of further SULs, although it must be noted that this would fall to two PCTs since the reconfiguration of the former Morecambe Bay PCT, and that the Trust would produce an action plan which would be shared with the CQC.

4.75 In response to the Flynn Report, Jackie Holt, Trust Director of Nursing, met with the director of nursing from Liverpool Women's NHS Foundation Trust and agreed the terms of reference for joint working by the two organisations' maternity units. These arrangements are described in a briefing paper by the head of midwifery at the time, and were based on the Trust “*observing, sharing and comparing*” practice in areas of governance, supervision and multidisciplinary working.⁴⁹ In August 2009, the Trust produced an action plan which was shared with the NW SHA and the CQC.⁵⁰ The action plan referred to the Flynn Report, and identified a series of actions, including the ‘twinning’ arrangements with Liverpool, the learning from the Baby Titcombe case, and the use of a maternity dashboard to report maternity outcomes to the Board.

4.76 One visit to Liverpool by the head of midwifery and the risk manager did take place in April 2010, and the documentation shows that CNST, governance and supervision were discussed.⁵¹ However, we heard from several interviewees that the arrangement did not prove of lasting benefit, and it is not clear whether any further meetings took place, whether other members of the multidisciplinary team were involved, and whether the initiative addressed the findings of the review, particularly in relation to multidisciplinary working.

4.77 There is no evidence that the Flynn Report was reviewed at Trust Board level or by the Trust Clinical Quality and Safety Committee. There is no evidence of formal tracking of the actions contained within the sustainability plan. In 2009, no Clinical Quality and Safety Committee meetings took place between May and September.

⁴⁷ University Hospitals of Morecambe Bay NHS Trust, internal audit report 2010–11, serious untoward incident – maternity (Flynn Report).

⁴⁸ Angela Brown interview.

⁴⁹ Briefing paper by Angela Oxley, 25 August 2009.

⁵⁰ Women's and Children's Services Improvement Sustainability Plan 2008/09 onwards.

⁵¹ Notes by Angela Oxley of the meeting during the visit to Liverpool Women's Hospital, April 2010.

Progress to Foundation Trust status

4.78 During 2009, achievement of Foundation Trust status remained a prime ambition for the Trust, and we heard consistently that this demanded a high proportion of time and attention from executive directors. In September 2009, the Board was updated about the *“continuing complex and frustrating delay with regard to our application”*.⁵² This was said to be in part due to the Healthcare Commission passing over responsibility to the newly formed Care Quality Commission which resulted in a change in systems, with an additional requirement that the CQC should register and satisfactorily risk-rate every Trust prior to its authorisation as a Foundation Trust, although it is clear to us that the delay was triggered by Monitor’s concern over the 2008 incidents. The minutes of the formal Board meeting record that the chairman and chief executive had met with the regional director and area manager of the CQC, and they had identified a number of key issues for the Trust, one of which was related to the need for an action plan and assurances in relation to the last 2008 incident.⁵³

4.79 The minutes of part 2 of the same Board meeting record that the chairman and chief executive had also recently met Monitor in London to *“get a handle on the process”*, as it had not been completely clear how the revised system would operate.⁵⁴ The minutes do not record that the wider maternity safety issues were discussed in either part of the meeting.

4.80 At the same meeting, the Trust Board also discussed the impending NHSLA assessment at level 2. The Trust had at that point achieved level 2 in maternity. It was noted that, if successful, this would lead to a reduction of 20% in its financial premium for the next quarter. It was also noted that the CQC would take this assessment into account when coming to a decision about the Trust risk rating, and the chief executive added that the assessment *“built confidence in the organisation”*.⁵⁵

4.81 Following this, the Trust put significant effort into achieving NHSLA accreditation. As described earlier, this was an externally assessed accreditation process that focused on the presence of sound policies and processes, and evidence from audits, document review and interviews with staff that policies and processes were actually being put into practice. In our opinion, the accreditation process was challenging, but formulaic in nature, and it was possible to be successful by applying a rigorous approach to ensuring that policy content, document control, audit and specific items of audit evidence were put in place. Qualitative issues and clinical outcomes did not feature in the assessment process. The Trust was successfully accredited at level 2 in January 2010.

The Fielding Report

4.82 Although on the evidence of her briefing to the CQC, the NW SHA’s clinical quality lead, Angela Brown, appeared reassured that the issues of concern related to maternity services were being appropriately addressed by the Trust, she described to us an informal meeting with the director of nursing and head of midwifery at a regional nursing event at which she expressed continued reservations. She told us that she suggested to them that they might need another review to make sure that nothing had been missed: *“There’s a thing about the different reports that you’ve got that’s a potential hole in the middle.”*⁵⁶ Her concern was, she told us, *“That they haven’t gone far enough to pick up what those systemic issues might be... This was around, ‘Have you understood everything that has happened that is important? Are you certain of that?’”*⁵⁷ It is unclear whether she expressed the view to the Trust officers that this would mean looking again at the previous incidents, but it is difficult to see how her question *“Have you understood everything that has happened?”* could

⁵² Trust Board minutes, 23 September 2009.

⁵³ Trust Board minutes, 23 September 2009.

⁵⁴ Trust Board minutes, 23 September 2009.

⁵⁵ Trust Board minutes, 23 September 2009.

⁵⁶ Angela Brown interview.

⁵⁷ Angela Brown interview.

be addressed otherwise. Ms Brown was clear to us that she expected the review to re-examine the incidents: *“Now, I made some assumptions around that... that, actually, within that kind of investigation, you would have looked at the incidents to see what had come out of them and then follow that on, but that was my assumption.”*⁵⁸ She said that the Trust had told her that *“they wanted to pick up all the other incidents but also have a piece of work that would enable them to move forward, and that actually made sense, as going to another stage to give them additional assurance, which seemed to add to that”*.⁵⁹

4.83 The chief executive introduced the idea of the external review at part 2 of the Trust Board meeting on 22 July 2009, describing it as a clinical governance review of maternity services, exploring safety, effectiveness, user experience and team-working. He suggested that an experienced manager and two clinical professionals should be engaged to do this. When challenged by the non-executive directors about the need to use external professionals, and the cost of doing the review, it is minuted that Mr Halsall replied that an objective independent review was required to *“challenge the mindset of the team and individuals”*.⁶⁰

4.84 We asked Mr Halsall how he would have identified a connection between the incidents. He told us that in his view, a connection could be characterised by clinical similarity of presentation or complications, or involvement of the same clinicians, or because they all demonstrated a similar pattern of deficit in clinical quality and standards. The review of the cases that had taken place did not indicate clinical similarities, but he did appreciate that the incidents may have been indicative of more generic failings in care and standards. Other interviewees were clear that at this time the view within the Trust was that the 2008 incidents were not linked.⁶¹

4.85 The chief executive told us that he decided that a review of governance was required in relation to all the units, because he did not want the impression to be given that this was just an issue affecting the maternity unit at FGH:

*“Because what we had is almost a denial from one part of the Trust that actually the problem was anything to do with them. So, you know, these issues happened at Barrow and therefore nothing to do with Lancaster and Kendal and everything else. So what I wanted to do, when we – when I commissioned [the Fielding review], was to say, ‘So what are the structures then?’ So putting that at one side, in terms of cases, what are the things that we would start to build was a sensible single clinical governance structure.”*⁶²

4.86 In addition, he said to us that even had the problem been restricted to FGH, options for dealing with the problem were limited, and in particular it would not be possible just to close the Barrow unit. Instead, he said, his strategy was to bring in clinicians from elsewhere to link with and influence the clinicians at FGH, in the form of the ‘twinning’ relationship between the Trust and Liverpool Women’s Hospital suggested by the Flynn Report, and to use the outcomes of the proposed review of governance as a stimulus to improve services across all sites.

4.87 We heard further detail from the medical director at the time. He described problems that were suspected at the time due to midwives and obstetricians acting as two separate professional groups, perhaps based on differences of gender and ethnicity.⁶³ In addition, he described to us poor relationships between the Lancaster and Barrow sites, with unwillingness by professionals to work across the two sites. The clinical director responsible for maternity services was based in Barrow and

⁵⁸ Angela Brown interview.

⁵⁹ Angela Brown interview.

⁶⁰ Trust Board minutes, 22 July 2009.

⁶¹ Peter Dyer interview; Jeanette Parkinson interview; Angela Oxley interview.

⁶² Tony Halsall interview.

⁶³ Peter Dyer interview.

was not popular with colleagues at Lancaster. We were told that these issues had been discussed at an Executive meeting, and it was hoped that the external report would shed light on these issues and their impact on services.

4.88 On the basis of what we heard, however, there were further objectives behind the way that the review was commissioned. First, it was seen as a means of ‘getting past’ a perceived loss of confidence in the Trust, as a result of the Foundation Trust application being put on hold:

“So the process at that point then was Monitor wanted the Care Quality Commission to then say, ‘Right, okay, we’ve reviewed everything. They’re on a risk rating and we’ve reviewed the risk rating down to green.’ That’s what the process was. We went – myself and Eddie Kane the Chairman went to see Bill Moyes and Miranda Carter at Monitor to say, ‘Right, okay, this is where we think we are, what is it – you know, what happens? What is it we need to do? What is it people want to see?’...”

I commissioned the report from Pauline Fielding... that was around trying to look at clinical governance and – not to review the individual cases, but to come back and say, ‘Look, in terms of the governance across this patch, what could we do? What structure could we put in place... that would get us past this?’”⁶⁴

4.89 Secondly, it is clear from what Mr Halsall said that he did not consider that this could be a long-term pre-existing problem, but rather he thought it was a recent issue that had been highlighted by a random increase in incidents:

“I mean I had no reason to believe that anything had happened or changed there that changed the overall safety of the Unit. I was assured by the Head of Midwifery and by the – and by the Associate Medical Director that the Unit was safe. We hadn’t changed anything in terms of number of midwives or doctor’s rotas or anything that would have... destabilised it in that sense. So I guess we were as confident as we could be that, you know, that we were dealing with something that we thought we understood.”⁶⁵

4.90 Although we heard slightly different accounts of how the team was identified to carry out the review, it is clear to us that the NW SHA’s clinical quality lead identified Dame Pauline Fielding, who had carried out similar work for the NW SHA previously. On this occasion, however, we heard that the NW SHA had left the commissioning of the review to the Trust. Dame Pauline told us that she had written the terms of reference herself, after a meeting with Mr Halsall at which she was explicitly told not to reopen the investigation into the five cases, as they had already been individually reviewed and it had been demonstrated that they were not connected. An external obstetrician and midwife were identified to provide expert clinical input. Although Mr Halsall put forward a different view, we believe, on the basis of what we heard consistently from a range of other interviewees, that the written terms of reference were not shared outside the Trust prior to the review.⁶⁶

4.91 Dame Pauline told us that she began the review in January 2010, later than hoped because of travel difficulties caused by the bad weather, and submitted her report in March. The review was, she told us, hampered by limited administrative support for the review and difficulty in accessing the individuals she needed to talk to, especially the Trust Board. Although confident in the midwifery advice she was receiving, she was less confident in the obstetric advice. Dame Pauline told us that she had concerns about some of her observations on the unit, but would have raised any significant issues urgently with Trust management.⁶⁷ The report identified a range of key issues that comprised

⁶⁴ Tony Halsall interview.

⁶⁵ Tony Halsall interview.

⁶⁶ Angela Brown interview; Julia Denham interview; Alan Jefferson interview.

⁶⁷ Dame Pauline Fielding interview.

a lack of robust clinical governance activity at unit level; the need for a continuing audit programme in response to the results of investigations; the need for midwife managers and supervisors of midwives to agree on criteria for dealing with staff following incidents; the need for a review of the supervisor role and way of working; acceptance criteria for the Helme Chase midwifery-led unit; a staffing level and skill-mix review (in relation to staffing levels at Royal Lancaster Infirmary); paediatric medical cover arrangements; improved systems for dealing with complaints and measuring patient experience; improved systems for implementing and monitoring guidelines and protocols; improving records; multidisciplinary working and leadership; and consideration of different models of midwifery service provision that might better meet the needs of the future.⁶⁸ Although, as with other reviews, there were some positive findings, the overall report painted a picture of a dysfunctional and compromised unit that required corrective action.

Unannounced Care Quality Commission inspection of maternity services at Furness General Hospital (June 2010)

4.92 The Trust received the first draft of the Fielding Report in March 2010. It was sent back for redrafting twice, and was not finalised until August 2010. The nature of the redrafting requested is not clear to us; neither of the previous drafts was retained, and the only suggestion that we heard was that the Trust requested the removal of some names, such as that of the associate medical director.⁶⁹ Interviewees including Dame Pauline were, however, clear with us that the changes made were only minor and did not affect either the findings or the recommendations. None of those we asked could account for why such minor changes took five months to complete.

4.93 In April 2010, the Trust was registered by the CQC without conditions. The CQC had already reduced its risk rating of the Trust from 'Red' to 'Amber', on the grounds that it believed that the 2008 incidents were unconnected, and that the Trust had an action plan in place in response to the last 2008 incident. In addition, the Trust had, in common with all NHS providers who were required to register at the same time, provided self-certification that its structures, processes and services were sound. It seems to us that it would have been inappropriate to omit reference to the concerns that led to the Fielding review, even had the initial draft report not been available at the time; but we could find no evidence of a reference.

4.94 Shortly after registration, the CQC reduced its risk rating of the Trust further to 'Green', and as a result the Foundation Trust application was reactivated.

4.95 The CQC made an unannounced inspection of Furness General Hospital in June 2010 to follow up discussions that had been taking place regarding service quality and care. The outcome of the review was that the service was deemed compliant in all respects. The report identified a number of positive developments: there was new documentation; maternity services had recently achieved NHSLA risk management accreditation at level 2; staff indicated that there was a closer working relationship between midwives and doctors; a full review of staffing had taken place; supervision and appraisals were more formalised; and more regular audits were taking place. The report provided an external perspective on the service that appeared to confirm that the shortcomings that had been identified in previous reviews were being resolved. However, this must be seen in the context that the Trust itself was far better placed than an external inspection process (which itself remained poorly developed at this stage) to assess the true picture, and even had Trust staff been able to convince themselves that the underlying problems were being addressed, those privy to the Fielding Report drafts knew that a rather more detailed assessment was much less optimistic.

⁶⁸ *Review of Maternity Services in University Hospitals of Morecambe Bay NHS Trust: Final Report (Fielding Report)*, 2010.

⁶⁹ Fraser Cant interview.

4.96 Meanwhile, the Trust continued preparation of the application for Foundation Trust status. Routine review of governance arrangements is not apparent from the evidence submitted to the Investigation. However, in July 2010 the Trust was required to submit to Monitor a Board statement and detailed Board memorandum on its quality and governance arrangements. This was a high-level assurance, addressing specific questions raised by Monitor. The assessment did not address clinical governance at divisional level.

4.97 The memorandum and statement were designed to show that the Board was satisfied that:

- *“the Trust has, and will keep in place, effective leadership arrangements for the purpose of monitoring and continually improving the quality of healthcare delivered to its patients; and*
- *due consideration has been given to the quality implications of future plans (including service redesigns, service developments and cost improvement plans).”*⁷⁰

4.98 The Board statement and memorandum were self-assessments of the governance and quality arrangements in place within the Trust. These were all signed off as being delivered by the Board.⁷¹

Response to the Fielding Report

4.99 Dame Pauline told us that following finalisation of her report in August 2010, she was surprised that she received no feedback and was not invited to present her report to the Trust Board. She told us that she had also suggested a follow-up review, but the Trust did not take that up either. She believed that all these expectations were shared with the chief executive before the review, and was left with the view that *“no-one was particularly worried”*.⁷²

4.100 We heard conflicting versions of how the Fielding Report was handled by the Trust. Ms Holt, Director of Nursing, subsequently mentioned to Angela Brown at the NW SHA that it had been taken to part two of a Trust Board meeting in 2010, but we could find no minuted evidence of this, and when the report was finally presented to the Board in April 2011, the record suggests to us that this was the first time the Board had seen it. The chairman at the time, Eddie Kane, told us that there was a very clear steer from the Trust Board, the chief executive, medical and nursing directors, that the action plan would be cascaded to those who needed to take action to implement the recommendations. The chief executive, Mr Halsall, told us that it had not been handled properly:

*“First of all, just say, you know, we handled the Fielding Report incorrectly. So, you know, even if we hadn’t liked the Fielding Report and didn’t think it was, you know, credible, or we didn’t like the information, it should have gone to a minuted meeting of the Board from a governance point of view, without any doubt. So, you know, I don’t believe for one second that that was done in terms of trying to cover up a report or to, you know, anything else. But there’s no doubt whatsoever we were wrong in terms of not ensuring that went to a minuted meeting of the Board, and I don’t think you can get past that, and I’ve never tried to sort of – to get past that, and I think in my dealings with Monitor etc. I’ve never tried to make – make that any different...”*⁷³

Ms Holt told us that she had spoken to the clinical team about it, but could not say whether it was *“embraced and owned”* by the clinical team.⁷⁴

⁷⁰ Board memorandum on quality governance arrangements – University Hospitals of Morecambe Bay NHS Foundation Trust, 1 February 2010.

⁷¹ Trust Board minutes, 21 July 2010.

⁷² Dame Pauline Fielding interview.

⁷³ Tony Halsall interview.

⁷⁴ Jackie Holt interview.

4.101 Both Mr Halsall and Peter Dyer, Medical Director, told us that they were disappointed with the content of the report, which did not highlight the issues that the executives were hoping for, and this, in their view, contributed to the report being 'lost', instead of being presented to the Board and communicated to staff in the divisions and at clinical level. Mr Halsall told us that one of the reasons the report was not taken to the Board was the lack of a Board secretary, and this resulted in less than adequate governance and follow-up at Board level and a risk of things slipping through the net during exceptionally busy times:

*"[The Fielding Report] was very much around, as I say, about trying to get an angle on clinical governance across the system. That first came back in around about the time where the Care Quality Commission had downgraded our rating from red to green and Monitor then triggered the next part of the process, and so we were just being asked for, literally, you know, hundreds of documents."*⁷⁵

Given the emphasis that we were told had previously been placed by the Trust on the Fielding Report, we did not find this a convincing explanation.

4.102 The evidence we heard from staff at divisional level indicates that there was no follow-up of the report in 2010, and many clinical staff remained unaware of its content. Fraser Cant, Divisional Manager, said:

"I can remember talking to Angela Oxley (Head of Midwifery) about that, and I remember Angela saying to me, 'What's happening about this report?' and I said, 'Well we haven't had it back to the division,' and I didn't know whether it was going to the Board, because I think the Board commissioned it. And I didn't know what was going on with it, to be honest with you, but we did – there was an agreement that we proceed, because there was, from a professional perspective, the midwifery service and the obstetric service had some issues with some of the content of it..."

*But it was not progressed in the way that I think it should have been progressed. In other words, where's the action plan? First of all, received by the Board, the action plan, [sic] how the reporting mechanisms and the delivery of it would be up through the organisation through the governance structures. That was not clear."*⁷⁶

4.103 The following year, when the Trust was asked to provide evidence of action in response to the report, a communication from the director of nursing suggested that, although there was no action plan, the Trust had been working on some appropriate measures, and stated that it was the division's decision whether to adopt all the recommendations of the Fielding Report. Clinical staff, including midwives and obstetricians, were unable to recall any specific action in relation to the report at all.⁷⁷ The maternity risk manager did not recall being asked about implementing the actions of the Fielding Report until sometime afterwards.⁷⁸

4.104 The Fielding Report was not shared with the NW SHA at the time of completion. Angela Brown told us that she asked Ms Holt for a copy of the report:

"Jackie said that she would let us have that report as soon as they could, and it didn't come in and it didn't come in."

What Jackie also told me was, 'It hasn't really told us anything that we didn't know and we weren't working on. This is work in progress, but it is about taking us forward.' So, she

⁷⁵ Tony Halsall interview.

⁷⁶ Fraser Cant interview.

⁷⁷ Jennifer Bowns interview; Vincent Bamigboye interview.

⁷⁸ Jeanette Parkinson interview.

sent to me a document that had some of the key recommendations or what I thought were the key recommendations, as well as what was the – she'd put on that as well the terms of reference, which was the first time I'd seen the terms of reference. And on the bottom of that was also confirmation that CQC had done a visit into the unit and that everything had gone well.”⁷⁹

She also said to us that:

“We had looked at some of the clinical indicators that were telling us this Trust was on an improvement process and this seemed to fit. But, as I say, the report just didn't come in and the next thing I knew they had gone to foundation trust status.”⁸⁰

4.105 After all we have heard of the events surrounding the Fielding review, it seems to us that the principal objective in Trust executives' minds was to use it as a means of getting the Foundation Trust process back on track. In fact, given the findings of the report, it was more likely to have had the opposite effect, and we believe it is in that context that the prolonged redrafting, lack of disclosure to the Board and relevant Trust staff, and the failure to share it with external bodies should be seen.

Summary

4.106 A number of things began to emerge to indicate problems in maternity services. There was a serious complaint, the letter of concern from Mr Misra, and a cluster of incidents, against a backdrop of strong suspicions that there was a dysfunctional culture in the unit. Appropriate actions were taken in terms of seeking external reviews and opinions, but the evidence and sequence of events suggests that these actions were prompted by a threat to the progression of Foundation Trust status, rather than a belief that the unit really did have serious systemic safety problems.

4.107 By the time the Fielding Report was completed, the Trust had achieved CNST level 2 accreditation, and the CQC had deemed the unit compliant with all standards, and was sufficiently reassured to reduce its risk rating to 'Green'. The Trust was authorised as a Foundation Trust in October 2010.

4.108 The findings, recommendations and actions of the reviews were not followed up by the Trust Board or the Executive; there was no ongoing scrutiny of the service or any rigour around ensuring that actions were being implemented.

Following Foundation Trust authorisation, 2010–12

Overview

4.109 In October 2010, the Trust was authorised by Monitor as a Foundation Trust.

4.110 The inquest into the death of Joshua Titcombe was scheduled to take place in early May 2011. The CQC became aware of the content of the Fielding Report in April 2011. The Trust commissioned NHS Audit North West to undertake a review of the Trust's response to the Fielding Report, which offered assurance despite the lack of a written action plan at the point the audit was commissioned. The Fielding Report was taken to the Board in April 2011, just before the inquest was expected to take place.

⁷⁹ Angela Brown interview.

⁸⁰ Angela Brown interview.

4.111 The coroner was critical both of the evidence he heard and of the care given, and issued a rule 43 letter following the inquest, setting out that the Trust needed to take action to improve staffing levels, multidisciplinary working and record keeping in order to prevent further deaths. The police became involved as a result of the coroner's concern over a missing observation chart.

4.112 The CQC carried out a further unannounced inspection of maternity services jointly with the Nursing and Midwifery Council in June and July 2011 that resulted in a warning notice being issued. At this point, the maternity services had clearly become a significant concern for the Trust Board, and were generating increasing external pressure on the Trust. By September, the Trust was responding to action plans in relation to the Fielding Report, the NMC report on midwifery supervision and the CQC inspection. Monitor found the Trust in breach of its terms and commissioned two further external reviews, one of maternity services (by a clinical team from Central Manchester Hospitals Trust) and one of Trust-wide governance (by PricewaterhouseCoopers). Both of these reports were highly critical. Other serious issues emerged. The transition to a new electronic patient management system highlighted a major problem with incomplete follow-up outpatient appointments. When national mortality data was published in September 2011, the Trust was identified as having the highest hospital standardised mortality rate in the country; this was subsequently demonstrated to be due to the new information system not identifying comorbidity or palliative care correctly, and returned to previous levels once this had been corrected.

4.113 All of these activities resulted in a plethora of inspections, action plans, interest and requests for information from the full range of external stakeholders, police involvement and intense media scrutiny that, we heard, threatened to overwhelm the Trust's ability to respond, whilst continuing to manage its services from day to day. An intervention known as 'Gold Command', more usually used as part of the response to a major incident, was initiated, we heard, by Jane Cummings, Director of Nursing and Performance at the NW SHA, as a way of bringing together the various stakeholders, coordinating action plans aimed at securing safety of services, pulling together the various strands of activity, assisting with communications, and controlling requests for information from multiple sources. Following the arrival of Sir David Henshaw as interim chairman of the Trust, there were extensive changes to leadership of the Trust, with, in effect, a new Board from mid-2012.

Authorisation as a Foundation Trust

4.114 Monitor made the decision to authorise the Trust as a Foundation Trust at its meeting on 29 September 2010. The summary of performance which was assessed by the Monitor Board indicates that the decision was based on the Trust's financial stability (scored as 3, the highest rating), together with good scores for quality governance and corporate governance. The measurable clinical quality indicators cited in the Monitor paper were reported numbers of MRSA and *Clostridium difficile* infections, accident and emergency (A&E) and cancer waits, and door to thrombolysis time following heart attack. On more qualitative issues, it was reliant on the opinion of the CQC, which had reported to Monitor at the time that it had "*no concerns*" about the Trust.⁸¹ The Monitor paper included evidence from the CQC that there were "*robust systems for multidisciplinary working in place*",⁸² that the Trust was "*compliant with all required standards of safety and care*",⁸³ with "*evidence of Trust-wide focus on supporting quality through systems, practice and people development post maternity challenges in 2009/10*" and that there was "*review of all unexpected deaths*".⁸⁴ Monitor itself noted that its observation of the Board and the Clinical Quality and Safety Committee provided evidence of direct challenge to the executive team by the non-executive directors on quality issues.

⁸¹ Monitor Board decision meeting, 29 September 2010, about University Hospitals of Morecambe Bay NHS Trust.

⁸² Monitor Board decision meeting, 29 September 2010, about University Hospitals of Morecambe Bay NHS Trust.

⁸³ Monitor Board decision meeting, 29 September 2010, about University Hospitals of Morecambe Bay NHS Trust.

⁸⁴ Monitor Board decision meeting, 29 September 2010, about University Hospitals of Morecambe Bay NHS Trust.

4.115 In line with Monitor's routine processes, Trust performance was reviewed on a quarterly basis following authorisation. From the time of authorisation until the early part of 2011, Monitor's documents indicate that it was aware of no serious problems. In the period from January to March 2011, Monitor first noted that an inquest was to be held that could generate negative publicity for the Trust. By the period April to the end of June 2011, the outcome of the inquest was known, and this prompted a joint responsive review of maternity services by the CQC and the NMC, which was to look specifically at midwifery supervision arrangements. Monitor also planned to initiate independent reviews of maternity services and Trust-wide governance.

Revisiting the Fielding Report

4.116 At the beginning of 2011, there was a clear increase in interest from external bodies, including the CQC, the NW SHA and Monitor, in the Trust's responses to previous incidents. We believe, on the basis of what we heard, that this was prompted by the impending inquest into the death of Joshua Titcombe. We found indications in contemporary documents that potential adverse publicity surrounding the inquest was a significant factor in reigniting interest in the Trust. Whilst we can well understand that 'reputation management' is a legitimate concern for any NHS body, we found it disappointing, and understandably distressing to families, that this appeared to be the trigger for further action, not the underlying concerns.

4.117 Following an email from one of the families in February, referring to a "secret report", the NW SHA's quality lead, Angela Brown, was concerned that this might refer to the Fielding Report. She contacted the Trust in February 2011 to check that the report had been shared with the appropriate people and was being actioned. She was told by Ms Holt, Director of Nursing, that it had been to part 2 of a Board meeting in 2010.⁸⁵ We could find no evidence that the report had been presented at a formal Board meeting in 2010, and when it was taken to the Board in April 2011 the minutes gave no indication that Board members had seen it before. On that basis, we believe that if the Fielding Report was presented to part 2 of a 2010 Board meeting at all, it received only a brief mention and was not discussed substantively. The renewed interest in the report in 2011 coincides with evidence from Trust staff that indicates a change of approach to the Fielding Report. The divisional manager for family services, Fraser Cant, exemplified this:

"The action plan started, I think, from memory, in February of 2011... The director of nursing following it up with one of the matrons... And then everything that should have formally [been] happening previously started to happen in terms of pulling together the evidence and demonstrating the change."⁸⁶

4.118 In April 2011, the Trust commissioned NHS Audit North West to carry out an audit of progress on the Fielding Report action plan. The Fielding Report was belatedly presented to the Board by the director of nursing on 27 April 2011, with the assurance that there would be an audit report available in mid-May. The Board was reminded that there would be a related inquest in early June, and that the Care Quality Commission had carried out a review of maternity services at Furness General Hospital in June 2010 that had been positive. As we heard from several interviewees,⁸⁷ and as is clear from documentation, there was no action plan in response to the Fielding Report in April 2011. Clinical and middle management staff told us that they were unaware of the Fielding Report until 2011 and that in 2011 there was no great priority given to responding. An email exchange from April 2011 exemplifies that lack of engagement of staff and the mixed signals. A maternity matron wrote to the director of nursing:

⁸⁵ Angela Brown interview.

⁸⁶ Fraser Cant interview.

⁸⁷ Jackie Holt interview; Tony Halsall interview; Karen Weakley interview; Fraser Cant interview.

*"Joyce [McGullion] and I are very concerned to hear today that we are going to be audited on the progress made to date on the Fielding action plan. We only saw the report a few weeks ago... Fortunately we have been working on a lot of the points raised... but... we need to undertake and update this piece of work prior to the audit."*⁸⁸

The reply was on the same day:

*"I was surprised to hear this from Sue [Knowles, acting Head of Midwifery] given there was a meeting... last year... and the Division were asked to work on an action plan... I also made it clear that it was the division to decide whether to adopt all the recommendations..."*⁸⁹

Whether or not the director of nursing had expected the division to produce and implement an action plan in 2010 – and the comment the she did not know *"whether that report was embraced... by the clinical team"* would make it an optimistic assumption – it is clear that it had not produced an action plan and that there was no follow-up in the interim to see if it had.

4.119 The audit was published in May 2011, with an audit opinion of *"significant assurance"*, although the majority of actions are identified as *"started"* or *"ongoing"* rather than completed.⁹⁰ In addition, recommendations that had not been accepted were recorded as completed. We can only conclude that the auditors failed to recognise that the action plan was retrospective and the recommendations optional. The internal auditors carried out several subsequent reviews of the action plan over the next year, with the audit demonstrating that increasing numbers of actions had been completed, although the reviews that were subsequently to take place suggest that these audit opinions were flawed.

4.120 It is the Panel's view, based on all the evidence we heard and saw, that the Trust was prompted to revisit the Fielding Report by the forthcoming audit and likely adverse publicity, and quickly produced an action plan and initiated an audit as a response. The reference to the successful CQC visit reinforces the belief that the Trust was placing more emphasis on the successful CQC visit as a source of assurance than on the more challenging Fielding Report.

4.121 The Trust had not informed the CQC either of the Fielding Report before 2011. The CQC regional director during most of 2010 was Sue McMillan, who was clear in speaking to us that she had no knowledge of the report before January 2011, when she received an email from Mr Titcombe asking if she had seen the Fielding Report, which he attached. Ms McMillan told us that within a matter of hours Mr Titcombe had phoned to ask her to delete the report at the request of his lawyer (it had been sent to Mr Titcombe as part of the papers for the forthcoming inquest into the death of Joshua). Ms McMillan checked that the Trust had not shared the report with the CQC and found that it had not. She formally requested all maternity documentation and reports, and obtained a copy from the Trust in April 2011: *"They didn't respond straightaway, but we pushed it and – we did, and eventually we got it in April."*⁹¹ In Mr Halsall's view, this was not deliberate, but was an oversight:

*"That first came back in around about the time where the Care Quality Commission had downgraded our rating from red to green and Monitor then triggered the next part of the process, and so we were just being asked for, literally, you know, hundreds of documents. I don't believe we purposely decided not to do anything... I think it got lost in between everything else that we were doing at the time, if I'm being honest."*⁹²

⁸⁸ Email from Karen Weakley to Jackie Holt, 14 April 2011.

⁸⁹ Email from Jackie Holt to Karen Weakley, 14 April 2011.

⁹⁰ *NHS Audit North West, University Hospitals of Morecambe Bay NHS Foundation Trust, Internal Audit Report 2011–12 (Fielding Report).*

⁹¹ Sue McMillan interview.

⁹² Tony Halsall interview.

Following the Joshua Titcombe inquest

4.122 The inquest took place on 2 June 2011. In giving his verdict, the coroner was strongly critical of several aspects of the accounts given by midwives in court and the loss of an observation chart, as well as of the clinical care.⁹³ It is clear to us, on the basis of the evidence we saw and heard, that the preparation of staff for the inquest went beyond what could be considered proper. At a meeting with midwives called to give evidence, a solicitor for the Trust's legal advisors presented a series of difficult questions that might be put to witnesses. There is no record of what discussion took place at the meeting, but Jeanette Parkinson, Maternity Risk Manager, told us that she then prepared a set of what we could only describe as 'model answers' to the questions and circulated it to all the midwives involved. The similarity of evidence, particularly on the lack of knowledge of the significance of a low temperature in a neonate, was noted by the coroner.

4.123 The chief executive reported the outcome of the inquest in part 2 of a meeting of the Board on 29 June 2011. It was reported that the chief executive and director of nursing had met with the Care Quality Commission two days previously. They learnt that the CQC was considering the Fielding Report and the subsequent follow-up audit report. The chief executive informed the Board that an in-depth review of the Trust's maternity services should be expected. At that point, a number of actions had been put in place. A new clinical lead for paediatrics and obstetrics, and a new head of midwifery had been appointed. This was thought to provide "*an opportunity for continual improvement in maternity services, facilitating an integrated service between midwives and clinicians*".⁹⁴

4.124 At around this time in 2011, the Trust's governance structure was reviewed, and responsibility for governance and patient experience moved to the nursing director. The nursing director was supported by a new post, the associate director of quality and governance, to whom, in turn, the head of patient safety, the head of risk compliance and the head of patient experience reported.

Care Quality Commission warning notice in September 2011

4.125 The inspection by the CQC took the form of an unannounced visit to the maternity units of the Trust between 18 and 20 June. It found poor compliance across six outcomes: three with major concerns and three with moderate concerns. A warning notice was issued in respect of the concern relating to the assessing and monitoring quality of service provision. The Trust was given until 21 November 2011 to become compliant with all the outcomes identified. Many of the issues of concern reflected those identified in previous reports, particularly the Fielding Report: privacy and dignity in relation to the layout of the unit and the route from labour ward to theatre, and emergency out-of-hours arrangements. And although the CQC found that there were systems in place to evaluate and monitor care delivery and practice, actions were not always taken in response to results in a timely manner.

Nursing and Midwifery Council report, October 2011

4.126 The NMC carried out a review of midwifery supervision in the Trust. Midwifery supervision is a mechanism intended to maintain standards and ensure safety in midwifery practice. It dates from the time when most midwives were independent practitioners responsible for home deliveries, and as a result it operates in isolation from other clinical governance and professional regulatory systems. This separation of systems had caused friction in 2008/09 when the chief executive had delayed the midwifery investigation, pending completion of the Trust's external investigation into a neonatal death. The subsequent midwifery report failed to identify shortcomings that were evident from the external review.

⁹³ Transcript of inquest into the death of Joshua Titcombe.

⁹⁴ Trust Board minutes, 29 June 2011.

4.127 The midwifery supervisory function in maternity units is overseen by the Local Supervising Authority, at that time hosted by the SHA (now by NHS England) but professionally accountable to the NMC. Marian Drazek, LSA Midwifery Officer until 2010, told us that supervision at the Trust was “*not as dynamic*” as in some others.⁹⁵ Whereas in some Trusts supervisors appeared to be proactive in contacting the LSA often to ask for advice or to make suggestions, the supervisors at the University Hospitals Morecambe Bay Trust just “*got on with it*”.⁹⁶ There were, she said, incidents that should have been notified but had not been. Her successor, Lisa Bacon, also told us that investigation reports from the Trust were not of good quality in terms of presentation, which, she felt, was likely to be indicative of the quality of the investigations also. We were struck by the observation that, despite these consistent concerns about the quality of supervisory investigations, the LSA system seemed unable to take action to intervene until the NMC review. Although the LSAMO could report concerns to the SHA, which could take them up with Trust management, this is an indirect route, particularly if the organisation is a Foundation Trust; this seems to us a cumbersome system where patient safety is involved, and ineffective in the case of this Trust.

4.128 The NMC attended the Trust to carry out its review in July 2011. This review focused solely on the arrangements for the statutory supervision of midwives, with the aim of identifying whether these arrangements were effective in supporting safe practice and identifying and responding to unsafe practice.

4.129 The report made 19 recommendations, 6 for the Trust Board, 2 for the Local Supervising Authority and 11 for supervisors of midwives. These covered governance, risk management, collaborative working and leadership, and again reflected many of the common findings within other reports, including the need for a systematic approach to developing and maintaining midwifery guidelines, better use, understanding and dissemination of the risk register, improvements to privacy and dignity of women going to theatre, security of records and collaborative working.⁹⁷ The final report was issued on 10 October 2011. Viewed with knowledge of the full range of failure within the maternity unit and Trust, the recognition of poor supervisory practice and inadequate investigations is weak. We believe that this reflects the narrow focus of the review that resulted, probably inevitably, from the isolation of the LSA mechanism from other clinical governance systems.

Trust response

4.130 The outcome of the CQC and NMC inspections and immediate actions were presented to private meetings of the Board in September and October 2011. Further leadership changes were made, with two new clinical leads working across the two obstetric units (FGH and RLI), one for obstetrics and one for gynaecology, and two new consultants were appointed. These changes removed responsibility for clinical leadership of the maternity unit from the previous clinical lead and associate medical director, Mr Ibrahim Hussein. The division developed an action plan to address the issues identified by the CQC, to be implemented over the next three years. Finally, the Board discussed the capital funding required to improve the maternity unit facilities and solve the problems in getting patients from the delivery suite to the obstetric theatre. The discussion reflected the difficulty of achieving improvement, both in finding the capital required and in identifying a physical solution that would not be detrimental to other parts of the service, but the Trust chairman made it clear that maternity, and achieving CQC compliance, were priorities for the Trust. Maternity was also placed at the top of the risk register.⁹⁸

⁹⁵ Marian Drazek interview.

⁹⁶ Marian Drazek interview.

⁹⁷ *Review of University Hospitals of Morecambe Bay NHS Foundation Trust*. Nursing and Midwifery Council, 2011.

⁹⁸ Trust Board minutes, part 2, 28 September 2011.

4.131 In October, the Board was informed of the plans for the clinical review commissioned by Monitor, and the Monitor governance review. The NMC review of midwifery supervision had been published, and the minutes reveal the Trust's disappointment that positive references to safe practice present in a previous draft did not appear in the final version: the Trust had been hoping to use selected quotes in a press release in response to the adverse CQC report. We heard and saw consistent evidence that at this time the Trust's emphasis in responding to reviews and reports was strongly on accenting anything positive and minimising the usually much more substantial negative findings. The chief executive told us that, although he was by now aware of significant shortcomings in maternity services, it was important that the service continue and "*we were trying... to keep public confidence*".⁹⁹ In our view, it is wrong to issue press releases claiming that services are of high quality when there is knowledge that they are not. Not only is this misleading and falsely reassuring, but it also serves only to increase the frustration and alienation of patients who have been harmed, and their relatives.

4.132 The Minutes also record that the Trust had engaged a consultant midwife from Imperial College London and a supervisor of midwives to assist with midwifery practice, and that it intended to undertake a detailed review of each midwife's performance with support from the director of nursing and the Human Resources Department. Midwives were also being transferred from the maternity unit at Lancaster Royal Infirmary to Furness General Hospital to provide support, while their positions were backfilled by locums. Two paediatricians had been appointed, with a brief to provide an effective link between maternity and paediatrics. A new associate medical director for family and clinical services, Dr Richard Neary, had been appointed. A Serious Untoward Incident Panel, a new sub-committee of the Clinical Quality and Safety Committee with executive, non-executive and PCT representation, was established in November 2011. A risk summit was planned to give a number of stakeholders (SHA, CQC, PCTs) the opportunity to identify concerns with Trust services, to take the form of a monthly meeting, with weekly conference calls. All of these actions seem to us to represent appropriate attempts to tackle problems. However, given the length of time those problems had been allowed to persist (on account of previous missed opportunities for intervention), we are bound to observe that the actions would take significant time to be effective.

Gold Command

4.133 Monitor found the Trust to be in breach of its terms of authorisation as a Foundation Trust on 11 October 2011. Accordingly it commissioned reviews of clinical services (the Central Manchester review) and clinical governance (the PricewaterhouseCoopers review). During the same month, the NW SHA declared a major incident as part of the National Quality Board process and established a Gold Command. We believe that this was in response to the high level of activity from both the CQC and Monitor regarding the Trust, although the use of major incident procedures is more usually associated with urgent crises, such as infection outbreaks. Two sub-groups were established, one for maternity/paediatrics and one for outpatients, in which problems had been identified with appointment scheduling. The NW SHA delegated the lead role in Gold Command to one of the PCTs, NHS Cumbria. The format was of regular, twice weekly, meetings of the sub-groups, each of which required briefings and updates from Trust staff and generated actions for the Trust to fulfil. After each meeting a briefing was provided to the Department of Health. Although a number of interviewees told us that this process was designed to support the Trust,¹⁰⁰ Trust executives explained to us that they did not find this to be the case:

"Well, we then had a situation where the organisation was under extreme scrutiny. There was a lack of capacity initially to deal with [the external bodies] I think. I have to say, personally, trying to manage the day job, the day job has to keep being delivered to patients, and

⁹⁹ Tony Halsall interview.

¹⁰⁰ Angela Brown interview; Jane Cummings interview; Mike Bewick, Peter Clarke, Neela Shabde interview.

*trying to manage an incident of a scale that was expanding was – I've never faced anything like that in my career... I was the lead executive for Gold Command and sometimes those meetings were twice a day."*¹⁰¹

*"What was frequently happening is that somebody who hadn't been part of something would see a piece of information and react to it, even if that had been dealt with, and even if we explained that this has been dealt with, you very often got to the point where you couldn't persuade people that it had been dealt with."*¹⁰²

4.134 We were unable to find clear evidence of tangible benefit for the Trust and its services from the Gold Command process, although it did clearly serve to keep the NW SHA and the Department of Health better informed. On balance, we were unconvinced that the process had achieved anything significant for the Trust and its services, but the requirement for briefings and updates did, we believe, act as a significant distraction.

The Central Manchester Report, December 2011

4.135 Monitor commissioned a clinical review of the Trust's maternity and neonatal services that was carried out by a team from the Central Manchester University Hospitals NHS Foundation Trust, comprising a senior nurse, midwife, obstetrician and neonatologist. The stated objective of the review was to ensure that all immediate and potential safety risks within maternity and paediatric services had been identified, and to assess and quality-assure the action plan that had been put in place by the Trust to address the risks identified in the diagnostic review.

4.136 The Central Manchester team found various action plans in response to previous reviews. The Gold Command initiative was also under way, and generated a high demand for briefings, updates and meetings, as well as further actions for the Trust to implement.

4.137 The Central Manchester review reported in November 2011. It was strongly critical of the lack of clinical leadership and the absence of an overarching strategy for the service. There was no detailed review of people and systems to provide the Board with assurance that the services were safe. The review team also found that the Trust did not have a robust mechanism for reviewing the service against national standards and guidelines, and there was no evidence of a systematic review being escalated through a governance or management structure.¹⁰³

4.138 Leadership within maternity services was identified as a major concern. There were no strong role models; meanwhile midwives and obstetricians did not work together and blamed each other for a lack of excellence. Given the recent serious incidents, the team found it inappropriate that there was no senior presence at the FGH site, other than a band 8a matron (middle manager), leaving a gap in visible leadership in an area of high risk. The review did not find any evidence of implementation of the strong governance arrangements for paediatrics that had been recommended by an external report in 2009.¹⁰⁴

4.139 Although the Central Manchester team identified changes that had been put in place to strengthen governance arrangements at FGH, including additional posts to support practice, and designation of a consultant obstetrician as labour ward lead, college tutor and lead for CNST, they found that it had had little effect in practice. Critical incidents were still being reviewed by the midwifery team rather than by a multidisciplinary team as was required, and obstetric incidents were not being reported to the Integrated Risk Committee and therefore the Board.

¹⁰¹ Jackie Holt interview.

¹⁰² Tony Halsall interview.

¹⁰³ *Report of the Diagnostic Review undertaken at University Hospitals of Morecambe Bay NHS Foundation Trust (Central Manchester Report)*, November 2011.

¹⁰⁴ *Review of Children's Services (Mitchell Report)*, 2009.

4.140 The review team discovered that, although systems and processes were in place, the assurance given to the Board was not robust. For example, the Trust set a target date for completion of mandatory training of November 2011, but by then less than 2% of doctors in maternity and paediatrics had undergone mandatory training. It found no joined-up approach to training and professional development. The complaints system was poor and slow, with no real-time feedback and an over-reliance on positive comments. The team concluded that the methodology used by human resources to provide assurance to the Board was flawed.

4.141 In summary, it seems clear to us from the Central Manchester review that the Trust had attempted to make some changes in management and governance structures and had action plans in place, but there was no sign in October 2011 that these were having any effect in improving services.

The PricewaterhouseCoopers governance review, 2012

4.142 The PricewaterhouseCoopers (PwC) review of Trust-wide governance was also commissioned by Monitor following the declaration that the Trust was in breach of its terms of authorisation as a Foundation Trust. It reported in February 2012. Almost without exception, the report is damning in its criticism of governance, the people, processes and systems at all levels. Some of the problems underlying these findings may have been exacerbated by a degree of organisational turmoil that undoubtedly resulted from the plethora of external reviews and their consequential action plans and other external interventions, such as Gold Command. This was the view of senior Trust staff,¹⁰⁵ and is reflected in what we heard from the report's author:

*"I mean, you have got a sense of a Board that was a bit overwhelmed really. We went in there at a time of, you know, they were in crisis mode at that stage after everything that had happened to them but I would summarise it overall by saying the governance processes and procedures were broken really and given the way governance was not working, it was not operating properly, I do not think the Board could have known everything that could have gone on because it just was not getting the right information and the problem was it did not realise it."*¹⁰⁶

4.143 We were also told by the report's author that his observations did not suggest that the problems were recent in origin:

*"I mean, there was a governance structure that looked like it could have worked, it looked like most governance structures... a Board and some sub-committees reporting in and then divisional governance below that... [but] there was a lack of prioritisation amongst a lot of people down at the divisional level. Middle management was overwhelmed by the amount of work it had to do. There were action plans all over the organisation but it would have been virtually impossible for anybody to actually locate them all and work out who was responsible for what... A lot of things you would expect clinicians to be leading on, divisional level, for example, it was the operational managers that were being held to account. So a lot of them did not have that responsibility and as a result were deeply disengaged."*¹⁰⁷

¹⁰⁵ Peter Dyer interview.

¹⁰⁶ Ian Elliott interview.

¹⁰⁷ Ian Elliott interview.

Response

4.144 In December 2011, at the time the findings of these two reviews were emerging, the chairman left the Trust. Sir David Henshaw was approached by Monitor to act as an interim chair. He told us that, although he had previously been the chairman of the NW SHA, he was taken aback by what he found on arrival at the Trust: “... when I went up there [to Morecambe Bay] and walked in and then pulled the filing cabinet out, I was just staggered. Staggered.”¹⁰⁸ He told us that poor governance was at the heart of the problem:

“The core of this problem was the lack of good governance of the Trust. It was – the Board was not in control. And ‘not in control’ covers the whole gamut from everything – there was no strategic vision other than, it seemed, to become an FT. That was the game at hand. Once they got – that occurred, it seems to be that the second line running was, ‘well, we will take over North Cumbria. That will become another game to play.’ So there was no clear vision, no clear strategy, the quality of the Board in its debates and the agendas and the papers was very poor. It was not what I [was] used to wherever I had been. The quality of the debate, as far as I could surmise when I interviewed all the members of the Board and then talked to people about how it had operated, I mean, it was clear to me that there was just an absence of what I would call even a partially functioning Board... the way the hospital was run... the clinicians were on the edges, hanging [back] and throwing the occasional brick, whilst managers stood there in the middle and did not lead or manage because there was a lack of strategy and vision... Commissioners were very disengaged.”¹⁰⁹

4.145 His initial actions were to replace key executives and non-executives:

“Tony Halsall and I on the very second week had a conversation, and, I think, I made it clear I didn’t see him as being the Chief Executive who would lead recovery on the basis of what I had seen in the previous 10 days... So the Medical Director, I [had a] conversation with him and he agreed he would stand aside once I found somebody that we could bring into the role.”¹¹⁰

Sir David Henshaw approached Eric Morton to take on the role of interim chief executive. Mr Morton’s first impressions were similar: he found that the Trust had lost its way as a result of being overly focused on achievement of Foundation Trust status to the exclusion of “the day job”;¹¹¹ it had a poor relationship with Clinical Commissioning Groups and clinicians, with both groups disengaged.

4.146 The interim chair and chief executive embarked on a series of changes of personnel, divisional structures and processes during their time at the Trust, with the aim of improving services and building confidence with the CQC and Monitor.¹¹² A new substantive chief executive, Jackie Daniel, was appointed in June 2012.

Summary, 2010–12

4.147 When under the pressure of external scrutiny, the Trust belatedly attempted to demonstrate that the Fielding Report had been subject to the proper organisational governance processes. Once the inquest into the death of Joshua Titcombe had raised the profile of clinical failures in the Trust’s maternity services, Monitor and the CQC initiated a series of inspections and reviews of the Trust. The outcome of these was consistently highly critical of both services and governance arrangements

¹⁰⁸ Sir David Henshaw interview.

¹⁰⁹ Sir David Henshaw interview.

¹¹⁰ Sir David Henshaw interview.

¹¹¹ Eric Morton interview.

¹¹² Sir David Henshaw interview.

in the Trust. Initial attempts were made to respond by improving leadership and management at clinical unit level and addressing processes; but as the degree of scrutiny increased, the Trust became overwhelmed by the level of external intervention and the additional activity generated. Finally, the Monitor-commissioned Central Manchester and PwC reviews unequivocally concluded that the actions that had been put in place had not served to improve maternity services, and clinical governance systems remained inadequate. The scale of intervention and lack of confidence in the leadership eventually resulted in the Board being dismantled and a new leadership appointed.

Whistleblowing response

4.148 The Investigation heard evidence from Sangeetha Kolpattil and Russell Dunkeld. Both interviewees explained to the Panel that they had raised concerns about serious incidents they had witnessed at the Trust and considered themselves to be ‘whistleblowers’.¹¹³ Both Dr Kolpattil and Mr Dunkeld were deeply disappointed and disaffected by how they considered they had been treated by managers and colleagues at the Trust following what they regarded as a brave step to whistleblow. Both expressed their distress that fellow clinicians did not share their concerns, even when they suggested that there was evidence to support their claims.

4.149 The Investigation also interviewed Kirk Panter, Chair of the Staff Side at the Trust, who stated that, from his experience, whilst serious concerns raised by staff at the Trust were not given urgent attention in the past, the current Trust Board is more responsive when concerns are raised by staff within the Trust. He considered that the Trust Board and senior managers take seriously and act upon the concerns raised by whistleblowers.¹¹⁴

4.150 Mr Panter told us that the Trust’s staff-side representatives encourage their members to use existing policies and procedures to raise concerns, and will raise concerns themselves with executive and non-executive directors, and that this is explained during the induction programme for all new recruits to the Trust.¹¹⁵

4.151 During the course of the interview programme, the Investigation Panel asked a cross-section of staff from the Trust (clinical and management) if they were aware of how to report a serious untoward incident, and whether information about the Trust’s whistleblowing policy was readily available. Staff advised the Panel that they were aware of how to report an incident, could access the current incident reporting system, knew where the whistleblowing policy could be found on the Trust intranet site, and knew that concerns could also be submitted in writing to the Trust Board.

4.152 The Investigation considered the results of the Trust’s staff surveys undertaken from 2004 to 2013 in respect of incident reporting and whistleblowing.¹¹⁶ Data on whistleblowing was not collected by the Trust prior to 2008, and it was not until 2010 that staff were explicitly asked “*if they knew how to report fraud, malpractice and wrongdoing and if they felt safe doing so*”.¹¹⁷

4.153 It should be borne in mind that only a random sample of Trust staff are surveyed annually (c.850) and of that group there is an average response rate of 65%.

¹¹³ Sangeetha Kolpattil interview; Russell Dunkeld interview.

¹¹⁴ Kirk Panter interview.

¹¹⁵ Kirk Panter interview.

¹¹⁶ NHS National Staff Survey brief summary of results from Morecambe Bay NHS Trust 2004–05; NHS National Staff Survey brief summary of results from University Hospitals of Morecambe Bay NHS Trust 2006–08; NHS National Staff Survey 2009 results from University Hospitals of Morecambe Bay NHS Trust; NHS National Staff Survey results from University Hospitals of Morecambe Bay NHS Foundation Trust 2010–13.

¹¹⁷ NHS National Staff Survey results from University Hospitals of Morecambe Bay NHS Foundation Trust 2010–13.

4.154 However, the results of the 2013 staff survey at the Trust suggest that, of those staff who responded, 87% knew how to report any concerns they had about fraud, malpractice or wrongdoing by staff, and of those 68% commented that they would feel safe raising their concern.¹¹⁸

4.155 In its response to the findings of the survey, the Trust Board committed to:

*“...ensure that staff are aware of the organisation’s whistleblowing policy and how to report their concerns”.*¹¹⁹

4.156 This view was reiterated by the Trust’s chief executive, Ms Daniel, when she gave evidence,¹²⁰ and by the Trust Board when its members were interviewed in respect of terms of reference 5 and 6.¹²¹

4.157 The Investigation did not have an opportunity to hear evidence explicitly regarding the Trust’s whistleblowing policy. However, the report of the Freedom to Speak up review was published in February 2015. The review, chaired by Sir Robert Francis QC, was an independent review into creating an open and honest culture in the NHS. Mr Dunkeld advised the Investigation that he had contributed to the Freedom to Speak up review, and Sir Robert Francis had already reported that he had received hundreds of detailed contributions from a wide range of staff working in the NHS and other organisations.

4.158 The Morecambe Bay Investigation is confident that its findings will be considered by the Secretary of State in conjunction with the findings of the Freedom to Speak up review.

Chapter conclusions

Key findings on the Trust’s clinical governance management

1. Clinical governance reporting structures and policies were in place at Trust level, and the Trust Board would have taken assurance from successful CNST accreditation that these were adequate. There were shortcomings in the way that they operated in practice, but the Trust was far from alone in needing to develop its understanding at this stage.
2. Management structures and understanding of the requisite roles and responsibilities were inadequate for effective clinical governance at divisional level before 2008. There was a fragmentation of the governance systems in the Trust, with managers responsible for finance and operations, while clinical directors were responsible for clinical governance. The two elements were treated separately, with performance and management targets given clear priority. Clinical issues were not addressed, even where there were committees in place, some of which did not meet or had poor attendance.

Key findings on the Trust, 2004–08

3. We believe that a combination of poor clinical skills and knowledge, lack of engagement, lack of ownership of problems, and failure to escalate concerns amongst maternity staff led to problems not being evident at Trust level. Governance systems were not sensitive enough to identify this problem in the absence of other indicators of poor outcome prior to 2008.
4. Had the clinical problems been escalated effectively to more senior level prior to 2008, it is possible that effective corrective action could have been taken before the dysfunctional

¹¹⁸ NHS National Staff Survey results from University Hospitals of Morecambe Bay NHS Foundation Trust 2013.

¹¹⁹ University Hospitals of Morecambe Bay NHS Foundation Trust 2013 Staff Survey Management Report.

¹²⁰ Jackie Daniel interview.

¹²¹ Trust Board interview.

nature of the unit that we have described elsewhere became embedded and more widespread.

Key findings on the Trust, 2008–10

5. The initial response to the letter of complaint by James Titcombe was appropriate, but became inadequate when further information became available subsequently.
6. The chief executive initially commissioned an external review of the Joshua Titcombe case and then a management review of clinical governance arrangements in the maternity unit. These appeared to be an appropriate attempt to identify underlying problems in the maternity unit, but this approach was not followed through adequately.
7. The subsequent Fielding review was poorly implemented and missed opportunities to identify the real problems. Insufficient attention was given to the commissioning and support of the Fielding review to ensure its success, given the potential significance of the issues that were suspected, and the evidence from serious incidents of the impact that these issues were having on quality and safety.
8. The way that the report was dealt with by the Trust was significantly flawed, partly shaped by the threat to the Foundation Trust authorisation process. Although we were unable to find definitive evidence, we believe that, on the balance of probability based on all that we did hear, Trust officers decided to give the report limited circulation amongst Trust staff and to delay sharing it with external bodies.
9. The Trust's achievement of the NHSLA risk management standards accreditation at level 2 in January 2010, the positive outcome of the CQC unannounced inspection in June 2010, and the downgrading of the risk rating from 'Red' to 'Green', allowing the Foundation Trust process to progress, all provided false reassurance that improvements had been made.
10. The failure to follow up formally the findings of either the Flynn or the Fielding review at the level of the Trust Board, or to continue to progress the original aim of exploring the acknowledged problems in obstetrics, once the external pressure had gone away, was a failure of clinical and corporate governance.

Key findings on the Trust, 2010–12

11. It is our view that the belated attention to the Fielding Report was stimulated by the threat of the imminent inquest in 2011 and the likely attendant publicity, and the consequent renewed interest and scrutiny by external bodies. The response was too little, too late.
12. Once the result of the inquest was known, a series of reviews was initiated. These were universally critical of the Trust. Prior to the outcome of the inquest, and without knowledge of the Fielding Report, the same bodies had produced reports that were positive.
13. The senior management and Trust Board responded by making changes in personnel, structures and processes, and the profile of maternity services was appropriately raised at Trust Board level; but these changes were not enough, by that point, to have sufficient impact. In addition, markedly increased levels of concern and intervention from external stakeholders generated a rapidly rising additional workload, which had the effect of overwhelming the organisation.
14. The Central Manchester and PwC reports revealed the fundamental and long-standing nature of problems at all levels. With the emergence of additional problems elsewhere in the Trust, it is our view that by this point a change in leadership was a necessary, but not sufficient, requirement to begin to restore confidence.

CHAPTER FIVE: External response

Introduction

5.1 This chapter considers the external environment in which the University Hospitals of Morecambe Bay NHS Foundation Trust (UHMB FT or 'the Trust') worked. It sets out our findings on the relationship and communications between the Trust and external organisations in accordance with our terms of reference 2(b), including the origins and responses to the externally commissioned reports that were identified in the terms of reference 3 (all those listed in paragraph 2.4 other than the Fielding Report and Clinical Negligence Scheme for Trusts (CNST) reports, which are considered in Chapter 4 of this Report, which deals with Trust governance).

5.2 During the period of the Investigation, there were times when the health system, through its interactions with the Trust, might have altered the response of the Trust and the health system to the incidents that prompted the establishment of the Morecambe Bay Investigation (MBI or 'the Investigation'). These are examined in detail.

5.3 The key events to be considered are:

- The North West Strategic Health Authority (NW SHA) advised UHMBT on establishing the Fielding review. It also made an assessment of whether the clinical incidents of 2008 were linked – concluding that they were not, on which other bodies subsequently relied and which the Trust took as confirmation of its view that they were not.
- The Secretary of State (SofS), on advice from the Department of Health (DH), approved the entry of UHMBT into the NHS Foundation Trust (FT) pipeline in February 2009.
- The NW SHA and Primary Care Trusts (PCTs) both had responsibility for assessing whether the Trust had properly addressed serious untoward incidents (SUIs) and discussing what was required with the Trust. This responsibility lay with the NW SHA at the beginning of the period with which the Investigation is concerned and then transferred to the PCT in 2009. The point of transfer enabled an overview of the Trust's incidents in maternity care to be taken. This was a significant opportunity to consider the quality of care and the possibility of systemic problems.
- In May 2009 the Care Quality Commission (CQC) was asked to consider investigating the incidents that had arisen in 2008. Having completed an initial screening, it concluded that the referral did not warrant investigation – in part because the incidents were thought not to be linked.
- The Parliamentary and Health Service Ombudsman (PHSO) considered, and ultimately rejected, a request to investigate the handling of one of the incidents. It is likely that the interpretation of this decision by other bodies, including the Trust and the CQC, led to them taking steps that would have been different had an investigation been launched.
- During 2009 and 2010, Monitor considered the application of UHMBT to be a Foundation Trust, culminating in its authorisation in October 2010. This was taken as further assurance by the Trust that it was well governed. The process of authorisation involved the PCTs and the NW SHA, and the CQC and Monitor took assurance on quality issues from these bodies.

- The CQC (initially through its predecessor the Healthcare Commission) monitored the quality of care in the Trust throughout the period of the Investigation. It decided in April 2010 to register it without any conditions, contrary to expectations held by other parts of the system in the months prior to that decision.
- Subsequent CQC activity included a number of visits to the Trust, regulatory actions including formal warnings, and in particular a section 48 investigation in 2012 designed to ascertain whether there were systemic failures within the Trust. The report made a substantial number of recommendations for improvement at the Trust.
- Monitor identified governance failures in the Trust during 2011, found an interim Chair and commissioned diagnostic and governance reviews, which reported in 2011 and 2012.
- Concerns about the effectiveness of midwifery supervision within the Trust led to an investigation by the Nursing and Midwifery Council (NMC) in 2011, with recommendations for the Trust and a follow-up report in 2012.
- Briefings were provided by DH officials to the Secretary of State in September 2011 and July 2012.
- Parliament considered the position in a debate on 19 June 2013.¹
- The PHSO considered a number of complaints about the supervision of midwifery system overseen by the NW SHA and undertook investigations, publishing its reports in 2013.

5.4 Each of these events is considered in the context of the framework for external oversight of UHMBT and in the light of the effectiveness of that oversight in assisting or requiring the Trust to improve the quality of its care and governance.

Context

5.5 The primary responsibility for direct clinical care sits with health professionals. The primary responsibility for clinical governance sits with the Trust Board. However, there are a number of external organisations who have responsibilities that relate to the scope of the Investigation. This section of the Report relates to the work of those organisations. The Report describes a health system, which has providers, commissioners and regulators. Within the system, responsibilities lie with each of these types of organisations. What communities can expect, is that the system works, each element does its part and that the components of the system communicate and work effectively together. This includes commissioning the services that the Trust provides so as to ensure they are safe and effective. Regulatory roles include ensuring that the Trust meets the prescribed standards for registration as a health provider and also the governance requirements for a licence to operate as a Foundation Trust.

5.6 This section examines the relevant aspects of the work of the following bodies who had oversight responsibilities in connection with the Trust:

- The two Primary Care Trusts that commissioned services from UHMBT: Cumbria PCT and North Lancashire PCT.
- The North West Strategic Health Authority, which was responsible for creating a strategic framework for the NHS in the region, performance management and building the capacity of the health system to improve. This included direct oversight of the performance of the PCTs and also UHMBT until its authorisation as a Foundation Trust in October 2010. The NW SHA had a specific statutory role as the Local Supervising Authority (LSA) in respect of the supervision of midwives.

¹ www.publications.parliament.uk/pa/cm201314/cmhansrd/cm130619/debtext/130619-0002.htm

- The Healthcare Commission and the Care Quality Commission, which regulated NHS providers. From April 2010 hospitals were not permitted to offer services unless they were registered with the CQC, and the Commission carried out an assessment process to determine whether UHMBT should be registered and whether this should be with any condition or warning. The two Commissions produced quality annual ratings for the Trust, carried out inspections and had powers to take a range of regulatory actions, which were used at various points in the period covered by the Investigation's terms of reference.
- Monitor, who regulated Foundation Trusts, including assessing whether UHMBT met the required standards for authorisation as an FT (during 2009 and 2010), and then keeping under review whether it complied with the terms of that authorisation. Monitor has a range of powers of intervention, which it exercised at various points during the years in question.
- The Department of Health had five basic roles: setting direction and priorities, supporting delivery, leading health and well-being for Government, accounting to Parliament and the public, and supporting DH staff to succeed.²
- The Secretary of State for Health, supported by his Ministerial team, has the fundamental statutory duty to promote in England a comprehensive health service designed to secure improvement in the physical and mental health of the people of England, and prevent, diagnose and treat illness.³

5.7 This section of the Report also considers the actions taken by bodies to whom matters within the scope of the Investigation were referred. These are:

- The Parliamentary and Health Service Ombudsman, who has jurisdiction to investigate maladministration on the part of NHS bodies. The Ombudsman was invited to consider two matters: the first concerned the handling of a particular patient issue; the second concerned the work of the NW SHA in relation to its responsibilities as LSA, ultimately leading to reports upholding the complaints.
- The Nursing and Midwifery Council, which was responsible for professional regulation, including the oversight of statutory supervision of midwives and also the fitness to practise of individual nurses and midwives who were referred to the Council.
- The General Medical Council (GMC), which regulates individual doctors and also aspects of medical education.
- The Health and Safety Executive (HSE), which is responsible for ensuring safe systems of work and entitled to investigate serious failures in such systems that cause death or risk of serious harm. The HSE was invited to consider exercising its powers in respect of some of the deaths that we have reviewed.

Primary Care Trusts

5.8 Until 1 April 2013 when they were abolished, Primary Care Trusts were responsible for a wide range of statutory and non-statutory functions. These functions shaped the role of PCTs in the health system – including their relationships with provider organisations, such as the University Hospitals Morecambe Bay Trust. It is in exercise of these functions that PCTs were responsible for the provision of hospital and community health services to their local population. In addition to the specific requirements set out in law – various Health Acts, human rights legislation and employment law – the Secretary of State for Health delegated powers to PCTs in order that they arrange for other bodies or persons to provide services. It is on this basis that PCTs are able to commission

² *The DH Guide: A guide to what we do and how we do it.* Department of Health, 2007.

³ National Health Service Act 2006, section 1(1).

services from secondary care and community providers, such as NHS Trusts, Foundation Trusts and independent providers.

5.9 In addition, PCTs had specific roles that they were expected to perform. These can be summarised as:

- strategic leadership and planning;
- partnership, engagement and planning;
- providing or securing services;
- monitoring and evaluating;
- accountability and assurance;
- workforce;
- estates and IT;
- service-specific responsibilities relating to:
 - mental health;
 - young people;
 - offender health;
 - continuing healthcare;
 - maternity (provision of a Maternity Services Liaison Committee);
 - primary care.

5.10 The role of PCTs was complex and wide ranging. Until April 2013, PCTs played a major role in the development and assessment of local health services. Their role was critical both in terms of maintaining high-quality services and in the development of service-change, based on population need. PCTs were required to monitor and evaluate local services, and to plan, in partnership with their populations, service strategies which were then delivered through their commissioned services. PCTs had a direct responsibility to ensure that high-quality services – including maternity services – were commissioned to meet the needs of their populations, and also, through the monitoring of the service providers, to ensure that this high quality of services was delivered.

5.11 PCTs had a responsibility for strategic leadership and planning. PCTs assessed the needs of their populations and prioritised the issues that needed to be addressed. There is clear evidence that the PCTs undertook both assessments of service priorities and population-based needs assessments.⁴

5.12 Both Cumbria PCT and North Lancashire PCT faced challenging agendas, and were dealing with significant service issues. In Cumbria, the focus was on the north of the county. Here, there were unresolved strategic questions about community hospitals, and the future of Westmorland General Hospital. In North Lancashire, the PCT's attention was split between the Royal Lancaster Infirmary, Blackpool's and Preston's hospitals and community services. Both PCTs were also engaged in reviews of mental health services. There does not seem to have been a direct focus on maternity services or Furness General Hospital, and there was no indication of significant problems before 2009. In 2009 Janet Soo-Chung became chief executive of North Lancashire PCT and she identified in her interview that a number of issues were raised with her about services at the Royal Lancaster Infirmary, but that maternity was not one of them.⁵

⁴ Board papers and strategies.

⁵ Janet Soo-Chung interview.

5.13 With significant strategic issues on the agendas of the PCTs, attention was not at this time on UHMBT, and where issues were being raised they did not relate to maternity services. Under such circumstances it is not unexpected that the attention of the PCTs was on other strategic issues. However, there is a clear responsibility placed on PCTs to provide strategic leadership and assessment of services. It is not unreasonable to expect a PCT to have a clear idea about a service and to have a strategy for that service. No evidence of a maternity service strategy at either of the two PCTs has been shared with the Investigation. Cumbria ran a major consultation in 2007, *Closer to Home*,⁶ on providing more healthcare in the community in the north of Cumbria, which covered maternity-related services; and there was also a report by the director of public health, *Born in Cumbria*, in 2009.⁷ Neither of these reports is a strategic plan for maternity services. Dr Hugh Reeve, former Medical Director at Cumbria PCT, told us that the Clinical Commissioning Groups (CCGs) had not inherited a service specification from the PCTs.⁸

5.14 However, the PCTs also had responsibilities relating to the contracting, monitoring and evaluation of existing services. In many cases an NHS Trust served the population of multiple PCTs. In large urban areas a great number of commissioners can contract with a Trust. Conversely, there can also be many different service options available to the population. In rural areas there are likely to be fewer commissioners and little competition to local services provided by a Trust. The latter was the case in Cumbria. The two main commissioners of the Trust were Cumbria PCT and North Lancashire PCT. In 2009/10 the two PCTs were responsible for 97% of the Trust's contracted income (56% from Cumbria PCT and 41% from North Lancashire PCT).⁹ Whilst there was some variation over the period of the Investigation, the two PCTs remained the main commissioners for the Trust.

5.15 It was normal practice where there were multiple commissioners for there to be a lead commissioner. It was the responsibility of this lead commissioner to act on behalf of all commissioners in the contracting of services with that Trust. The lead commissioner would agree with other commissioners a commissioning plan and then negotiate, contract and monitor the services provided for the populations. In this way a coherent and single approach to service provision can be agreed, monitored and evaluated, without the provider trying to meet differing and potentially conflicting requirements from other commissioners. Lead commissioning was common practice across the NHS during this period. However, when questioned about this, the two PCTs were unclear about who had lead responsibility, with both PCTs indicating that the other had responsibility and the NW SHA stating that, in the North West, UHMBT was the only Trust where there was no lead commissioning in operation.^{10, 11, 12}

5.16 Where lead commissioning was not in operation there is always the potential for differing strategies to be developed that might not provide a consistent and unified service for the population. Priorities will be different and the lead arrangements can be used to reconcile this so that a single approach to a Trust can operate. Communication between PCTs is paramount, in order that they can understand and monitor the services they are commissioning. Without a lead commissioner this can become fragmented and ineffective. The absence of lead commissioning arrangements cannot have helped in the management of contracts by the PCTs. It demonstrates a lack of effective communication between commissioners and a lack of focus on the Trust. This is further reinforced by Cumbria PCT mainly looking to the north of the county and North Lancashire PCT looking at one

⁶ *Closer to Home*, September 2007.

⁷ *Born in Cumbria*, September 2009.

⁸ Hugh Reeve interview.

⁹ Morecambe Bay Board to Board report, 7 May 2009.

¹⁰ Sue Page interview.

¹¹ Janet Soo-Chung interview.

¹² Jane Cummings interview.

part of the Trust (Royal Lancaster Infirmary) and then, not as a major focus of attention. Without focus on a provider, it is easier for issues to be missed or not followed through.

5.17 Monitoring of contracts and latterly the performance management of the Foundation Trust by the PCTs should have provided evidence to the commissioners of major failings in service. Routine assessments and monitoring meetings were held and these should have identified service issues. Indeed, monitoring did identify issues, but these were not related to maternity prior to 2008. Monitoring raised concerns about outpatient follow-ups, urgent care and other services, but did not specifically raise issues relating to maternity.

5.18 The other issue of concern was financial balance. There were clearly financial problems within the Trust and dialogue over the levels of activity being undertaken by the Trust and the efficacy of demand management. Debate between the Trust and the PCTs focused on cost improvements and activity reduction plans – as was not uncommon at the time. There was recognition by the PCTs that the Trust needed some further investment but the ability of the PCTs to do this was seriously hampered by the problems in the north of Cumbria.¹³ Arbitrations by the NW SHA ended in support for the providers in the north, which the PCT felt removed its ability to follow its priorities and invest additional resources in UHMBT.

5.19 In summary, prior to the SUIs, there were no specific concerns about maternity services being raised with the PCTs through the contract and service monitoring. There were concerns being discussed but these were not maternity focused. GP feedback was not picking up problems, patient feedback was not raising significant concerns and subsequently attention was elsewhere.

5.20 Public Health had looked at population issues and provided a population-based assessment of the whole life course in a series of reports and there was work planned on the impact of services on small ethnic groups. Cumbria PCT did commission some investigation into maternal mortality, but this focused on population-based analysis and there is no evidence that it identified any major concerns or outliers, or that it was used specifically to look at cases at UHMBT.

5.21 The Investigation is satisfied that there were no significant signs of problems relating to maternity services prior to 2008 that should have been picked up through the routine monitoring of contracts by the PCTs. Nevertheless, there was a recognition that such monitoring was not the only thing that might trigger concerns. Professor John Ashton, former Director of Public Health, Cumbria PCT, and former Regional Director for Public Health North West, clearly recognised this when he told us:

“... at the same time as there were three maternal deaths – three maternal deaths in two years; two in one year and one the year before or the year before that. There were three. And I’m thinking nationally there are about 60 a year, and you’ve got three in Barrow in a couple of years. Now this could be nothing, small numbers, statistically it could be an aberration. They were all women that were born overseas as well, and you thought is there something to be looked at further here? Are there cultural issues about access to good services? What does it mean? Does it mean anything? Does it mean nothing? We need to know more about this.”¹⁴

5.22 One of the specific functions that a PCT was required to provide was a Maternity Services Liaison Committee. We could find no evidence that there had been one in place for the period under investigation. It is possible that if this had been in place, concerns might have been raised earlier about maternity services but this is by no means certain, as the feedback from GPs, service users and from external assessments such as the CQC and the CNST were all positive at the time.

¹³ Sue Page interview.

¹⁴ John Ashton interview.

However, the committee should have been in place and could have acted as another route by which concerns were received by the PCT.

5.23 A specific area of interaction between the PCT and the Trust related to the application for Foundation Trust status. Initially the two PCTs indicated their support for the Trust's application for FT status.¹⁵ However, when the application was deferred, following concerns about the SULs, the two PCTs met with Monitor and expressed concerns about the viability of the Trust's business plan and the competency of the Board.¹⁶ It was also stated that these concerns were raised with the NW SHA. It is unclear how these issues were handled. The Investigation has not found evidence that the PCTs wrote formally to Monitor or the NW SHA on these issues, relying on the meetings to express their concerns. Monitor believed that the PCTs had been asked to place any concerns in writing, but these were not received. What actually happened remains unclear but no objections at this time were raised in writing by either the PCTs or the NW SHA about the Foundation Trust application, and Monitor took the formal written responses on file as the position of the PCTs and the NW SHA. Whilst on their own these views are unlikely to have made a material difference to the Foundation Trust application, the concerns of the PCTs were further evidence of disquiet about the capacity and capability of the Board at the Trust. In his evidence the current chief executive of Monitor said that, under the current arrangements, these concerns would have been fully investigated before approval to Foundation Trust status was made. The emerging picture shows that there was no really significant evidence of service failure available to the commissioners prior to the SULs but there were a number of small pieces of evidence that needed further investigation. Any pattern was missed.

5.24 It was clear that there were examples of poor relationships between the PCTs and the Trust, but it is difficult to gauge how widespread tensions were. Although the Cumbria PCT's medical director described a good relationship with the medical director of the Trust, he also recounted an example of barriers being raised to communication between clinicians:

"Just to give you an example, Neela [Shabde] and I, we discovered an incident. This was post Gold Command starting, and this was early on, and there was an incident happened, and we requested to go down and see the clinicians there, and we were refused entry. We were halfway there, driving down Cumbria, and we were told to turn back, that we wouldn't be welcome until they'd looked at it themselves. Now, we thought we were building a relationship then, and there was still a mistrust around.

And there were difficult discussions about who they sent to Gold Command, for instance, at the beginning. They sent at times relatively junior people in the organisation, for what was a major incident, and we had to criticise for that, but that did change, I have to say, as time went on and we got high-level representation, and the [inaudible] has also put a lot of its own resources into the programme office, etc, and recruit from outside to give, you know, fresh eyes and fresh perspective."¹⁷

5.25 Similarly, there was an angry exchange of correspondence in May 2010 when North Lancashire PCT received a paper setting out concerns that the chief executive of the Trust felt had not been raised with him.¹⁸ However, it is not clear that this was something that might not have happened in other health economies when they were under pressure.

¹⁵ Letters of support from two PCTs.

¹⁶ Sue Page interview; Janet Soo-Chung interview; Dr Geoff Jolliffe interview.

¹⁷ Mike Bewick, Peter Clarke, Neela Shabde interview.

¹⁸ Letter to Tony Halsall from Janet Soo-Chung, 5 May 2010; Letter to Janet Soo-Chung from Tony Halsall, 28 May 2010.

The North West Strategic Health Authority

5.26 Strategic Health Authorities (SHAs) came into being with effect from 1 October 2002, when 28 SHAs were created. A number of the functions of the Secretary of State for Health were delegated to these new organisations – subject to limitations set out in the Regulations and subject to any further directions he might make.¹⁹

5.27 The main functions of the SHAs were set out in a Department of Health document published in January 2002, *Shifting the Balance of Power: The Next Steps*. The document laid out three key functions:

- creating a coherent strategic framework;
- agreeing annual performance agreements and performance management;
- building capacity and supporting performance improvement.

5.28 The document described the style of working expected of the new SHAs – a focus on delivery, exercising consistent performance management principles across the whole SHA and commitment to service quality and patient safety (ensuring effective clinical governance was in place within all NHS organisations) – creating an environment where they were the centre of decision-making. There was also a focus on empowering and devolving to local services where appropriate.²⁰

5.29 Performance management became a key tool for SHAs. It was through performance management that SHAs were expected to manage local services on behalf of the Secretary of State. Performance was assessed on the basis of an agreed set of priorities which would, in turn, ensure progress towards the longer-term goals of the NHS. Performance management was based on the concept of ‘earned autonomy’, by which good performance was rewarded by greater operational freedom for the NHS organisation – a ‘light touch’ approach. Where there was poor performance, greater scrutiny would be used and interventions made where necessary. The first responsibility was for the organisation to manage itself, to produce and utilise the necessary information to allow it to scrutinise its own performance. The organisation would then be externally scrutinised by the PCTs, the SHA and increasingly by external regulators.

5.30 An emphasis on quality and patient safety was also prerequisite. An Appendix to *Shifting the Balance of Power*, entitled Quality and Safety: Maintaining and Developing the NHS Quality Framework, reinforced the duty of quality placed on all NHS organisations, including SHAs.

5.31 The original 30 SHAs envisaged in *Shifting the Balance of Power* eventually became 28 SHAs who, in turn, were responsible for 303 PCTs. This was a significant slimming down of the previous intermediary tier and a budgetary cap of £11m was placed on the new SHAs which in turn limited their size and capacity. The original 28 SHAs were designed to cover an average population of 1.5m each, roughly aligned with clinical networks. While the responsibility for securing local health services was devolved to PCTs, the SHAs provided strategic leadership to ensure the delivery of improvements in health and health services locally by PCTs and the NHS.

5.32 In 2006 the number of SHAs was reduced to ten, keeping the powers of the previous organisations but taking on responsibility for larger geographical areas.²¹

5.33 The North West SHA was created by combining the Greater Manchester SHA, Cheshire and Merseyside SHA and Cumbria and Lancashire SHA. Michael Farrar, former Chief Executive of

¹⁹ The National Health Service (Functions of Strategic Health Authorities and Primary Care Trusts and Administration Arrangements) (England) Regulations 2002.

²⁰ *Shifting the Balance of Power: The Next Steps*. Department of Health, 2002.

²¹ The Strategic Health Authorities (Establishment and Abolition) (England) Order 2006.

NW SHA, described the new SHA in his interview as *“the second largest SHA behind London”*.²² The newly created SHA had a vast geographical area to cover and a mix of both urban conurbations (primarily Greater Manchester) and large rural areas such as Cumbria. Unlike other areas of the country, the North West SHA was relatively financially stable. Mr Farrar stated that:

*“We identified at the time that financial stability was very good in the North West; it had a long track record of being able to deliver... but it had very poor to variable quality. And we had very, very poor underlying health, so we had high problems associated with lifestyle factors and diabetes, high smoking rates.”*²³

5.34 Given the relative financial stability, the SHA felt it had the freedom to focus on tackling the very real health problems within its patch. Its approach was to devolve the responsibilities for tackling problems to as close to the front line as possible. As Mr Farrar put it:

*“We tried to work very much with the National Health Service as opposed to trying to adopt a commander control model.”*²⁴

5.35 The NW SHA identified some key issues that it would need to be directly involved with in order to ensure health improvement. These quality improvements were part of the NW SHA's approach to quality. It adopted an ‘Advancing Quality initiative’, based on research from the United States. It followed an evidenced-based approach and focused on five key areas of intervention. They were:

- myocardial infarction;
- coronary bypass graft;
- congestive heart failure;
- hip and knee replacement;
- community acquired pneumonia.

5.36 Success in these areas led to further interventions by the NW SHA. One of these was maternity and paediatric services in Greater Manchester. There was no specific focus by the NW SHA on maternity services in Cumbria, although they were involved in the consultations undertaken by Cumbria PCT in the north of Cumbria, *Closer to Home*. This was in part because the NW SHA's monitoring system of health outcomes and organisational performance reported to the Board in the form of a ‘dashboard’ did not flag UHMBT as being an outlier, so there was no trigger for further inquiry.²⁵

5.37 These initiatives were well received nationally and were the catalyst for similar work around the country. However, while the focus on a small number of interventions did lead to measurable improvement in outcomes, it does not remove the overall duty of quality placed on the SHA or relieve it of its overall responsibilities to manage the system. Such work should be seen as complementary to its core function of managing the local health services on behalf of the Secretary of State.

5.38 Performance management by the NW SHA was described by Jane Cummings, the former Director of Nursing at NW SHA, as *“complex and it was difficult because it was so big”*.²⁶ To manage this complex situation, three associate directors of performance were created, covering the former SHA patches. It was the responsibility of these associate directors of performance to act as the links between the NW SHA and the local NHS organisations. They were there to build relationships with

²² Mike Farrar interview.

²³ Mike Farrar interview.

²⁴ Mike Farrar interview.

²⁵ Mike Farrar interview; Jane Cummings interview; Michael Cheshire interview.

²⁶ Jane Cummings interview.

Trusts and commissioners.²⁷ These posts also combined subject expertise – such as A&E and waiting times. A similar structure was created for patient safety, where there was subject expertise in mental health, safeguarding and general acute services. The expectation was that the PCTs would provide a great deal of local support in direct performance management. This localised and topic support was complemented by system expertise. This provided dedicated support to NHS organisations facing significant problems, such as managing winter pressures. This support would enable expert help from key individuals as well as peer support between organisations. In summarising the approach by the NW SHA, Mrs Cummings stated:

“We monitored it very closely, we provided help and support, we encouraged the PCTs to do a lot of performance management locally because that is their job, and there was only four of us, five of us in total and I, as you know, had nursing quality and subsequently commissioning to do as well.”²⁸

5.39 This view is not shared by one PCT. Sue Page, former Chief Executive of Cumbria PCT, stated:

“MRS PAGE: ... in the North East you would have a plan, you would be held to account for it, the performance management was far better. In the North West, that performance management did not exist.

PROF. MONTGOMERY: And a lot of was devolved down. We understand that. Can I –

MRS PAGE: I do not think it was devolved, I do not think it existed.”²⁹

5.40 Ms Soo-Chung stated:

“I would describe the relationship as being light touch, and in support of those comments, I think that we would meet the SHA regularly for our performance review meetings. We would flag concerns and issues with the SHA if we felt that was necessary, but I wouldn't describe it as very heavily performance management. I have worked in other SHAs where, perhaps, that approach is a little bit more to the fore, perhaps.”³⁰

5.41 There is a very different opinion about the performance management approach of the NW SHA. Given the limited resource put into performance management, it is hard to see how an effective understanding of all the organisations in the NW SHA could be gained and maintained. The reliance on PCTs to do the day-to-day performance management is clear, with interventions by the NW SHA being limited and only once a significant problem had been identified. Where there is such a heavy reliance on PCTs, there needs to be, at the very least, excellent communication between the SHA and the PCTs to ensure that issues emerging locally are picked up and actioned.

5.42 The relationship between the NW SHA and Cumbria PCT has been described by both parties as “difficult”. Such a relationship would not help with the effective performance management of the Trust. The way in which both parties handled concerns raised by the PCTs about the Foundation Trust application highlights the problems. The concerns of the PCTs were raised with the NW SHA, and with Monitor, but for reasons that are unclear, they were never followed up in writing or used to change the previous position stated by the PCTs and the NW SHA. In a system where both parties were working together to manage the system, scrutiny of the position would be expected and a joint view formed. There is no evidence of this.

²⁷ Jane Cummings interview.

²⁸ Jane Cummings interview.

²⁹ Sue Page interview.

³⁰ Janet Soo-Chung interview.

5.43 The relationship between North Lancashire PCT and the NW SHA was clearly better, but their discussions about the Trust focused solely on the Royal Lancaster Infirmary and did not cover any issues relating to maternity services.

5.44 In her interview, Mrs Page summarised the performance regime in the following way:

“MR BROOKES: I get a sense that pre-FT, you would expect a very strong performance management from the SHA, in partnership with the PCT’s commissioning responsibilities. I have a sense from what you said that that was never the culture of the SHA, never its approach compared with what you were used to.

MRS PAGE: Yes, I probably am able to say that because I came from 17 years in the North East, and you could see the comparison was just – in fact, I used to go home at night saying, ‘God, you know, how can the NHS be so different in two different bits?’ I was expecting it to be the same. I know when we have talked about, you know, mistakes and errors, I have assumed they had backed me over maternity and paediatricians because if you went to the North East, as I did, with a plan to reorganise maternity services in Northumbria, we did it. And we were held to account for it and we implemented it. And I was expecting that in the North West and it was not there. It took me 18 months to two years to realise that, actually, you know, why would you not hold people to account for implementing service change and they did not even do it in the north and the north is still not sorted because they were not held to account for the change. So it was very different.”³¹

5.45 This was also identified as a weakness by Sir David Nicholson, Chief Executive of the NHS. While the NW SHA was strong on development, it was less effective at getting to grips with difficult decisions:

“... dealing with big problems, outliers... we thought they had some problems in all of that because many of the things, when you were dealing with an organisation, which is in serious, serious trouble it is not like dealing with organisations that have got some problems. It is very different. We raised that as one issue, we were concerned about their ability to do that... [T]he second criticism was that they did not, they sometimes struggled with really tough decisions. When it became really difficult decisions, they did not want to stand by them because they put a lot of store by developing the relationships with individual organisations and some of the relationships were very productive.”³²

5.46 Throughout their existence one of the key responsibilities of the SHAs was the management of the health system. The role changed as more Foundation Trusts were established, but the overall responsibility remained. As the responsible organisation for all non-Foundation Trusts in the region, the NW SHA remained accountable for the performance of UHMBT until it became a Foundation Trust, when the responsibilities changed. The resources of SHAs were limited, capped nationally to reduce the management burden on the NHS, although we were told that there was some adjustment for the NW SHA in recognition of its size. Flexibility afforded to SHAs in terms of how they structured themselves led to different approaches in the way that they fulfilled their functions. In some areas, in both the north and south of the country, a strong performance management regime was created and this was used as a way of ensuring that NHS organisations were held to account for their performance. In other areas, a devolved model was adopted, placing more responsibility on PCTs and the local system to manage itself. Both systems had their merits and weaknesses. A strong centralist control could lead to a dependency culture and lack of innovation and responsibility being taken by organisations for their problems. Conversely, without outside scrutiny, problems and issues might not be identified or, if identified, not resolved.

³¹ Sue Page interview.

³² Sir David Nicholson interview.

5.47 In the North West, the system was devolved, limited SHA capacity was developed and the managing of the systems fell to a small number of people. Such a system can only operate successfully where there is a strong partnership between the SHA and the PCTs. This was clearly not the case in Cumbria where the relationship was not strong and where the focus was not on the entire portfolio of organisations but on specific issues in the north of the county. The systems were unlikely to be robust enough to identify early signs of problems within the Trust and, even where those signs were identified, not coherent enough to take effective action.

5.48 The need to use a Gold Command to deal with the problems once identified shows a lack of effective routine management grip and systems that could manage difficult decisions. Normal arrangements had to be over-riden in order for control to be established. This should not have been necessary in a health system that was working effectively.

5.49 In its assurance review of the NW SHA in 2009, the DH panel described it as having a “*reactive approach to addressing performance issues*”, found that it did “*not always effectively manage and deal with conflict in the system*”, and that it saw a “*reluctance to make difficult, potentially unpopular, decisions in respect of the system as a whole*”. It regarded this approach as “*unsustainable*”, although it noted that it was “*currently delivering results*”.³³

5.50 Two specific aspects of the NW SHA's work need to be examined in some detail to understand the missed opportunities to pick up the issues that have prompted the Investigation. These concern, first, the assessment by the NW SHA of whether the Trust had responded appropriately to the events of 2008. Prior to this point there had been no specific warning signs relating to the Trust, but at this point there was clearly a question to be asked as to whether there were systemic problems that required the NW SHA's attention. Second, there is the specific responsibilities of the NW SHA in relation to the oversight of midwifery through the statutory duties concerning supervision of midwives. These are considered in detail in the next two sections.

Assessing whether the Trust had responded appropriately to the events of 2008

5.51 Officers at the NW SHA were aware of a group of incidents that occurred in 2008. An early conclusion was reached that the incidents were not linked and that the Trust was addressing them. While this decision was understandable at the time, it appears never to have been directly considered by more senior staff and it does not seem to have been revisited, despite this conclusion becoming a key part of assurance to the CQC, Monitor and the DH. It is not clear, for example, that any of the directors of the NW SHA had read the Fielding Report at the time when the organisation was telling other organisations (incorrectly) that Dame Pauline Fielding had reviewed the clinical incidents and found them to be unconnected. It seems that neither Mr Farrar³⁴ nor Mrs Cummings³⁵ saw the report at the time.

5.52 Mr Farrar summarised his perceptions of the report, once he had read it, as follows, and suggested that, had he read it at the time, he might have expected a different response from the NW SHA:

“So when I read the Fielding Report, which was well after... the event, what I effectively saw was some points that said, ‘There are some things about this Trust,’ and because the things about the Trust that she said were positive related in part to the responsibility that my organisation had had around that – the two things in particular, was Pauline, did she feel that they were making progress against their untoward incident action plans? She says right up front, and I’ve no reason to believe she would have put that unless she believed

³³ NW SHA Assurance Panel Report.

³⁴ Mike Farrar interview.

³⁵ Jane Cummings interview.

it, 'Yes, I think they were.' If she'd not been sighted on it I don't think she would have necessarily commented. That was my reading.

And the second thing was that she does actually describe this issue of judgment about the connectivity of the cases and she says, 'I think that was a reasonable thing to do,' as far as I read that. Now, when you go into those things, and I've now gone into them, there are things – all kinds – so one is the journey time between units, and is there a place for the midwives to eat their food? You know, so at one level there's some things, but then there's another one which frankly would have worried me enormously. It says, 'The Trust has got no concept, or it's got a very poor concept of clinical governance.' You know, that would have – that is a very damning bit of the Fielding Report, which no-one should take any assurance from at all. Frankly, that – as I say, had I been aware of that and seen that and said, 'There's no issue with clinical governance,' I think that is something that would have triggered a different reaction from the SHA."³⁶

5.53 It is important therefore to understand how the NW SHA made its assessment of the Trust's response to the incidents, as this proved to be a very important aspect of the understanding by the wider regulatory system of the situation. The key figure in this assessment, on whom the NW SHA directors relied, was Angela Brown, Associate Director and Senior Nursing Officer at the NW SHA, who was responsible for patient safety and quality, nursing and the link with the LSA.³⁷

5.54 Ms Brown described to us how she was promptly made aware of the death of Joshua Titcombe in November 2008:³⁸

"My assistant director at that time, Linda Ward, came through and said, 'We've had a really serious incident at Morecambe Bay,' described what had happened, that the baby had been transferred – Joshua had been transferred to Newcastle.

He had developed an infection that hadn't been recognised. It had been completely missed. The chief executive had phoned to say they'd really let the family down, and was going to get an independent investigation under way. And potentially he was going to look – sort of looking at the clinical governance systems as well.

Certainly, from the first understanding of that, he was taking it very seriously. We talked through what else could possibly be done, because he was in contact with the family, which is what we would expect, but he was having it investigated and felt that the Trust had responded appropriately with that, and we would see what happened subsequently with that.

I was also aware that there had been other incidents, maternal deaths, of which some work was being done with John Ashton in Cumbria, who was looking at the maternal deaths. Linda Ward was our assistant director for patient safety at that point, because the team got larger once we built up the patient safety action team, but she was also working with the children's team, with Ann Hoskins, so was very conversant with CEMACH³⁹ work. And she was in contact and had contacted Marian Drazek, who was the lead for the LSA. And they were making contact with John about what was happening around the maternal review, so there was work that was happening."⁴⁰

³⁶ Mike Farrar interview.

³⁷ Evidence supplied to Morecambe Bay Investigation.

³⁸ Evidence supplied to Morecambe Bay Investigation.

³⁹ CEMACH: Confidential Enquiry into Maternal and Child Health.

⁴⁰ Evidence supplied to Morecambe Bay Investigation.

5.55 Ms Brown was fully aware of the question of whether there might be some link between the events:

"MS BROWN: They connected, because there appeared to be a cluster of incidents that had all happened in that sort of 2008 period. They were all different, but they'd all come together. And, having had the two maternal deaths, one was quite late in being recorded, because it had happened in the community. What John [Ashton]'s concern was 'Was that more than you would anticipate? And was there a problem?' and he was wanting to look at that.

PROF. MONTGOMERY: And what did he conclude?

MS BROWN: I've never seen the results of that. I know we discussed it later when we had a meeting when we were handing over the management of serious untoward incidents with the PCT, and that happened in the June. It was discussed about whether this was an unusual number, and part of the issue they were looking at was the CMATS⁴¹ information. And Morecambe Bay was not seen as an outlier, but that information was not broken down into unit level; it came at Trust level. It wasn't seen as the outlier, but you get into small numbers."⁴²

5.56 In April 2009, Ms Brown looked again at the issues, during Monitor's consideration of the Foundation Trust application by UHMBT. The need to look at these matters had been prompted by an enquiry from Monitor, not by the NW SHA's internal review. By this stage the Secretary of State had already approved the Trust's entry into the application process and maternity issues at the Trust had not been raised in the briefing to invite that decision.⁴³ It appears that it was only prompting by Monitor that raised the profile of the question about a potential cluster at the NW SHA. As Ms Brown had not been asked about incidents relating to the Trust prior to the NW SHA recommending the Trust be approved to apply for FT status, it seems likely that the NW SHA failed to consider material on serious incidents as part of its own consideration.⁴⁴ Ms Brown told us that, in April:

"I was asked by the team to look at these incidents. I wasn't an integral part of the Foundation Trust process, but I was asked by the team to look at them. And Tony [Halsall] gave me all the information and the reports and sort of laid them out and matched them to see what was here, really.

And from that perspective, when I looked at them, there was what happened to Joshua, which was neonatal sepsis which had not been recognised – and that was very much round systems failure. There were some individual errors in that, but a lot of that was systems failure.

Another was the stillbirth, which was [deleted]. Some of these I didn't know the names of; I've come to know them later. When that was failure to monitor and prolapsed cord, and it had been a difficult birth, a dystocia, and that was very much about an individual midwife.

The further one was the amniotic embolism, which my understanding of that – and I'm not a midwife, but my understanding of that is actually that was difficult to predict. It was a devastating event, and then the other one was the lady who had died in the community and there was possible cardiomyopathy underlying condition, which seemed different at that stage.

⁴¹ CMATS: Case Management and Activity Tracking Service.

⁴² Angela Brown interview.

⁴³ Foundation Trust Applications – from John Holden, 4 February 2009.

⁴⁴ Evidence supplied to Morecambe Bay Investigation.

*So, they'd happened in the same area, but they seemed to be from different causes, but it was sort of the clinical team. So, could those have been related? They might have been, but it wasn't immediately obvious."*⁴⁵

5.57 The NW SHA's Strategic Executive Information System (StEIS) database held limited information and it was insufficient to enable Ms Brown to answer the question raised. This clearly raises questions about the adequacy of the NW SHA's processes to oversee possible clusters of events. Consequently, she made her rapid assessment with the cooperation of the Trust's chief executive, who provided her with the Chandler, Hopps and Farrier review and also the internal root cause analysis.

"We did this by phone. How this happened was they came through to me. There's a time constraint. I pulled the information. I asked my assistant director, 'Can you get me the information on the incidents?' so I had the StEIS reports in front of me. I rang Miranda [Carter at Monitor] at that point and said, 'These are what we have. These are the incidents,' and explained the process whereby we would be performance monitoring them.

*And she was asking me two quite specific questions. And one was, 'Were there more incidents than we would expect? And were they connected?' And from the information I had in front of me, I gave her what I could at that point, but then I said, 'I need to ring you back. I need to go back to the Trust.' I then rang the Trust and Tony [Halsall] sent me the information in terms of the investigation reports."*⁴⁶

5.58 On 29 May, Ms Brown alerted Mrs Cummings to the fact that she had been unable to give Monitor all the assurances that it wanted, and summarised the information she had available. Ms Brown advised Mrs Cummings that the Trust should be able to go forward, that there were further investigations to be done and that these were in hand.⁴⁷

5.59 Two months later, on 26 June 2009, Ms Brown formally advised the CQC, on behalf of the NW SHA, that the assessment of the Trust's response to the Baby T incident was that it was "appropriately reported", "investigated thoroughly", action had "already been taken to address the urgent issues and following the management report the Trust will refresh the action plan to ensure the longer term issues of team/multidisciplinary working, are addressed and embedded". She also confirmed that the NW SHA had reviewed the HSMR (hospital standardised mortality data) and CEMACH mortality data and that the Trust was not an outlier.⁴⁸

5.60 The issues around the Foundation Trust application prompted further discussions about the need for an independent review. Ms Brown spoke to Angela Oxley, Head of Midwifery, about the need for a further examination beyond the enquiries already undertaken. Ms Brown was clear that there were gaps in the Trust's understanding of what had happened:

"DR KIRKUP: Just to be clear, this is a gap in our understanding of the past as opposed to the present. I think there are three things that might be going on. One is, 'We've looked at these things that have happened and we might not have seen anything.' So, that's one gap. There's one, 'We have some action plans in place. Do they address all the things that have come out of those reports?' And then there's, 'Have those action plans worked?' which would be more future looking.

⁴⁵ Angela Brown interview.

⁴⁶ Angela Brown interview.

⁴⁷ Evidence supplied to Morecambe Bay Investigation.

⁴⁸ Briefing for CQC re SUIs by Angela Brown, NW SHA, 26 June 2009.

MS BROWN: Yeah, 'Have the action plans worked?' would have been much further in the future. I think certainly in 2009 it was, 'We have action plans in place.' What we don't have then is the impact and outcome question. 'Will they address everything? Will we know they have worked?' That comes further. This was around, 'Have you understood everything that has happened that is important? Are you certain of that?'

Some of my experience has obviously been with the large mental-health investigation work that we had. The standard practice then was there might be an internal one, and then you have a big one that covers everything, like the work that HASCAS⁴⁹ did, that you absolutely know. And some of this was instinctive, that I just felt, 'This doesn't feel as though we've covered everything; it's really important that we do for further assurance.'

MR BROOKES: So, would you have expected that piece of work you're describing – I just want to be clear on this – to have looked at whether there was an interrelationship between those cases?

*MS BROWN: Yeah.*⁵⁰

5.61 The commissioning of the Fielding Report was prompted by this concern from Ms Brown,⁵¹ but it did not in fact address the questions that she was concerned about. She had approached Dame Pauline Fielding on the Trust's behalf saying that they were looking for someone to carry out "a table top case review to ensure that they have addressed all the issues".⁵² She told us:

"It was the Trust who then said, 'Actually, we're going to ask Pauline to look at something different, looking at the issues from all the serious untoward incidents,' and I thought, 'Actually, that makes sense.' And it was what was of value to them.

PROF. MONTGOMERY: So, your understanding of what they were commissioning was a report to investigate that group of potentially connected but possibly not connected incidents.

MS BROWN: Yes, it was – they said two things to me. One, that they wanted to pick up all the other incidents but also have a piece of work that would enable them to move forward, and that actually made sense as going to another stage to give them additional assurance, which seemed to add to that."⁵³

5.62 It was some time before anything related to the Fielding Report came to Ms Brown's attention again.

"But it came to the fore again when we went into the second Foundation Trust discussion. And I was approached again by the [NW SHA team dealing with the FT process], as to, 'would we contribute to that process and where were they with it?' and I said, 'I know there's been good progress made on the action plan, because I'd seen the emails that it was going off to the Trust; it was going off to CQC.' And I had Jackie's feedback, but I said, 'But the one thing we haven't had is the Pauline Fielding report, and I think we should get it.'

Right, so, [the NW SHA FT team] kept asking the question, 'Have we got it yet?' I said, 'No. They're looking to make sure of the detail of that and we're going to take it to Board.' So,

⁴⁹ HASCAS: Health and Social Care Advisory Service.

⁵⁰ Angela Brown interview.

⁵¹ Angela Brown interview.

⁵² Evidence supplied to Morecambe Bay Investigation.

⁵³ Angela Brown interview.

there was coming up a time constraint and I felt this sort of time constraint. And this was obviously going to create a problem, so I said, 'Well, maybe if I speak to the Trust and see if we can find an option, a way through this, in that they give us headlines and... So, that might be enough so that we can kick-start the process, but I think we do need the report in.'"⁵⁴

5.63 Ms Brown told us that, in conversations with Trust officers, she was given the impression that a response to the Fielding Report was being actively pursued, and was given no reason to support the idea that its purpose had been different from the one she had previously discussed.

"It probably would be June 2010 that I had that conversation with Jackie [Holt], but what I also had had – when we'd been working through the LSA investigation and we'd had the first report back from Yvonne Bronsky, I'd been out to see Tony [Halsall] to talk about the findings and, 'Is there anything additional that we needed to do with that?' And that would be in the May.

And he'd mentioned the Pauline Fielding report then and he said what they wanted was a report that would move them forward, and his priority was very much about getting the maternity unit functioning well and providing a good service. So, I knew it was in train.

What Jackie also told me was, 'It hasn't really told us anything that we didn't know and we weren't working on. This is work in progress, but it is about taking us forward.' So, she sent to me a document that had some of the key recommendations or what I thought were the key recommendations, as well as what was the – she'd put on that as well the terms of reference, which was the first time I'd seen the terms of reference. And on the bottom of that was also confirmation that CQC had done a visit into the unit and that everything had gone well.

*And I made some assumptions from that that CQC were sighted and this was a very joined-up piece of work, so I was getting... I felt reassurance, assurance – I think it's reassurance, really, that this was a managed process and things were going well."*⁵⁵

5.64 By this stage there was a draft, but not final, version of the report.

5.65 The Monitor approval of the UHMBT Foundation Trust application did not take place until October 2010, but it did not seem that the NW SHA took steps to draw Monitor's attention to the existence of the Fielding Report, despite Ms Brown making the FT team within the NW SHA aware of its existence.

"PROF. MONTGOMERY: Did your FT team in the SHA know that the Fielding Report had been commissioned? You clearly knew, but anybody else?

MS BROWN: Yeah, I told them, because I said... That was the whole conversation we'd had. And I said, 'We haven't got it in yet and I think we should wait.' And then it was, 'We're running out of time,' so we came up with that compromise, and that came in and looked at it. And what the recommendations – I looked at it and thought, 'These are recommendations that are about strengthening clinical governance. They will take them to the next step.'

⁵⁴ Angela Brown interview; Evidence supplied to Morecambe Bay Investigation.

⁵⁵ Angela Brown interview.

I'd already got – we had looked at some of the clinical indicators that were telling us this Trust was on an improvement process and this seemed to fit. But, as I say, the report just didn't come in and the next thing I knew they had gone to Foundation Trust status.”⁵⁶

5.66 In late October 2010, Ms Brown was provided with a hard copy of the Fielding Report by Jackie Holt, Director of Nursing at the Trust (after prompting), and was assured by her that it had been considered by the Trust Board.⁵⁷ The Investigation has been unable to identify a point at which the Trust Board considered the Report prior to 27 April 2011,⁵⁸ although it was told in interviews that it had been discussed in an un-minuted meeting.⁵⁹

MS BROWN: “I can't actually tell you when it did come in, because it didn't come in on my emails. It came in hard copy. And I think it must have come in, hard copy to me, by mid/end of October.

DR KIRKUP: 2010?

MS BROWN: Yeah. It came in to me then, because I had done all the analysis work, actually, and we'd got a very clear picture about what was and wasn't working. So, it just appeared on my desk when I'd completed all of this, and I opened it and thought, 'This has arrived at last.' I was heading to a different meeting, put it in a drawer and came back to it. And I read it as evidence for my report.

I read the first bit and saw the words 'improvement' and 'making progress'. The SULs were a legal process and have been completed, but I then assumed that Pauline had looked at them and she said that the incident process seemed to be working well and there was risk management in place, so I thought that they had made progress against their action plan.

So, I looked at that and I read the beginning and then I cherry-picked what I read. So, I went to the incident stuff; I went to the LSA stuff. And I thought, 'That seems to marry with what I've got, so that's good,' and then I looked at some of the clinical governance stuff. And I thought, 'That's got to the basis of this; this is really going to move them forward.'

And then I went through in my mind what else I knew, because I knew CQC had been in, done a visit in 2009, because after the work in 2009 the Trust were dropped until CQC did that further work. And they had gone in and tested their assurance and decided not to investigate the incidents, but were concerned about the clinical governance. And that was passed on.

And then they had been in the Trust and had given the unit the okay. And I thought, 'CQC have got the clinical governance covered. Good work by Monitor, because they must know about the governance, so this is on track and she's identified some risks.' I was, by that point, involved with some other Trusts, doing detailed work, and a lot of the stuff you lose some detail to do others – but it sat there.”⁶⁰

5.67 In preparation for a meeting with one of the families in November 2010, Ms Brown reconsidered the information she held about the Trust and confirmed her initial opinion that the SULs were unconnected. She based her conclusion partly on her reading of the Fielding Report and partly on assurances given to her by Ms Holt. Regarding the former point, Ms Brown incorrectly understood

⁵⁶ Angela Brown interview.

⁵⁷ Evidence supplied to Morecambe Bay Investigation.

⁵⁸ Trust Board Meeting, 27 April 2011.

⁵⁹ Tony Halsall interview; June Greenwell interview.

⁶⁰ Angela Brown interview.

the remit of the Report. She believed that the Fielding team had reviewed the incidents and satisfied themselves that there were not common factors.

5.68 We believe, on the basis of what we heard, that this was an honest mistake. There were a number of factors that made Ms Brown's interpretation seem plausible to her. She approached the report in the light of her expectation of its scope, informed by her involvement in its commissioning through the identification of Dame Pauline Fielding as a suitable investigator and assisting the Trust in identifying possible experts to work with her. She believed that the purpose for which the Fielding review was commissioned was to check whether there were 'holes' in the understanding of the issues that had emerged from the Trust's internal clinical reviews, the LSA report and the two external reviews that had already been received (Chandler, Hopps and Farrier; Charles Flynn). She expected that this would involve a review of the incidents as well as consideration of the actions that the Trust should take to improve its services.

5.69 There are statements in the Report that would have seemed consistent with Ms Brown's interpretation. In particular, the Executive Summary states that:

*"The review team recognised that recent adverse clinical events, whilst unconnected, at FGH had had a profound negative impact on staff morale both in Barrow and across the Trust. The apparent 'cluster' of these episodes appeared to the review team to have been coincidental rather than evidence of serious dysfunction."*⁶¹

5.70 The opening sentence of the Report also uses the adjective "unconnected" in reference to the events. However, reading carefully, it can be seen that this was the view of the Trust rather than the review team. The report explicitly stated that this question had not been considered directly.

*"This review of maternity services was commissioned by the Chief Executive with the support of the Trust Board following five unconnected serious untoward incidents (SUIs) at Furness General Hospital (FGH) during 2008. It was not the purpose of the review to reinvestigate these incidents."*⁶²

5.71 The Investigation was able to read the terms of reference in the light of the evidence given by Dame Pauline Fielding about the scope of the review and of the material that it considered. With the benefit of this it has become clear that it was inaccurate to describe the Fielding Report as providing independent confirmation that the incidents were unconnected. However, this would not have been apparent to Ms Brown when she received a copy of the terms of reference and a summary of recommendations on 30 June 2010.⁶³ The first of these terms of reference began by setting out that the review was:

"To provide further assurance that the Trust has addressed any issues highlighted by its review of maternal and infant deaths."

5.72 From the evidence now available to the Investigation Panel, it is clear that the words "its review" referred to the work already undertaken on behalf of the Trust (so that the pronoun 'its' referred to the Trust) and not to the review being commissioned from Dame Pauline Fielding. Read carefully, this is clear from the grammar of the sentence but it is easy to see how ambiguous the wording is. It would have been much clearer if reviews had been in the plural. We can understand how Ms Brown reached her interpretation of the scope of the Fielding Report. Nevertheless, it was mistaken. This misunderstanding was significant because it provided the basis on which the NW SHA advised the Department of Health, and in turn the DH advised Ministers, that the incidents at Morecambe Bay in 2008 were not connected.

⁶¹ *Review of Maternity Services in University Hospitals of Morecambe Bay NHS Trust: Final Report* (Fielding Report), 2010.

⁶² *Review of Maternity Services in University Hospitals of Morecambe Bay NHS Trust: Final Report* (Fielding Report), 2010.

⁶³ Evidence supplied to Morecambe Bay Investigation.

5.73 It is more difficult to understand why no-one other than Ms Brown examined the Fielding Report directly. There was very limited capacity at the NW SHA to oversee serious untoward incidents in the region. Mrs Cummings told us that for this reason management was devolved to PCTs. Her recollection was that this had occurred by the time of the Joshua Titcombe incident in 2008, although in fact this was handled by the NW SHA and responsibility was not transferred until September 2009.

*"They were all tragic and terrible for the families but, at the time, there was not anything obvious that linked them."*⁶⁴

5.74 It is not clear to the Panel who in the NW SHA had responsibility for overseeing responses to the concerns that SUIs raised.

5.75 Mrs Cummings told us that agreement of the terms of reference for the Fielding Report were not within her remit, although it seems to be Ms Brown, who reported to her, who was the main person from the NW SHA involved and Ms Brown briefed Mrs Cummings on progress on a number of occasions.⁶⁵ Mrs Cummings told us:

*"I do not remember seeing the report. It was not my area, although – because I didn't cover maternity, and although I did quality and SUIs and stuff were mine."*⁶⁶

5.76 Mrs Cummings had not read the Fielding Report when it became available to the NW SHA, and when asked what she might have done if she had seen it she told us:

*"I think, if I had been given that report and I would have wanted to have, I think, I would have had a wider discussion probably with the author and the panel that were involved and probably with the Trust to be – although by the time I got it they were in FT, I would have, I think, I would have challenged and queried it more."*⁶⁷

5.77 Mrs Cummings also indicated that:

"What we should have done, and what maybe one of the things I would like to see in the future is rather than just having lots of incremental reviews, where we do an internal review, followed by another review, followed by an NMC review, followed by CQC review, followed by independent review is that there is a decision taken where you are bring all of the relevant parties together and say, 'is this incident so serious that we should go straight for, you know, an external independent review or we agree that it is going to be a review that is like this?' Rather than and we absolutely and we have got everybody involved to sign off and it would be, with the benefit of hindsight, if I had been involved a bit more, I may have said, 'this is an SHA commissioned review, not a Trust commissioned review..."

*... with benefit of hindsight, at that stage, three reviews in – or four if you include the NMC review, we that would have been better to do it completely externally to the Trust."*⁶⁸

5.78 That would have ensured a degree of oversight. The Investigation Panel notes that the Fielding review was, in fact, already the third report commissioned in relation to maternity services at Furness General Hospital. The existence of the two earlier reports was known to the NW SHA when it helped to identify Dame Pauline Fielding as a suitable person to lead the third review. This might have triggered closer oversight from the NW SHA, but it did not. If there was a need for such an externally commissioned review, Mrs Cummings was clear that the NW SHA would have been the organisation

⁶⁴ Jane Cummings interview.

⁶⁵ Evidence supplied to Morecambe Bay Investigation.

⁶⁶ Jane Cummings interview.

⁶⁷ Jane Cummings interview.

⁶⁸ Jane Cummings interview.

to commission it. When asked where in the current NHS structure responsibility for this might sit, now that SHAs no longer exist, Mrs Cummings identified Quality Surveillance Groups as the most suitable place. If this is the case, it would need to be clear that this was their responsibility and that NHS organisations were obliged to cooperate with such reviews.

5.79 Turning once more to the Fielding Report, Mrs Cummings noted that it was difficult to judge from the text of the report what consideration had been given to the evidence that the incidents might be linked. The fact that no-one in the NW SHA other than Ms Brown looked directly at the report, and she did not read it closely, is especially unfortunate given that the NW SHA gave repeated assurances to outside bodies that the incidents were not connected and cited the Fielding Report as support for this view. This included statements to the regulators and the DH who used it to reassure Ministers.

5.80 Mrs Cummings's recollection was summarised as follows:

*"What I can remember is that there were three or four different investigations that looked into it and, from memory, not one of them linked any of the SUIs as being something that you – was a, you know – something that we should be particularly concerned about. Yes individually, but there was – if you look at the individual – what happened to those individual cases, nobody at the time so none of the other LSA reviews, none of NMC reviews, they did not pick up any particular issues. Alongside that, we had an organisation that had been given a 'Green' rating and a clean bill of health by CQC. They... were middle of the pack in terms of all the other indicators. There was nothing obvious to indicate that they were massively going off or that we had – that we should be really concerned."*⁶⁹

5.81 Two things seem clear from this. First, that no-one other than Ms Brown at the NW SHA ever considered directly whether the incidents were linked. Instead, the NW SHA relied on its belief that this question had been asked by others, even when matters escalated so that there was direct contact with one of the affected families and individuals were asked to brief upwards about the safety of services at the Trust. Second, assurance was taken from the CQC's assessment of the issues. Given that the CQC sought assurance from the NW SHA and based its assessment on that, this was assurance built on smoke and mirrors.

5.82 At chief executive level, Mr Farrar relied on his senior staff to exercise their professional judgment on whether the incidents were connected:

"So in essence, I relied on their approach to effectively assessing the judgments that they made about were matters systemic, or were they isolated to particular incidents, and we took different perspectives on different occasions. And I think it's absolutely critical in the context of this investigation that the grouping or the number of serious untoward incidents relating to children and childbirth and maternal deaths were scrutinised and seen as disconnected incidents. They weren't described as a cluster with a systemic underpinning – you know, that was a judgment... made inside my organisation..."

I wasn't involved in any specific judgment myself that said, 'Are we sure or not?' There was an integrated governance committee that sat and oversaw, so there was a kind of form with the process, but the original judgments, and I think it would be important to ask my clinical colleagues as to what basis. I mean I've looked at them and I've read the ombudsman's report, and I've looked at the Fielding Report, and all seem to suggest, but I think you would take a view that that was a reasonable decision to take..."

But the key thing from my perspective is it would have changed the nature of the intervention, so where we had things that were systemic, for example... when Dr Foster first produced

⁶⁹ Jane Cummings interview.

our reports on HSMRs, we had nine Trusts that were effectively in the bottom group. Now, what we did as a consequence of that was the SHA then acted, we set up a collaborative, and that collaborative improved performance with those nine Trusts."⁷⁰

5.83 Ms Brown reflected on the way in which the original assessment of information was fragmented and that no-one had checked with her the key question of whether the incidents were related.

"Well, curiously enough, nobody came back and said, 'Do you think they're linked or not linked?' because, actually, with all patient safety, you just keep finding out more and more and more – and it develops. And that's what it did continually with these cases.

I think another point that has struck me since – because we changed this later in the SHA – is that at that time we worked in parallel and we had conversations that went through, whereas in later years, when the quality was much more central to the process, is that it became integral.

And the point where I really felt, 'We've got this right,' was much later when I joined the Board that actually reviewed the Foundation Trust, because you then have a rounded conversation and everybody carries information in their head and then they share it. And you think, 'Well, if I understood that, I would have asked that.'

PROF. MONTGOMERY: When did that happen? When did that Board get created?

MS BROWN: The process started to take shape, I would think, in late 2010, because then the Department of Health were wanting more of a quality input, so our team – together, we devised a process whereby we met the Trusts... And it sort of probably took six months.

We did a visit to the Trust, and that supported Mike Cheshire [former Medical Director, NW SHA], who then needed to go to Sir Bruce Keogh, but then also answer the DH questions. And then we took another leap, which would be in 2012, which is when I joined the main group, and then we had the proper conversations about it."⁷¹

5.84 At the crucial time, however, the NW SHA gave significant assurance to the wider health system based on inadequate information and insufficient consideration at director level. Many regulatory decisions were based on this assurance.

Supervisors of midwives and Local Supervising Authority

5.85 The system for statutory supervision of midwives is unique to the profession and has been the subject of considerable scrutiny following events at Morecambe Bay. The Parliamentary and Health Service Ombudsman has upheld three complaints from families that the North West Strategic Health Authority (as Local Supervising Authority) failed to carry out its duty to perform open and effective supervisory investigations in line with relevant standards and established good practice and was guilty of maladministration. The Nursing and Midwifery Council has carried out an investigation of local arrangements and also commissioned a report on the future of supervision of midwifery. This section considers the operation of supervision in Morecambe Bay and the North West region. This was the responsibility of the NW SHA as the LSA. Matters that have emerged from our Investigation that have a bearing on wider policy issues about supervision are discussed in the section on the Nursing and Midwifery Council below. In this way, we hope to distinguish findings that relate to the poor operation of the supervision of midwifery during the matters within our terms of reference from those that relate to whether the system itself is fit for purpose.

⁷⁰ Mike Farrar interview.

⁷¹ Angela Brown interview.

5.86 Each LSA appoints a practising midwife, known as the Local Supervising Authority Midwifery Officer (LSAMO), who has responsibility for carrying out the statutory authority functions in all midwifery services, whether NHS or independent. Supervisors of midwives (SoMs) are appointed by the LSA and, crucially, they are accountable in their role to the LSAMO and not to their employer. When acting in their capacity as an SoM, they are expected to be wholly independent of their employers, investigating and reporting directly to the LSAMO when there are concerns about safe practice. In practice, this led to some confusion of roles in the circumstances of the Trust.

5.87 The Investigation interviewed the current LSAMO, Lisa Bacon, who has been in post since 2011, and Marian Drazek, the LSAMO from 1996 until 2010, as well as the previous LSA midwife, Judith Kurutac, who was in post at the North West LSA from 1999 to 2013. All of the LSA staff interviewed by the Investigation explained that the North West was the largest geographical LSA region in England.

5.88 Ms Drazek told the Panel that, considering their workload, the LSA function in the region was under-resourced. Whilst she was in post she was successful in securing approval and funding for a part-time midwife to support the function (Mrs Kurutac) and this was subsequently increased to a full-time role. In addition, the LSA office employed an administrative assistant, the LSA service manager; but even with additional resources, undertaking development work beyond the statutory requirements of the LSA was rarely possible. As the LSAMO, Ms Drazek explained that she had a statutory responsibility to advise in excess of 4,000 midwives and support 400 SoMs.⁷²

5.89 Mrs Kurutac explained that the North West LSA was responsible for supporting midwives in 32 maternity units in the region as well as those midwives who operated independently. This included some work supporting midwifery care through workshops and other development activities, but it does not seem that these were provided at Furness General Hospital.⁷³

5.90 The LSAMOs told the Investigation that, as a direct result of their limited resources, the annual audit requirement was routinely completed from information collected from a variety of sources: via an annual visit to each unit, such as the University Hospitals Morecambe Bay Trust (the Trust); from data and information supplied directly to the LSA by the Trust; reviews of records carried out by SoMs; and from information supplied directly to the LSA by SoMs at the Trust. It is unclear what value this process added.

5.91 Ms Drazek explained the way in which quality was assured:

*"The main system was the audits of supervision in the units, which were annually, every year at their request. And also, I suppose, when any documents came in from the supervisors of a particular Trust, you could tell the standards of supervision by the way the investigation has been carried out, by the way the report is written, and so on."*⁷⁴

5.92 The documentation seen by the Investigation of audits and their presentations at meetings of SoMs suggests that they were reported at a very high level and did not identify any reasons for concern about the services at the Trust. The reviews from the PHSO of particular investigations found that the second assurance referred to by Ms Drazek was ineffective, as the LSA failed to identify serious failings in the quality of investigations and never drew any inference that there might be issues about the quality of services from the poor quality of the documents.

5.93 Ms Drazek was very confident of the integrity of midwives who undertook the supervisory role and resisted suggestions that there might be conflicts of interests.

⁷² Marian Drazek interview.

⁷³ Judith Kurutac interview.

⁷⁴ Marian Drazek interview.

“PROF. FORSYTH: Do you think this works well, because it does seem a bit, to use the word, incestuous, but midwives who are supervisors, have been working in the same unit, where there’s been a problem with a midwife, for them to then investigate. Do you think they can remain objective in that position?”

MS DRAZEK: I think 99% of the time they’re very objective, because they do see their role as separate from being an employee, and a lot of time is spent when they’re educated and trained as supervisors to make sure they understand. But there can be [inaudible] but they need to realise that it’s a strict employment and their role as supervisory midwives and clearly, any supervisor that wasn’t confident with doing that, wasn’t certain with the investigation, could say, ‘I don’t feel right to take it on’ and somebody else would do the investigation.

PROF. FORSYTH: So you feel confident that there is not a situation where a supervisor would be reluctant to make recommendations that might jeopardise midwives, as fellow midwives continuing employment within the unit, for example?

MS DRAZEK: No, because their main aim is to protect mothers and babies, and therefore if there’s any suggestion that a midwife’s practising poorly, or making mistakes, or needs some updating, or is dangerous and should be considered for removal from the register, then obviously that is there primarily for supervisor midwives to identify that and come up with a plan to address it.”⁷⁵

5.94 In respect of the Trust, this confidence was misplaced. Ms Drazek explained at her interview that supervision at the Trust was not as dynamic as it could have been, and was probably not adequately resourced by the Trust and that, retrospectively, there were incidents that the LSA felt it should have been notified about but was not. She felt that the investigations carried out by SoMs at the Trust were very slow in getting started, possibly due to the lack of resources, and that the midwives were not given adequate time to undertake the investigations. However, Ms Drazek did feel that the reports were up to the required standard when they reached her.

5.95 In Ms Drazek’s view, supervision was not high on the agenda at the Trust, and some trends and consistent failings were not raised by the SoMs with the LSA. It was felt that this was due to the role of supervision not being fully understood by key individuals at the Trust. The LSAMO confirmed this by giving the example of the Trust’s former chief executive, Tony Halsall, asking for all internal investigations to stop because of the ongoing external investigations. This caused unease for SoMs and midwives at the Trust as the LSAMO was advising SoMs that their investigations should continue.⁷⁶ It also meant that a statutory requirement for supervisory investigation was being obstructed by the actions of the chief executive of the Trust. The PHSO noted that the NW SHA stated that the supervisors “*confused their responsibilities as senior midwives to the Head of Midwifery and accountability to the LSA for delivering the local elements of the LSA function*”.⁷⁷

5.96 From the interviews with midwives, SoMs and the current head of midwifery at the Trust, the Investigation established that midwives had their annual reviews and that all had appointed supervisors. The impression gained by the Panel was that annual reviews undertaken by SoMs were a formality rather than in the spirit of how the LSA anticipated these annual reviews were to be managed.

⁷⁵ Marian Drazek interview.

⁷⁶ Marian Drazek interview.

⁷⁷ Midwifery Supervision and Regulation – A report by the Health Service Ombudsman of an investigation into a complaint from Ms Q and Mr R about the North West Strategic Health Authority; Midwifery Supervision and Regulation – A report by the Health Service Ombudsman of an investigation into a complaint from Mr L about the North West Strategic Health Authority.

5.97 However, one midwife (Joan Moorby), who had previously undertaken the training but had never practised as an SoM, felt that supervision was not available when she needed it. There were band 6 midwives at Furness General Hospital who had undertaken the SoM training. However, there was a view that this was more of a 'token gesture' as they did not feel that they had a voice within the group of SoMs at the unit. They considered this disappointing as the SoM was not a hierarchical role or responsibility.⁷⁸ This view was confirmed by another SoM (Kathryn Hampson), who felt that there was obstruction by the senior SoMs and midwives at the unit who had management roles, which created a blurred understanding of the role and responsibility of an SoM.⁷⁹

5.98 Ms Drazek told the Panel that, in the latter years that the Investigation is reviewing, there were complaints from some midwives at the Trust about the SoMs. In her view, the complaints were about incidents that exposed a bullying culture within the unit.⁸⁰

5.99 The operation of supervision of midwifery at the Trust, and its oversight by the NW SHA, was examined by both the NMC and the PHSO. In July 2011 the NMC reported:

*"We were concerned to note a culture at Furness General Hospital Maternity Unit of supporting midwives and past midwifery practice, rather than focussing on what needs to be done to fulfil the primary purpose of supervision which is protecting mothers and babies. This culture was not found at Kendal maternity [sic] led unit or at Royal Lancaster Infirmary. Neither was this evident in the attitudes of senior midwives who work across the sites."*⁸¹

5.100 The NMC reviewed progress on the action plan to address these, and other flaws identified in the supervision system, in December 2011 but was not satisfied that monitoring could be returned to the LSA until September 2012.⁸²

5.101 The PHSO initially declined to investigate complaints about the LSA's handling of families' concerns, but subsequently examined three cases. It found that the individual investigations that it scrutinised were fundamentally flawed. In one case, two supervisors reviewed records and found that there were no midwifery concerns that would warrant a supervisory investigation despite the fact that the care involved a high-risk mother with diabetes, who was having her labour induced, where the midwife had failed to monitor the baby's heart beat continuously. The LSA review failed to carry out a thorough investigation of the decision not to undertake a supervisory investigation. It took an investigation by the PHSO to establish that cardiotocography (CTG) monitoring was never actually started, information that was crucial in responding to the family's complaint.⁸³

5.102 In a second case, there were also failures of monitoring. In this case, there was an LSA investigation but it did not start for seven months when it should have been completed within 20 days. When the woman complained to the PHSO and the NW SHA agreed to investigate under NHS complaints procedures, it still took over a year for them to respond to the family. There were also a number of other failures. The death was not reported to the LSAMO as it should have been. The reports lacked detail and were not thorough. There was a failure to examine whether similarities with an earlier case warranted further investigation. *"An assumption was made that the length of time that*

⁷⁸ Joan Moorby interview.

⁷⁹ Kathryn Hampson interview.

⁸⁰ Marian Drazek interview.

⁸¹ *Review of University Hospitals of Morecambe Bay NHS Foundation Trust*. NMC, 2011.

⁸² *Review of University Hospitals of Morecambe Bay NHS Foundation Trust*. NMC, 2012.

⁸³ *Midwifery Supervision and Regulation – A report by the Health Service Ombudsman of an investigation into a complaint from Mr M about the North West Strategic Health Authority*.

*had passed was sufficient to conclude that there was no pattern and that training would be enough.*⁸⁴ When the LSAMO became involved she did not explore the issues directly but asked whether the other supervisors had agreed with the conclusion that supervised practice was unnecessary.⁸⁵ In effect the LSAMO should have provided external scrutiny, but in fact merely ensured that there was a consistent view. This would have served to obscure and reinforce poor practice not challenge it. The PHSO found that this amounted to maladministration. It also found that *“for almost two years a midwife with potentially unsafe practice was not appropriately supervised because the LSA had failed to identify that her practice in Baby Q’s case was not in line with the standards required by the NMC”*.⁸⁶

5.103 A third PHSO investigation identified a further series of flaws. There was a series of inappropriate assumptions made, which served to protect midwives from scrutiny. One was the assumption that a baby’s temperature was as the midwives described it, despite the lack of records. Linked to this was an assumption that the lack of documentation of observations constituted *“poor practice”*, *“but did not reflect the care given”*. The PHSO expert midwifery advisor noted that assumptions should not have been made about the standard of care in the absence of records.⁸⁷ The effect of the supervisor making these assumptions was that the supervisory investigation did not hold the midwife to account or protect the public in any meaningful way. The PHSO noted that:

*“Midwife A concluded that she was ‘satisfied that this midwife provided a high standard of care despite the lack of appropriate evidence’... this was an assumption and Midwife A should have explained how she reached this conclusion... . Again Midwife A made an assumption about the midwife’s fitness to practise... she believed that if this midwife had found any deviations from the normal in Baby L’s condition she would have asked for assistance.”*⁸⁸

5.104 Midwife A assumed what she was supposed to be investigating. The findings of this investigation in relation to poor relationships between professionals suggest that the assumption that the midwife would have referred to another professional group was deeply flawed. This has been a consistent finding in the series of investigations into care at the Trust. At the very least, the supervisory investigation was a missed opportunity to scrutinise serious problems in midwifery practice at the hospital. It is entirely understandable that families got the impression that supervision of midwifery served to protect midwives rather than hold them to account. This was exacerbated by the blurring of roles, whereby the supervisor was also the risk manager for the service. It is reasonable to conclude that the way in which supervision operated served to hide these issues from the LSAMO, who exercised insufficiently close oversight to pick them up.

5.105 A second significant feature that the third PHSO report identified was the demarcation of responsibilities so that the supervisory jurisdiction could not examine the care given holistically, always stopping short when care by staff of another professional group became relevant. It is hard to see how the circumstances of the case in question could ever have been properly considered without consideration of the respective responsibilities of the different professional members of the team and the relationship between them.

⁸⁴ Midwifery Supervision and Regulation – A report by the Health Service Ombudsman of an investigation into a complaint from Ms Q and Mr R about the North West Strategic Health Authority.

⁸⁵ Midwifery Supervision and Regulation – A report by the Health Service Ombudsman of an investigation into a complaint from Ms Q and Mr R about the North West Strategic Health Authority.

⁸⁶ Midwifery Supervision and Regulation – A report by the Health Service Ombudsman of an investigation into a complaint from Ms Q and Mr R about the North West Strategic Health Authority.

⁸⁷ Midwifery Supervision and Regulation – A report by the Health Service Ombudsman of an investigation into a complaint from Mr L about the North West Strategic Health Authority.

⁸⁸ Midwifery Supervision and Regulation – A report by the Health Service Ombudsman of an investigation into a complaint from Mr L about the North West Strategic Health Authority.

5.106 In summary, this suggests that supervision of midwifery in relation to staff working at the Trust was dysfunctional and poorly overseen by the LSA. When Ms Bacon, the current LSAMO, took up her post at the LSA, she was not made directly aware of the issues with midwives at the Trust. She established greater information and detail about the incidents that had occurred at the midwifery unit at Furness General Hospital through discussions with colleagues elsewhere within the former NW SHA.

5.107 Ms Bacon advised the Panel that there was now a greater awareness and understanding of the role and responsibility of midwifery supervision than there was in 2008 when a number of incidents occurred within the midwifery unit at Furness General Hospital.⁸⁹

5.108 The Panel was advised that there is now greater guidance available for midwives and SoMs and, importantly, there is a national database available for LSAs to record all ongoing investigations enabling these to be tracked and chased up as appropriate. In addition there is mandatory training provided to all SoMs as part of the supervisor's course on how to undertake an effective investigation.

The Care Quality Commission

5.109 The Care Quality Commission (CQC) regulates quality in the NHS. Organisations cannot provide health services unless they are registered with the Commission and it monitors the quality of services, with powers of investigation and the ability to impose conditions and require compliance with established standards of care. In relation to UHMBT, the former chief executive of the CQC, Cynthia Bower, identified three particular 'missed opportunities' from the work of the Commission: the non-investigation of a referral in 2009 by the central team inherited from its predecessor the Healthcare Commission; registration of the Trust in 2010 without conditions; and not following through on failure to comply after a warning by including maternity in an inquiry into systemic failings in the Trust in 2012. This section examines those three decisions.

May 2009: The Care Quality Commission declines to undertake an investigation into University Hospitals Morecambe Bay Trust

5.110 In 2009 the CQC was in a transitional phase and still had in place a national investigation team that was a legacy from its predecessor, the Healthcare Commission. The Trust was not flagged as requiring attention at the point of transition between the Healthcare Commission to the CQC.⁹⁰ This was a surprise to Ms Brown at the NW SHA who told us that, in her conversations with the Healthcare Commission, the Trust featured as a significant area of concern.⁹¹

5.111 However, in May 2009 Alan Jefferson, North West Regional Director for the CQC, contacted Amanda Sherlock, the CQC's Director of Operations, to see whether she had been made aware of a series of serious incidents. They agreed that this should be referred to the central CQC investigations team, which was done by Julia Denham, Area Manager for Lancashire and Cumbria, on Wednesday 20 May and referred on to Sarah Seaholme, Investigations Manager for the CQC, for consideration on Friday 22 May 2009.⁹²

5.112 The summary of the issues on the CQC's referral form described it as related to a single specific tragedy: "*Death of a baby due to staff shortages and negligence. Loss of medical records*". This may have created some confusion over whether the referral to the investigation team was primarily a response to the communication from the father to the CQC, received on 18 May 2009

⁸⁹ Lisa Bacon interview.

⁹⁰ Alan Jefferson interview; Amanda Sherlock 1st interview.

⁹¹ Angela Brown interview.

⁹² Sarah Seaholme interview; email from Christine Braithwaite to Sarah Seaholme, 22 May 2009.

and passed to the regional team for response,⁹³ or to a request from Monitor for the CQC to advise on the level of concern that it had over the Trust.⁹⁴

5.113 The referral was supported by the report into the particular incident,⁹⁵ and some emails from Monitor, which detailed a number of SULs, so Ms Seaholme knew that the Trust had 12 SULs and that there were 5 in particular that were connected to maternity. She was also aware of two other reviews: an LSA investigation into the midwifery team and a management review.⁹⁶ In contrast to the summary on the referral form, the covering email from the regional team drew attention to the fact that Monitor had recently informed the CQC of 12 SULs, 5 relating to maternity, and also pointed out that there seemed to be parallels between the issues identified in the review and the weaknesses identified in the recently submitted UHMBT self-assessment.⁹⁷

5.114 Ms Seaholme decided that it did not meet the criteria for an investigation at the initial screening stage, when the decision was for her alone.⁹⁸ She told us that:

*"[The] criteria for investigation was that... there needs to be a risk to the safety of patients, and that would be a higher number of unexplained deaths, serious harm or abuse, that there'd be a pattern of adverse events, and that would be within an area, or potentially serious failures in teams that had been highlighted."*⁹⁹

5.115 Ms Seaholme took into account the fact that the CQC's mortality outliers surveillance system had not flagged up an unexpected number of deaths. She had the list of SULs with the main causes of death, but did not see the root cause analyses that had been undertaken. In the light of the inadequacy of those root cause analyses, this would not have added significantly to the information that she had available, but it seems to us inappropriate for her to take a decision without seeing them. She did not seek clinical advice from a maternity specialist. She also took into account the fact that the Trust had taken action with regards to this SUL, and that there was a number of external reviews happening with recommendations. This gave her confidence that the Trust was being responsive to the concerns and that it was looking to learn from the SULs.¹⁰⁰ In an email to Ms Denham she also expressed the view that the number of SULs was not high and that two of the deaths were unavoidable.

5.116 This was disappointing to Ms Denham, although it addressed the issues she thought needed to be examined:

*"Is five in maternity unusual? And ultimately, of course, we were trying to seek that advice from the Strategic Health Authority who monitored the serious untoward incidents and we felt would have a far better handle on that than we would. So yes, it kind of felt to me that there are other things there, maybe it does indicate that so would the investigations team take it on. I've got to be honest. I was disappointed. Yes, I was disappointed."*¹⁰¹

5.117 She also told us that she had followed up with a telephone conversation:

⁹³ Email from Enquiries to Julia Denham, 19 May 2009.

⁹⁴ Julia Denham interview.

⁹⁵ *External Investigation into Serious Untoward Incident At Furness General Hospital: Baby Joshua Titcombe* (Chandler, Hopps and Farrier), 2009.

⁹⁶ Charles Flynn interview; Sarah Seaholme interview.

⁹⁷ Email from Julia Denham, 20 May 2009.

⁹⁸ Sarah Seaholme interview; Amanda Sherlock interviews.

⁹⁹ Sarah Seaholme interview.

¹⁰⁰ Sarah Seaholme interview.

¹⁰¹ Julia Denham interview.

*"Sarah indicated that it – I don't think it indicated systemic failure. I think that was part of the reasoning and also because the Ombudsmen had already had a referral and were therefore also looking at it, that there was nothing further to be gained from us also picking that up."*¹⁰²

5.118 Ms Seaholme summarised to us her reasons for not accepting the referral, even to progress to the stage at which it would get more detailed consideration, in the following terms:

*"... that there was action by the Trust in order to address the issues, the parliamentary health ombudsman was reviewing the case, and that was being – that was in progress. It didn't appear on the mortality outlier surveillance data as a high – as an outlier, for women or the babies, and on review of the incidents I didn't feel that there was a pattern there. If there was a pattern I would have accepted it as initial consideration into the investigations team."*¹⁰³

5.119 With hindsight, she regretted the fact that she had not reached a different conclusion, but told us that at the time she had followed the strict procedures that were in place:

*"On reflection, I really do feel that if I'd accepted the case it would have – there would have been more focus on the Trust and that maternity. I'm really sorry that I didn't make that decision at that time really."*¹⁰⁴

5.120 She also explained what would have happened if she had accepted the referral and moved on to more detailed consideration:

"What happens then is that it's allocated to an investigations officer and we dig a little bit deeper into what the concerns are. So we would initially do a documentation request to the Trust and ask for the SULs, to ask for some key maternity documents, particularly looking at the governance arrangements at the Trust and how they learn from things.

*We would quite often do a visit to the Trust, which would be an announced visit, which would be with a – experts with us, to the team. And within that we would look – we'd speak to key people in the maternity unit as well as having a walk around and talking to staff in the unit to, kind of, like, get a feel of how things were working in the unit. From then we would decide whether we felt that the Trust was doing enough action or not. We would make a decision about whether we'd give recommendations, or if we felt that there were still lots of concerns at the Trust then we would request an investigation, a full investigation."*¹⁰⁵

5.121 Ms Seaholme referred the matter back to the region on 27 May 2009 expecting that there would be further monitoring activity, and in the belief that an additional review would be counter-productive.

*"What I advised the region was that they should follow up with the Trust the outcome of the SULs and the action plan, to make sure it was implemented, and also follow up with the Parliamentary Health Ombudsman with regards to their findings. And as a result of that they could always come back to the investigation if they thought that the concerns weren't being – the improvements weren't being made or it wasn't being managed well. But I did feel that there was a lot of activity that was happened already with regards to the maternity that it didn't need somebody else coming in to do another, kind of, like, review."*¹⁰⁶

¹⁰² Julia Denham interview.

¹⁰³ Sarah Seaholme interview.

¹⁰⁴ Sarah Seaholme interview.

¹⁰⁵ Sarah Seaholme interview.

¹⁰⁶ Sarah Seaholme interview.

5.122 This was a decision taken after a brief period of consideration because the CQC was being asked for an urgent response by Monitor as to whether it intended to undertake an investigation. At 11.28am on 26 May, less than three working days after the receipt of the referral, Ms Seaholme was sent an email headed 'FW Morecombe (sic) Bay – URGENT' reminding her that Monitor was seeking information urgently. She responded five minutes later to confirm that, although she was on a visit that afternoon, she would respond in time for a response to be sent to Monitor before 10am the following morning.¹⁰⁷ She responded to her manager at 7.41am on 27 May to say that she did not think the case (described as relating to a single issue, "*the tragic death of Joshua Titcombe*") met the criteria, and advising her to "*contact the PHSO and request to be updated on the outcome of the case*". Dawn Hodgkins, CQC Assessor, communicated this to the CQC regional team and recommended further action: a "*conversation with the SHA regarding the external review, the number of SULs, stating that she still did not know whether the number was excessive or if the SHA was concerned*".¹⁰⁸

5.123 There was a clear opportunity here for the CQC to have taken further steps to examine whether there were fundamental and systemic problems in the maternity services at the Trust. The referral was rejected at the screening stage, mainly on the basis that the maternity cases were not related. This was a decision taken on minimal information – the absence of a flag from mortality surveillance and a list of the causes of death – by a non-maternity specialist without expert clinical advice. It was taken in a context in which there was a degree of perceived urgency because of the need for Monitor to consider the implications of the CQC decision in relation to the application from UHMBT for Foundation Trust status. It might therefore be considered that the short period of consideration that was given to the matter was due to this context. However, if it were not for the actions of Monitor, the evidence suggests that the CQC would not have been aware of any other SULs relating to maternity services when it considered its response to questions raised by the father over the death of Joshua Titcombe. The Foundation Trust application process was thus the first prompt for external agencies to consider the possibility of systemic issues in relation to the quality of care in maternity services. It is also clear that the CQC's decision not to investigate was influenced by the perception that the PHSO was also considering the Joshua Titcombe case and that there was nothing to be gained from an additional review from the CQC. We shall set out later that there was a mirror to this pattern at the PHSO, where its decision not to investigate was taken in the context of an expectation that the CQC was considering the situation and that there was nothing to be gained from an additional review by the PHSO.

5.124 When Mr Jefferson wrote to Joshua's father, James Titcombe, in December 2009, he stressed the fact that the CQC no longer had jurisdiction to investigate complaints about individual issues, as the Healthcare Commission had under the previous legislation.¹⁰⁹ This understanding was repeated to us in interviews.¹¹⁰ However, this account is not easy to reconcile with the contemporary documentary evidence, as summarised above. There was considerable confusion as to whether the decision not to investigate was based on the fact that the CQC no longer had jurisdiction to consider such cases, whether it thought that it could only investigate systemic problems and that the perceived lack of connections between the incidents meant that it did not meet its criteria, or that a judgment had been made that the issues were insufficiently serious to warrant investigation. As the history of the regulatory interventions unfolded, the view seemed to take hold that the CQC had considered the issue and did not feel it necessary to investigate. This was used to give assurance

¹⁰⁷ Email from Dawn Hodgkins to Sarah Seaholme, 26 May 2009; email from Sarah Seaholme to Dawn Hodgkins, 26 May 2009.

¹⁰⁸ Email from Sarah Seaholme to Dawn Hodgkins, 27 May 2009.

¹⁰⁹ Letter to James Titcombe from Alan Jefferson, 16 December 2009.

¹¹⁰ Alan Jefferson interview.

that the problems had been addressed. With the benefit of hindsight it is clear that such assurance was false and based on a misunderstanding of what had been considered.

April 2010: The Care Quality Commission registration of University Hospitals Morecambe Bay Trust without conditions

5.125 The chief executive of the CQC, Ms Bower, told us that she believed that it had been a mistake to register UHMBT without conditions. There was no particular pressure to avoid registering Trusts with conditions and it had been anticipated that up to 10% of Trusts would have been given conditional registration (although in the event it was a little less than that). From the CQC perspective the main consequence of registration with conditions would have been an early inspection. Given that this occurred independently of any condition, it is not clear that the CQC would have behaved differently in the months after registration. However, the Trust and other bodies took assurance from the 'clean bill of health'. Thus Ms Bower said to us:

*"... it was a mistake... because we sent the wrong message into the system that everything in the Trust was alright."*¹¹¹

5.126 This was corroborated when Mr Farrar, Chief Executive of the NW SHA, took the messages coming from the CQC to indicate that there were no systemic concerns:

*"My view is that they were not telling me that Morecambe Bay had systemic problems, so they chose to license them in April without condition."*¹¹²

5.127 On 29 July 2009, Mr Jefferson confirmed to Miranda Carter, Assessment Director at Monitor, that the Trust continued to be rated as a "serious concern – Red". His letter also indicated that the CQC's concerns about the SUIs had decreased, following conversations with the NW SHA and the PCT that suggested that the incidents did not have common causes. The note of a subsequent telephone call recorded that "on registration it is... likely there will be some 'requirements' attached. These will be less formal than conditions... . Morecambe Bay is probably the Trust which most concerns Alan in the region." The note of the conversation indicates that the CQC perception was that "inconsistencies in practice may be present for other specialities, not just maternity". This assessment was based on the problems identified by the Flynn Report.

5.128 It also seemed clear that the view that the incidents were unconnected became settled in the minds of those at the CQC. In August 2009, Mr Jefferson sent an email to Ms Sherlock that said:

"As the most recent North West Risk Panel concluded, many of the uncertainties have now been resolved. The seriously untoward incident reports turned out to have no common thread. The SBA [Standards Based Assessment] inspection has revealed only minor concerns. The fact that the Trust has unequivocally accepted that it messed up with the Baby T case renders the outcome of the Ombudsman inquiry fairly irrelevant, though, for the record, we've not heard whether or not the Ombudsman intends to pursue the complaint. The recent Risk Panel decision to reduce the risk from 'Red' to 'Amber' was appropriate in the circumstances... . What we are left with is an external evaluation that says that communication between maternity services in the Trust's three sites is inadequate; that midwifery, obstetrics and paediatrics do not communicate properly and that there is a unidisciplinary approach to issues that should be dealt with in a multidisciplinary framework. The external report also says that, notwithstanding the significant screw-up in recording the events surrounding Baby T's care and the Trust's consequent decision to purchase a new recording system, insufficient priority has been given to training staff to use it. We have

¹¹¹ Cynthia Bower interview.

¹¹² Mike Farrar interview.

very recently received an action plan from the Trust that tells us what they intend to do to rectify matters.”¹¹³

5.129 By the time the decision about registration approached, the view in the CQC was that the position had altered. Ms Denham told us:

“It had changed, it had changed because we had the reports from the LSA, Charles Flynn, birth rate plus and we had the information from the Trust itself in terms of what action it was taking and from the strategic health authority in terms of its view of the progress that the Trust was making. And so by the time that we were considering the actual registration decision, the assessment record that the – that [an assessor, CQC] completed identified for me one significant area that wasn’t resolved which was falling out of the birth rate plus report, they’d made recommendations about staffing.”¹¹⁴

5.130 Although the CQC did not receive a copy of the Fielding Report until April 2011, the existence of the review was known to the CQC in January 2010,¹¹⁵ and there was already awareness in the CQC of management issues from May 2009 when the national investigation team was asked to consider the referral.¹¹⁶ It cannot be said that the decision to register the Trust was taken without awareness of those issues. The ‘Red’ rating was prompted by the receipt of the Flynn Report, while the provision of the Trust’s action plan, in combination with the perception that the 2008 incidents were unconnected, was sufficient to reduce it to ‘Amber’ on 13 August 2009.¹¹⁷ The CQC took assurance from the Trust’s recognition of the need to change, evidenced by its acceptance that the care it had given was not good enough and the commissioning of a review. It expected that the Trust would see its action plans through, but had no direct evidence that it had in fact done so.

5.131 Ms Sherlock told us that the CQC’s decision that no conditions were required on the registration of the Trust relied in part on the perception that the NW SHA and the PHSO were content that the problems were being resolved.

“DR KIRKUP: Was there any implication for the CQC in the fact that the PHSO had decided not to investigate?”

MS SHERLOCK: There was. It added to our evidence base around consideration of Morecambe Bay’s application for registration under the Health and Social Care Act, that the problems that had been evident in 2008, when Joshua had died, had been resolved or were actively being resolved to the satisfaction of the Strategic Health Authority, and the CQC, taking that information from the PHSO’s decision, together with assurances from the Trust itself and the SHA, was one of the determinants in not registering the organisation with conditions.”¹¹⁸

She confirmed that her interpretation of the PHSO’s decision was that the matter was regarded as resolved.¹¹⁹

5.132 It is clear from the correspondence between the PHSO and Mr Titcombe that the PHSO decision not to investigate matters relating to the general quality of care was based on the understanding that there were outstanding actions to be taken by the Trust, but that the Trust had

¹¹³ Email from Amanda Sherlock to Miranda Carter, 24 August 2009.

¹¹⁴ Julia Denham interview.

¹¹⁵ Internal CQC review into regulatory actions at UHMB – 2011.

¹¹⁶ Letter from Alan Jefferson to Miranda Carter, 29 July 2009.

¹¹⁷ Alan Jefferson interview; letter to Miranda Carter from Alan Jefferson, 29 July 2009; call with Alan Jefferson on 31 July 2009.

¹¹⁸ Amanda Sherlock 2nd interview.

¹¹⁹ Amanda Sherlock 2nd interview.

taken the concerns seriously and drawn up an action plan that would be “a robust way of addressing the failings in Joshua Titcombe’s care”. The Ombudsman was satisfied that the CQC was exercising “close oversight” of the Trust’s delivery of the required changes.¹²⁰ It was therefore incorrect to draw the conclusion that the substance of the matter was regarded as resolved. At best, the solutions had been identified and progress started on implementing them. Both Monitor and the CQC were informed that the PHSO’s view was that “it is now for the CQC to monitor the Trust’s compliance with its action plan and to ensure that services are improved”.¹²¹ It was therefore clear that the issues within the Trust were not thought by the PHSO to be resolved, but that an investigation by the Ombudsman’s Office would be “unlikely to achieve any more in this area” than was already in place and being monitored.¹²²

5.133 Similarly, the CQC considered the NW SHA’s lack of concern as evidence to support registration without conditions and the NW SHA took this to be evidence that the CQC did not believe there were major issues. To a substantial extent, this process seems to have been one of mutual reinforcement of views rather than consideration of direct evidence. It led to a false sense of assurance. Mr Farrar’s expectation was that the CQC was a source of assurance to him, not a body that merely re-presented the NW SHA’s views:

“So I think the problem I have is that the CQC is supposed to be an external inspectorate that goes in and looks at these things independently, and it should have been signalling to me, or to the SHA.”¹²³

He continued:

“The assurance process had to be that we gave all the information we could about that Trust to CQC. CQC decided whether that information met their own. They had the opportunity to go into the Trust. They had the opportunity to test our assumptions against anybody else’s assumptions. They had powers that we didn’t. We were not an inspectorate. You know, what I expect of the people in the SHA, and I’ve no reason to believe they didn’t do this, was to give CQC all the information that they had, hard and soft about the Trust. And then CQC legally had the responsibility to take action.

And if CQC concluded that they weren’t doing their job properly and they should be licensed with conditions, it then came back to us to make sure that they were going to improve. And that’s the way it should have worked.”¹²⁴

5.134 A similar picture was conveyed in the papers to the SHA’s integrated governance committee, as Dr Ruth Hussey, former Regional Director for Public Health North West, put it:

“I’ve questioned myself severely in terms of the reports to the integrated governance committee in terms of the reports into the tragic case of Mr Titcombe and reading through the account, you know, obviously knowing what I know now, what I have read since then, I took it on trust and I think it came again at the end of 2010 it was reported as people were satisfied and there had been an investigation and CQC had been involved. So there were points where, you know, again in hindsight you might have wanted to, ‘Are you sure? Have you looked further’, you know, and so on. But if you read the material it’s very much it’s a resolved issue. Matters have been looked at; other people are looking at it.”¹²⁵

¹²⁰ Letter from Ann Abraham to James Titcombe, 3 February 2010.

¹²¹ Letters from Kathryn Hudson to Alan Jefferson and Miranda Carter, February 2010.

¹²² Letter to James Titcombe from Ann Abraham, 3 February 2010.

¹²³ Mike Farrar interview.

¹²⁴ Mike Farrar interview.

¹²⁵ Ruth Hussey interview.

5.135 Assurance was taken from the fact that other bodies were assured. Ms Bower, Chief Executive of the CQC, told us that:

“... looking back and trying to piece together what was happening, there seemed to be assurance that the regional team were taking from the SHA, and from the legacy staff who’d come in from the Healthcare Commission, that matters were in hand.”¹²⁶

And:

“... I’ve done is gone back and talked to people after the event and, you know, the only thing that I got back was always that ‘We believed that in this period the Trust were doing the right things and the SHA had oversight of this’.”¹²⁷

And:

“As far as I could see, the SHA were the ones that the assurance was coming from, was that the issues had been dealt with or they were supporting the Trust in saying that those issues had been dealt with.”¹²⁸

5.136 In summary, therefore, each of the three organisations took false assurance from what they perceived the others to have done or be doing. The CQC thought that the NW SHA had oversight of the issues and that it had noted that it had confirmed the view that they were not linked. It interpreted the PHSO’s decision not to investigate as an indication that the problems were resolved, while the PHSO was expecting that continuing close scrutiny by the CQC would be a more effective way of finding out if this was the case than a PHSO investigation. The chief executive of the NW SHA believed that its role was to provide information to the CQC so that the CQC could assess what the quality issues were and that the registration without conditions was a signal that there was nothing requiring follow-up by the NW SHA. These assumptions meant that there was a widespread belief in the system that closer scrutiny on the issues had been, and was being, taken than was in fact the case.

2012: The Care Quality Commission investigation of emergency care systems at University Hospitals of Morecambe Bay NHS Foundation Trust

5.137 In 2011 the CQC position changed significantly. A planned inspection of the Trust’s services in April 2011 found a number of areas of non-compliance against the essential standards, and as per the risk management process and operations, it was escalated by the region to the national risk register.¹²⁹ This was followed up in July with an inspection into maternity services. Ms Sherlock described her thinking in these terms:

“There’s an email actually between myself and CQC’s head of legal services at that time where I asked him whether CQC still had the power of special measures because I was seriously concerned after the July inspection of maternity services that this was not just a service that had for some time had failings but appeared to be deteriorating even from a quality and safety base. I wasn’t convinced that using the compliance powers was going to be effective in making short-term change. And the other area of concern that I had is that there are quite strict regulations around what you can say in the public domain when you’re using your section 60 registration powers. So I asked for advice from our head of legal services. He came back to me and said no, that CQC had lost in the 2008 legislation the powers to invoke special measures but we did have the section 48 powers.”

¹²⁶ Cynthia Bower interview.

¹²⁷ Cynthia Bower interview.

¹²⁸ Cynthia Bower interview.

¹²⁹ Amanda Sherlock 1st interview.

So through August [2011] the region were preparing and issued warning notices, further warning notices under the section 60 registration powers on the maternity unit. I was discussing with the regional director, colleagues in CQC at the Department of Health and in particular with Monitor about what and whether we would do a section 48 investigation. The issuing of the warning notices in late August, I think it was, triggered Monitor to increase their risk rating on UHMB and to formally consider intervention using their powers. So these discussions were taking place daily.”¹³⁰

5.138 From the perspective of the local health economy, this was a dramatic change in attitude. Mike Bewick, former Medical Director at Cumbria PCT, described it as a complete u-turn, which prompted re-examination of the health economy’s understanding of the situation:

“... after what can only be described as a complete volte face on behalf of the CQC, having found a competent and, in Peter Dyer’s words, exemplary maternity unit not long over a year before, it then found great problems in the maternity unit. And this was backed up by the Nursing and Midwifery Council’s visit.

And it was at that point, when we looked at our own evidence, which we were concerned about, and we’d had discussions in the June of 2011 with CQC, but mainly with the SHA again reviewing these, that we felt things needed to change. And during that period, June to October, there was a great deal of information coming in and a great deal of involvement of ourselves with the SHA, particularly Angela Brown, who was leading on it for the SHA at that time, to make sure that we were looking at this more critically and it was something we were doing.”¹³¹

5.139 It had also become apparent that the past CQC regulatory regime did not give Monitor confidence, and it therefore took independent steps to examine the quality concerns that had arisen, commissioning a review of maternity services from Central Manchester. David Bennett, Chief Executive of Monitor, put it as follows:

“There was then a period of further CQC investigation and so forth; the result of which was I was left feeling that we didn’t have sufficient clarity about really what was going on in this maternity area. And I then asked for an in-depth review by real maternity experts, because at that time the CQC approach was not to use experts in their reviews.

That absolutely convinced me that where we have these sorts of situations where there are lights flashing, suggesting there may be problems at an organisation, under the old CQC regime we had to send real experts in, and I agreed with the CQC at that time that if anything like that were to happen again, that’s what we would do.

As it happens, of course, that principle, that actually you need real experts spending real time on the ground, possibly quite a number of them, to understand what is going on in the Trust, was picked up when Bruce Keogh did his review of 14 Trusts, and has now been factored into Mike Richard’s approach to all his inspections.”¹³²

5.140 Ms Sherlock explained the CQC’s thinking at this time:

“During September the organisation reported a SUI through to the Strategic Health Authority, I believe, that concerns, that concerned outpatients services. That was brought to the regional director’s attention and she was having conversations about the significance of this with Monitor and with the SHA keeping me advised and informed as it related to the

¹³⁰ Amanda Sherlock 1st interview.

¹³¹ Mike Bewick, Peter Clarke, Neela Shabde interview.

¹³² David Bennett interview.

broad context of Morecambe Bay, but again at that time through September my primary attention was on maternity services.

There was also, I believe, another infant death during September 2011 that was reported to the regional director to Sue McMillan. Sue called me and I asked for an urgent teleconference with the regional team, myself and Louise Dineley [Head of Regulatory Risk at CQC] and our director of communications and engagement. That teleconference took place around, it's around 25th/26th September where I asked the region to go back in, even though the warning notices were set until November, I asked the region to go back in and check as there had been this further infant death and also to consider whether we went for urgent action and asked the region to consider whether there was evidence to suspend maternity services as a regulated activity at Morecambe Bay.

The region, I believe in discussion with the Strategic Health Authority and Monitor, did review the current status and the current evidence. Sue McMillan came back to me, and it's documented in an email traffic, that they didn't feel that there was sufficient evidence to warrant a suspension of the regulated activity but in light of other emerging concerns that the Strategic Health Authority were going to set up what was called Gold Command to have oversight of all of the emerging concerns which CQC and Monitor would corroborate in full. In light of the setting up of Gold Command the regional director advised me or recommended to me that we hold off any further regulatory interventions or, going forward, a section 48 investigation to see how effective Gold Command could be in getting a grip on Morecambe Bay as it were.”¹³³

5.141 Serious consideration was given to the use of the CQC's power to suspend the Trust's right to provide maternity services, but it was concluded that *“the risks of suspending the regulated activity outweighed the risks of all the organisations collectively coming together to address the quality and safety concerns of the service”*.¹³⁴ There was also consideration of the imposition of restrictive conditions:

“... but that would have taken a considerable amount of time because of the rights of representation against the placing of a restrictive condition and also restrictive conditions are quite complicated legal tools to use on an NHS organisation because they are the NHS organisations registered to provide regulated activities at certain locations. So a restrictive condition could be, and we did use at Barking, Havering and Redbridge, could be you can only admit so many women to give birth if you've only got this number of staff on duty. So at this point you have to divert to another provider. That would have been hugely problematic at Morecambe Bay. At Barking, Havering and Redbridge you've got a dozen Trusts within half an hour's drive. That's not the case at Morecambe Bay.”¹³⁵

5.142 The CQC had little confidence in the ability of the Trust to address the issues, Ms Sherlock told us:

“They didn't know what to do, they were being propped up by the Gold Command resources and the oversight. They were waiting for the Central Manchester Review, the outpatients review and the governors review to report. They didn't appear to me, but I was quite distanced so it is impressionistic on what I was being told by colleagues, they didn't seem to be taking of their own accord any urgent or remedial actions to address the problems.”¹³⁶

¹³³ Amanda Sherlock 1st interview.

¹³⁴ Amanda Sherlock 1st interview.

¹³⁵ Amanda Sherlock 1st interview.

¹³⁶ Amanda Sherlock 1st interview.

5.143 Despite this focus and level of concern, when the CQC did send an expert team into UHMB FT it was not to examine its maternity services but to consider the emergency care pathway. The Panel has not been able to understand fully why maternity services were excluded.

5.144 The purpose of an investigation under section 48 is to enable the CQC to consider systemic problems in a provider organisation. They are not common occurrences and there were only six undertaken by the CQC from its creation in 2009 until May 2013.¹³⁷ The nearest comparator to the Morecambe Bay investigation concerned Barking, Havering and Redbridge Trust, where there had been *“a longstanding history of concerns around some of its services, interest in maternity services... lots of turnover at senior significant financial problems and a shared recognition... that there were some pretty intractable problems and it would be of benefit if the CQC were able to use the section 48 powers of investigation to take a more strategic look”*.¹³⁸ The Barking, Havering and Redbridge Trust investigation examined both the emergency care pathway and maternity services.

5.145 In December 2011 it was decided to initiate such an inquiry into UHMB FT. At this stage there was a warning notice in place declaring that the Trust was in breach in relation to maternity services. However, they were not within the scope of the inquiry. Consequently, while the report of this inquiry contained a detailed account of the history of concerns about the maternity services, it did not examine the safety or culture of that area of the Trust's work and consequently could provide no assurance to the families affected that services had improved or any advice to the Trust about what it needed to do. It also had the effect of focusing Trust attention on developing actions to respond to the problems identified, from which maternity was necessarily excluded. This was balanced in part by the work of Gold Command, which had a programme of work around the safety of maternity services and is considered below.

5.146 The Investigation was told that the reason for the section 48 investigation concentrating on emergency care was that this was thought to be a good case study to enable the CQC to assess the effectiveness of the overall management of an organisation. We heard a number of accounts of why maternity was excluded. The lead for the CQC, Amanda Musgrave, Compliance Manager, told us that as *“Monitor had already conducted two clinical service reviews of maternity... arguably we could have found the same things.”*¹³⁹

5.147 The section 48 investigation had a significant impact. On the third day of the site visits to the Royal Lancaster Infirmary, Ms Musgrave concluded that the team were identifying issues that were sufficiently serious to require escalation for the consideration of enforcement action. She described *“mounting information in terms of concerns and the general safety, privacy, dignity that patients were being afforded... . Patients weren't being monitored appropriately within the emergency department... that was a real concern of the emergency nurse, the consultant”*.¹⁴⁰

5.148 Ms Musgrave told us about a surprising lack of engagement from the members of the Trust Board with her team. She told us that:

*“The chief executive was not present to receive me when I arrived at the organisation... had that discussion with him of how surprised I was that he wasn't present... and did he really appreciate the seriousness of the action CQC was taking... I didn't see the director of nursing at all... she never introduced herself to me... I think I interviewed the medical director... but that was purely the circumstance of one member of the team had to leave... so I stepped in.”*¹⁴¹

¹³⁷ Amanda Sherlock 1st interview.

¹³⁸ Amanda Sherlock 1st interview; reference to the Barking, Havering and Redbridge Report.

¹³⁹ Amanda Musgrave interview.

¹⁴⁰ Amanda Musgrave interview.

¹⁴¹ Amanda Musgrave interview.

5.149 Following the departure of the Trust chief executive during the second week of the site visits, she did not see the Trust Chair or any of the non-executive directors, and her point of contact was the interim head of governance. There were also some challenges in getting the information that was wanted from the Trust. Ms Musgrave said to us that she told Ms Sherlock that:

"The Trust are not always being as cooperative as they could be in providing information that she is requesting. On the other hand, they were drowning her with information that almost felt like a marketing campaign yes, it was really bad then but look at what we are doing now."

PROF. MONTGOMERY: She is being sent loads of stuff but not what she has asked for?

MS SHERLOCK: Yes, and it is not really pertinent to what she is looking in the investigation.

MR BROOKES: It is what they wanted you to know rather than...

*MS SHERLOCK: Yes. She has some rather robust conversations with the Trust and that starts to resolve itself. Mandy then starts to pull together the investigation report; I see a draft probably late April into May. The Trust then submits some additional information, I think, on the back of the new incoming chief exec and chair. That is basically a series of action plans and this is what we are going to be doing to address the historical concerns. Mandy says thank you very much but the investigation evidence will inform my recommendations, not what you aspire to do in the future that is right and proper, but it did delay by a few weeks finalising the report."*¹⁴²

5.150 This approach from the Trust seems indicative of a general failure to appreciate the weakness of its clinical governance, which failed to provide a systematic approach to identifying and addressing risks. When asked about her perceptions of the quality culture at the Trust, Ms Musgrave said:

*"My view was that there wasn't a quality culture... When the organisation was presented with a problem, I think it's clear from our inspection reports, they took action to address that problem. They didn't look at 'Is that problem elsewhere in the organisation that we need to take a proactive approach to manage...'. Staff were saying to me... I'm really worried because there's some maybe infectious patients here... My response would be, 'So have you escalated that risk?', because clearly it is a risk to patient safety. The response was, 'No, because nobody listens to us, so what's the point?'"*¹⁴³

And later:

"My view was that there was no strategic oversight of the concerns within the organisation. I formulate the view on the basis of the pockets of concern that were arising in different services and the lack of strategic oversight to draw those issues together to establish, 'If it's happening there, is it happening here?' The focus was very narrow, almost like firefighting, I think that, probably would be the term that I'd use."

*I think we need to raise the organisational turmoil within CQC and other organisations at key times in the saga. Handovers were less than complete, the concerns about MB seem to have not been communicated between successor parties and there is concern that the post holders were not always experienced in NHS management and services. Little expert advice was sought and understanding was fractured, limited and the conclusions often inaccurate."*¹⁴⁴

¹⁴² Amanda Sherlock 1st interview.

¹⁴³ Amanda Musgrave interview.

¹⁴⁴ Amanda Musgrave interview.

5.151 Having identified these fundamental problems in the Trust, the CQC had to consider its regulatory options. Ms Sherlock identified the difficulties in using the stronger sanctions because of the impact on services:

"We discussed what our options were, and I suggested that [we] worked with our legal team to propose a restrictive condition but a restrictive condition on their elective services, so that there would be greater capacity created in the organisation to resolve what were very serious and immediate concerns in emergency services.

We drew up a restrictive condition that proposed restrictions on their knowledge of elective so that the Trust could move around its capacity and move around its staffing, which I ran operations in a large acute Trust it would seem a sensible thing to do; if you have got pressures, you look at your emergency.

We advised the Trust and advised NHS England by that time, it was the New Year, that it was moving from the SHA to the new north region of NHS England, and were met with massive resistance from those organisations about going down that regulatory route.

I had conversations with Jane Cummings and Stephen Singleton; advised them why we were going down this route. Their view was that they weren't trying to interfere with the regulatory decisions but did we understand the impact that this would have. My response that did go back in writing is that I understood perfectly the impact, it wasn't a decision that we were seeking to take lightly; if they could come up with an alternative that would leave the same changes and have the same impact, then I was very happy to have that discussion with them.

*In the event, within a couple of days the PCT and NHS England took the decision voluntarily to suspend some elements of elective admissions and create some immediate capacity to try and resolve the emergency care issues in the Trust, so we didn't have to impose the restrictive condition."*¹⁴⁵

5.152 It seems clear that none of these parties believed the Trust could address the problems internally. The section 48 review finally exposed the depth of the problems at the Trust and suggested that, in addition to very serious concerns about maternity services, there were fundamental problems with the management across the Trust. The discussion within the CQC about regulatory sanctions also identified the difficulties in applying them without destabilising a health system and also the interface between the responsibilities of the CQC and Monitor.

*"A lot of the problems emerged because of poor leadership and poor risk management. Whilst they are a component part of CQC, it is more intrinsic to Monitor's oversight than the CQC, and because of the way the essential standards were written and they were about outcomes for patients rather than the fitness of an overall organisation, it can be quite difficult to disentangle where it is poor leadership against an outcome for an individual patient."*¹⁴⁶

Monitor

5.153 Monitor was established in 2004 under the Health and Social Care (Community Health and Standards) Act 2003. It is responsible for authorising, monitoring and regulating NHS Foundation Trusts. As such, it oversaw the FT process for UHMBT and approved its authorisation in 2010. Once an organisation has become a Foundation Trust, Monitor acts as regulator, ensuring it meets

¹⁴⁵ Amanda Sherlock 1st interview.

¹⁴⁶ Amanda Sherlock 1st interview.

its licence and continues to provide high-quality services. Prior to an NHS Trust entering the FT process, the Trust is reviewed by the Department of Health and, on recommendation, approved by the Secretary of State for Health to enter the FT process. Once in the FT pipeline the process is overseen by Monitor.

5.154 Monitor oversaw the process and ultimately authorised UHMBT to become a Foundation Trust. However, it relied heavily on input from the Trust itself, as the existing process, in place until after 2010, was based on a lot of self-assessment. Monitor also looked to the NW SHA, for insight and information on the Trust as its performance manager, as well as to the Healthcare Commission and then the CQC. Dr Bennett, Chief Executive of Monitor, described the position before his arrival in 2010 in the following way:

“So, at the time the HCC, the Healthcare Commission was looking at, in particular, at the quality side of provider organisations, Monitor was set up to look at the overall governance of the organisations, and also to make sure that they were financially sound.”¹⁴⁷

He went on to say:

“So, it was still the case that the presumption would be that the primary test of whether or not a Trust was providing good-quality care would be the quality regulator, and this – just as I joined it had become – well, I think possibly a year before I joined it had become the Care Quality Commission when the HCC was merged with various other bodies. But the principle was still the same, it was their job primarily to establish that good-quality care was being provided, but we had started to look at things that we could do to support that process, in the light of lessons learned from Mid Staffs, so that was just beginning to happen.”¹⁴⁸

5.155 There is some sense in the division of labour. If Monitor was to have assessed the clinical quality of services it would have needed experienced clinical staff and it could be argued this would duplicate the role of the Healthcare Commission and the CQC. Nevertheless, the fact that the CQC only became aware of the group of SUIs concerning maternity services when Monitor brought it to its attention provided an indication that reliance on its procedures might have been unwise. Similarly, the fact the NW SHA had not addressed those in its own assessment of quality in relation to the FT application would also have raised concerns about the robustness of its processes. These weaknesses were also exposed by the Francis Inquiry into the failures of care and governance at Mid Staffordshire NHS Foundation Trust. It should be noted, however, that Monitor drew attention to the possibility that the cluster of incidents might constitute a pattern when this had not been raised by others.

5.156 The Trust started its journey towards Foundation Trust status in March 2009. Normal practice would be for the Trust to reach FT status in time for the beginning of the next financial year – April 2010. However, Monitor became aware of a number of SUIs that concerned them. Dr Bennett described the issue:

“But just a couple of months into that [year], the process had been stopped, and it had been stopped because the assessment team had said there seemed to be some concerning – a concerning pattern of quite a number of serious and untoward incidents over a relatively short timescale, there were 12 and 5 of them were in maternity. So, they had said this looks concerning, they stopped the assessment and they asked the CQC to look at it.”¹⁴⁹

¹⁴⁷ David Bennett interview.

¹⁴⁸ David Bennett interview.

¹⁴⁹ David Bennett interview.

5.157 The question of the handling of the maternity SULs was raised by Bill Moyes, the previous Monitor chief executive, at a Board to Board meeting between Monitor and the Trust on 7 May 2009. The briefing papers for that meeting clearly identified the nature of the SULs and the fact that external investigations had been commissioned (this did not include the Fielding Report, which had not been commissioned at this stage and therefore could not have been disclosed).¹⁵⁰ It is apparent from the meeting papers that Mr Moyes was specifically prompted to ask a question about the SULs, which he did.¹⁵¹ The purpose of this was to assess whether the directors of the Trust were aware of them, as a test of their grip on governance processes. It was not to explore what the incidents showed about the quality of services at the Trust. Assurance on that matter was sought from the CQC and NW SHA.

5.158 The CQC undertook an assessment and provided assurance to Monitor that the Trust was sufficiently sound and should proceed with the authorisation process. Monitor questioned this and further discussion ensued. Dr Bennett explained:

*"They then, after some discussions between us and them, they then looked again and then they said, 'Yes, we're going to have to investigate more closely.' They, as I understand it, they briefly, for about a month, rated it the Trust as 'Red' in their mentorship. I think that was essentially a holding position, whilst they began their investigation. A month later they downgraded it to 'Amber'; and then it stayed at 'Amber' during the period when they were looking, doing further investigations and requiring some changes until eventually, when we restarted the assessment they moved it back to 'Green'."*¹⁵²

5.159 Heavy weight was placed on the assurance gained from the CQC. In particular, the risk profile, the fact of registration without conditions and the CQC's recorded level of concern. We heard during the Investigation that if the CQC had placed conditions on registration, or had rated the Trust's level of risk as 'Red', or had recorded more than 'minor concerns' then the FT application would not have been revived. Monitor suspended the application because of the CQC's 'Red' rating and revived it principally because the CQC stopped flagging concerns. This was interpreted as removing the quality impediment to authorisation.

5.160 Further assurance was received from the NW SHA who described the action under way to resolve the issues at the Trust. Monitor accepted these assurances on face value. There is no evidence that Monitor looked at the primary evidence surrounding the SULs, but relied on the two organisations it assumed could provide that assurance.

5.161 The Monitor assessment team noted:

*"The SHA have informed us that there will be an inquest into the specific SUI but they believe that there are no further facts to uncover or issues to deal with. In addition the Ombudsman has confirmed that they have decided not to investigate the T complaint."*¹⁵³

5.162 Assurance had become circular. The CQC was taking reassurance from the fact that the PHSO was not investigating; the PHSO was taking assurance that the CQC would investigate, the NW SHA was continuing to give assurances based in part on the CQC position. Monitor asked for assurance and received the perceived wisdom – that the issues were under control and minimal. At no time did Monitor question these circular arguments or the improbability of cultural concerns being resolved within six months.

¹⁵⁰ Morecambe Bay Board to Board Report, 7 May 2009.

¹⁵¹ University Hospitals Morecambe Bay Trust Application for Foundation Trust Status Board to Board meeting, 7 May 2009.

¹⁵² David Bennett interview.

¹⁵³ Compliance Executive Committee 5 September 2011 – key issues preventing authorisation – CQC concerns with the maternity services.

5.163 The Trust had started the authorisation process, and Monitor had deferred the application. As the application was deferred, rather than rejected, it remained in the Monitor process, and so wholly the responsibility of Monitor. As described above, if the application had been rejected, the whole process would have had to have been restarted – including getting Secretary of State approval. This was not likely to be forthcoming because officials were already considering whether to ask Monitor to suspend the application in July 2009 once concerns were heightened.¹⁵⁴ The deferral, however, was just that – a time where the specific issues and concerns identified by Monitor were assessed by the CQC and reassurance was sought.

5.164 There was a second Board to Board meeting on 8 September 2010. Monitor used a quality dashboard to assess Trusts and this was in the briefing pack, which, as before, summarised the SULs and noted the external reviews.¹⁵⁵ This did not include the Fielding Report, which had by this time been received by the Trust but not shared with Monitor, despite Ms Holt's expressed belief to Ms Brown in April 2011 that the Trust had done so.¹⁵⁶ While there was no specific question recorded on clinical governance,¹⁵⁷ handwritten notes of the meeting indicate that processes were discussed.¹⁵⁸ However, there was no discussion of the maternity SULs at the September 2010 Board to Board meeting.

5.165 Dr Bennett summarised the position:

"Quality governance, well I think it was 'Amber'/'Green', so it was at that point where we say 'Is this okay or not?' Now perversely, because this was a Trust where we'd already asked questions about quality of care, and we'd got specific reassurance, I think that's what tipped us over to say, well, this was only the very first ever, and it was only a very quick look at quality governance, there's been lots of people asking very – in significant detail, about whether the quality's okay here, and they said it's okay. So, we went ahead, in retrospect perhaps it was signalling something which the others had missed."

And:

"When, in late 2011 it became clear that things had been missed; was a commission a review from our auditors of how we had conducted the review and why we had missed things and what lessons we could learn. One of the things they said was that there were a number of slightly concerning issues which individually didn't tip over, but if we'd looked at it in the round we might have said, 'Aren't there just too many mildly flashing amber lights here?'"

And so, we've introduced a scorecard which essentially looks at everything we look at and sort of RAG ['Red'/'Amber'/'Green'] rates it all and then the teams now explicitly step back from that and say, 'Even if, in some numerical sense, it all adds up to a pass, are there enough amber lights on there that we really ought to go back and look again.' So you're right, with the benefit of hindsight, there were a number of things that, if you look at them in the round, you might have said, 'Isn't this just a bit too worrying to simply go ahead?'"¹⁵⁹

5.166 Having received assurance, the process continued and Monitor authorised the Trust in October 2010. The PricewaterhouseCoopers (PwC) subsequent review makes it clear that the governance standards at the Trust were far below what would have been required to succeed on

¹⁵⁴ John Holden email, 2 July 2009.

¹⁵⁵ University Hospitals Morecambe Bay Trust Board to Board Meeting, 8 September 2010.

¹⁵⁶ Evidence supplied to Morecambe Bay Investigation.

¹⁵⁷ University Hospitals Morecambe Bay Trust Board to Board meeting, 8 September 2010.

¹⁵⁸ University Hospitals Morecambe Bay Trust Board to Board meeting handwritten notes, 8 September 2010.

¹⁵⁹ David Bennett interview.

the revised processes,¹⁶⁰ and its author was surprised that the Trust could have passed scrutiny in 2010.¹⁶¹ It seems probable that the Monitor approval process that was in place in 2010 failed to expose the inadequacy of the Trust's clinical governance systems. This was the conclusion on Monitor's own Internal Audit review *Learning and Implications from UHMB NHS FT* (KPMG, July 2012).¹⁶²

5.167 At no time during this period was Monitor made aware of the findings of the Fielding Report. Monitor was aware of the existence of the Fielding review prior to authorisation (albeit in a muddled way); however, its content and its significance was not known.

5.168 This makes it important to assess the view that the lack of disclosure of the Fielding Report was significant. We asked Dr Bennett whether the main cause for concern was the fact that the report was not shared or its substance. He told us:

"I think the most important point was the content, because it indicated that there were more deep-seated issues in maternity, all of which – the moment you see evidence of governance processes not working properly, and potentially cultural issues then you know you've got a big, and potentially quite lengthy job on your hands to get it sorted out. And my recollection was that the Fielding Report gave indications of these sorts of more deep-seated issues.

*Of course the fact that they didn't, the Trust didn't make it available to CQC when they were concluding their review was presumably one of the reasons why the CQC didn't, at the time, discover that there were these more deep-seated problems."*¹⁶³

5.169 So the Fielding Report was of key importance, in that it would have provided yet more evidence of systemic problems in the Trust and in particular maternity services. The absence of this critical information allowed the assurances that had been received to be accepted. It was another missed opportunity when closer scrutiny or less reliance on assurance from external bodies might have identified the problems in the Trust. It is likely this would have stopped the FT process, but it is unclear whether it would have led to a more rapid examination of the problems in the Trust. But it might have.

5.170 Monitor kept the performance of the Trust under review and drew together intelligence from a number of sources. On 5 September 2011, the Compliance Executive Committee considered questions about the failure to disclose the Fielding Report during the application process and the paper recorded widespread concern about the Trust's follow-up of issues and lack of a proactive governance culture:

"The RM [risk management] team are concerned that the same issues appear to have been raised on a number of occasions suggesting that the Trust has not taken appropriate or timely action in response to risks identified. A number of concerns raised in the draft August 2011 CQC report are the same as those raised in the Fielding report 12 months previously. Issues were raised in the media in March 2011 around the storage of medical records, the draft August 2011 CQC report suggests that issues remain. CQC raised a major concern that actions arising from monitoring do not always take place in a timely manner and that concerns are not always escalated appropriately (mirrors the McKinsey concern), and

¹⁶⁰ Ian Elliott interview.

¹⁶¹ Ian Elliott interview.

¹⁶² KPMG Learning and Implications from University Hospitals of Morecambe Bay NHS Foundation Trust, reissued 12 July 2012.

¹⁶³ David Bennett interview.

highlighted that Trust is reacting to events rather than promoting a preventative/proactive culture. This is consistent with the RM team's view of the Trust."¹⁶⁴

5.171 Monitor intervened and required the commissioning of external reviews of the Trust: a governance review by PricewaterhouseCoopers and a diagnostic review by Central Manchester University Hospitals NHS Trust. These provide the most robust and public examination of the governance failings in the Trust. Both suggest that the fundamental problems identified in the Fielding Report had not been resolved.

5.172 It is far from clear that the Trust appreciated quite how damning the assessments were. In April 2013 a meeting of the Trust's Intensive Support Programme for Women and Children's Services considered feedback that it had not provided sufficient evidence on delivery on its action plan. The Minutes suggest that key figures in the Trust believed that the issues were about evidence rather than substance.¹⁶⁵ George Nasmyth, the Interim Medical Director, was recorded in the Minutes as stating that he thought *"a lot of the criticism was not about the service but the way assurance is or is not given to the Board"*. He went on to note *"various positive regulatory reviews in 2012 giving external endorsement on the progress made"*. Sascha Wells, the Head of Maternity, noted that divisions *"had worked well in providing assurance with returns to the CQC and NMC"*. A consultant obstetrician/clinical lead, David Burch, is recorded as suggesting *"that the issues were process rather than outcomes"*. Overall, this meeting suggests that the Trust did not believe there were problems with its services and took external reviews as assurance when they were positive but felt they had misunderstood progress when they were critical.

5.173 Monitor was concerned in February 2012 that the Trust was *"reliant on external bodies to identify the risks that it should be identifying"*. It noted that the Trust had stated it was compliant with the maternity warning notice of September 2011 but had remained unaware of other related significant risks that were identified by the Central Manchester Diagnostic Review. It pointed out that *"there is a continued lack of incident reporting in obstetrics, which has been an area of intense scrutiny for some time and where there have been issues relating to reporting risk known for some time by the Trust."* Monitor pointed out that: *"The Trust does not appear to have the capacity or capability to act effectively on existing and future issues without the external scrutiny and support currently being provided... . Actions recommended in respect of paediatric services remain outstanding two years after being made to the Trust."*¹⁶⁶ This indicates a fundamental failure of governance with little evidence to suggest that the Trust could put this right.

5.174 The Monitor approval process brought clinical governance issues forward that had previously been neglected by both the CQC and the NW SHA. It was Monitor that prompted them to consider the issues. However, as with other parts of the system, Monitor took the assurances that they provided at face value and made no independent scrutiny of the effectiveness of the Trust's clinical governance systems when it authorised it in October 2010. As subsequent reviews have shown, those systems were wholly inadequate. Monitor has made significant changes to its assessment systems and there is a high degree of confidence that the organisation would not have been authorised in 2012 when the PwC governance review reported. It seems likely that this should have been apparent even in 2010. Although there has been demonstrable progress in clinical governance arrangements since the 2012 PwC review, it is difficult to assess whether the current governance system would pass the approval process if it were presented today. The author of the PwC review expressed the view to us that it would take some years for the problems to be resolved.¹⁶⁷

¹⁶⁴ Compliance Executives Committee, 5 September 2011.

¹⁶⁵ Minutes of the Intensive Support Programme for Women's and Children's Services, 30 April 2013.

¹⁶⁶ Notification of Monitor Board Determination re Intervention, 6 February 2012.

¹⁶⁷ Ian Elliott interview.

The Department of Health

5.175 The Department of Health (DH) was and is primarily responsible for the creation of national health policy and related legislation. Through the discharge of these responsibilities the strategic direction and vision for the NHS in England is delivered. The Department of Health is responsible for ensuring the integrity of the health system and assuring the delivery and continuity of services and accounting to Parliament for the way resources are utilised. The Department of Health and its Ministers are responsible for the promotion of a comprehensive health service (generally free of charge at the point of delivery) and for securing the provision of hospital and other health services.¹⁶⁸

5.176 The powers prescribed to the Secretary of State for Health by statute within the Investigation period were predominately undertaken by PCTs, NHS Trusts and SHAs. They acted as the agents of the Secretary of State. Policy was developed in conjunction with the NHS and then implemented through the actions of the local health system. The progress and impact of the various health strategies were assessed and monitored to ensure that the outcomes prescribed were delivered. Information was passed to the DH through a complex system of weekly, monthly, quarterly and annual returns. These formal routes were complemented by informal and formal networks and ad hoc briefings.

5.177 Day-to-day management of the system was the responsibility of the PCTs and the SHAs. It was through the performance management of these organisations that the system was kept focused on the agreed deliverables. Sir David Nicholson described the role of the Department of Health in a very practical way, saying: *“the Department of Health is responsible for making sure the whole system works”*.¹⁶⁹

5.178 Although the overall responsibility for the NHS lies with the Secretary of State for Health, the management responsibility for the NHS and Department of Health varied over the period covered by the Investigation. Nigel (later Sir Nigel) Crisp took up post as chief executive of the NHS and the Permanent Secretary for the Department of Health in 2000. This joint role continued until he stood down in 2006. At this stage the roles of NHS chief executive and Permanent Secretary were split. David (later Sir David) Nicholson came into post as chief executive of the NHS in September 2006, following acting up arrangements through which Sir Ian Carruthers took temporary charge. This was a post Nicholson held until 2011, when he became chief executive of NHS England. Hugh (later Sir Hugh) Taylor became Permanent Secretary in 2006 and remained in that position until 2010, when Una O’Brien took up the post.

5.179 The responsibility for the NHS and the running of the Department of Health fell to these key individuals. Clinical advice and leadership was provided for part of the period covered by the Investigation by Sir Bruce Keogh, who became the first medical director in 2007, and by the chief nursing officer, namely Christine (later Dame Christine) Beasley (2004–2011) and Jane Cummings from 2012.

5.180 The Investigation has looked at the involvement of the Department of Health in a number of areas – including its role in the FT application and its management of concerns raised through the FT process and through complaints.

5.181 The creation of Foundation Trusts has been a significant element of the government’s strategy since they were first announced in 2002. The first FT was created in 2004. UHMBT was authorised as an FT in 2010 amidst the clinical concerns described within the Investigation. It is not within the remit of the Investigation to comment on the creation of Foundation Trusts, what is of interest is whether the involvement of the Trust in the FT process had an adverse impact on the services provided by

¹⁶⁸ National Health Service Act 2006.

¹⁶⁹ Sir David Nicholson interview.

the Trust; and whether there was intelligence arising from the FT process and the monitoring of the NHS available to the DH that could have been used to identify failings within the Trust.

5.182 In his interview, Sir David Nicholson stated:

“There is no doubt when I first started in this job [2006] that the Prime Minister at the time saw Foundation Trusts status or numbers of Foundation Trusts as a measure of how committed to reform the Department of Health was. If you think about it, the Foundation Trusts process was taking Foundation Trusts out of the control of the department so it was not a natural thing for the Department of Health to want to do.”¹⁷⁰

5.183 There was a real desire to maximise the number of Trusts achieving authorisation as FTs. But did this translate to targets within the NHS?

5.184 Mr Farrar stated:

“You know, there wasn’t in the SHA a desperate desire to get everybody to FT. I wasn’t – I wasn’t on performance related pay by getting people to FT, that was not one of our – FT status was a means to an end. Obviously it was the Government’s priority, and they expected us to support Trusts to become FTs, so don’t get me wrong, it was part of the job.

So I never agreed with any of the SHAs’ chief executives that you have got to do four by this date or five by this date or whatever. I genuinely – I was never part of it. I never got into the place with SHA chief executives where I was saying, ‘you are not doing enough’. I cannot remember a time when I did that. Now that is when you will find something but I genuinely, I literally cannot. It was not the way that I would have operated.”¹⁷¹

5.185 Sir David Henshaw, former Chairman of the NW SHA, stated:

“I remember the politics of the time or the Government at the time was anxious to get as many Provider Trusts into FT status... So there was a political, I think imperative to try to get as many Provider Trusts into FT status.”¹⁷²

5.186 Whether there was an explicit target that specified numbers of Trusts were to be FTs by a specific date is unclear. What is clear is that there was a culture generated within the NHS where the achievement of FT status was looked on favourably and that progress towards FT was expected for all NHS Trusts.

5.187 The Trust’s chief executive from March 2007, Mr Halsall, explained the position he found on taking up post:

“So when I go there they saw themselves as having been an applicant, and that the desire was that, you know, to get to Foundation Trust status. So it’s clear when I was appointed that that was the ambition of the organisation, to become a Foundation Trust. And at the time, of course, the whole NHS was geared towards providers becoming Foundation Trusts, or being part of Foundation Trusts so, you know, the better providers wanted to be recognised as being FTs.”¹⁷³

5.188 Trusts were expected to become Foundation Trusts and the health system was actively involved in supporting the process. Monitor was the final arbiter of the process and it was expected

¹⁷⁰ Sir David Nicholson interview.

¹⁷¹ Mike Farrar interview.

¹⁷² Sir David Henshaw interview.

¹⁷³ Tony Halsall interview.

that Trusts would need to reach specific standards to become FTs. However, within the process the Department of Health had a specific role of approving aspirant FTs to go forward to Monitor. The situation with UHMBT was unusual. It received approval from the Secretary of State to proceed to authorisation on 5 February 2009 but then the application was deferred. As the application was deferred not rejected, the Trust did not have to start the process again once Monitor decided it was fit to proceed, and no further approval was required from the Secretary of State.

5.189 As concerns mounted, the DH faced a dilemma – should it step in or remain independent from the process and leave it to Monitor? Advice was sought. Internal DH correspondence suggested that in their view if the application were to go before the DH Applications Committee, as things currently stood:

“It was highly unlikely that a recommendation for Secretary of State support would be made.”¹⁷⁴

Further, the correspondence reported that:

“DH legal have confirmed there is no power to withdraw Secretary of State support once an application has moved to the Monitor stage of assessment.”¹⁷⁵

5.190 Two options were under consideration – either to do nothing, allowing Monitor to make the decision, or to be active and ask senior officials to discuss the case with Monitor, requesting it to be removed from the process on the grounds that it would not currently receive Secretary of State approval. No further correspondence has been found on this issue but it is clear that the DH did not take the second of these options.

5.191 The Investigation understands that the environment at the time was focused on maximising the number of FTs created, and that there was direct and indirect pressure on organisations to progress as rapidly as possible to FT status. However, the DH in this particular instance believed that its hands were tied by the legal framework it was working within and did not choose to discuss with Monitor the withdrawal of the Trust from the process. This does not seem to be due to a focus on getting all Trusts to FT status as soon as possible, but as a response to the DH's reading of the legal framework and the advice it received.

5.192 However, the decision not to intervene by the DH, which held the view that the current position of the Trust did not warrant approval by the Secretary of State, and its concern not to overstep its authority, is clearly a missed opportunity to reinforce existing concerns about the Trust. At any point an intervention that broke through the perceived assurances and forced a relook at the position is likely to have taken events down a more favourable path. This did not happen.

5.193 The DH did alter its approach in response to the weaknesses identified by the Francis Inquiry in relation to the processes for approving FT applications. Sir Bruce Keogh described a new system, introduced just too late for UHMBT, in which medical directors considered quality issues around aspirant FTs. This was operational before Monitor approved UHMBT but it did not go back through DH assessment because previous Secretary of State approval was still valid. This might have been different if the application had been rejected rather than deferred. However, this would have been dependent on regional medical directors raising concerns and this did not happen with UHMBT. Indeed, at the time that the Trust was entering the FT pipeline, the primary quality responsibility at the NW SHA sat not with the medical director but with the director of nursing and quality.

¹⁷⁴ Memo from Helen Hamilton to John Holden, July 2009.

¹⁷⁵ Memo from Helen Hamilton to John Holden, July 2009.

5.194 One way in which the DH might become aware of issues in an organisation was through letters and complaints sent directly to Whitehall. In relation to Mid Staffordshire NHS Foundation Trust these were extensive, but Ms O'Brien told us that there was no similar pattern in relation to UHMBT:

*"Certainly as far as maternity services were concerned, we did not have much, if any, correspondence at all on this matter... with Mid Staffs... there were many letters that you can see with hindsight were raising a flag. I don't see a similar body of correspondence about this service in this Trust."*¹⁷⁶

5.195 Practice within the Department of Health was to seek briefing and assurance from the appropriate SHA, who had local responsibility and could provide through their managerial links to specific organisations briefing on the issues raised. The briefing received by the DH from the NW SHA identified the SUI cases that had occurred, but relied on the existing perception that the cases were not related to each other and were not an indication of systemic failure. The Investigation is not aware of a new investigation into the circumstances being generated by the complaint letter. Instead, the existing briefings on the issue were revisited and the original conclusions were reiterated – that the cases, whilst concerning and tragic, were not linked and not a sign of organisational or systemic failure.

5.196 This is a missed opportunity. If there had been a review of the information available at that time, by the NW SHA, it is possible that the conclusions reached in this Investigation would have been reached then. Instead the 'understood' position was reinforced and the opportunity lost.

5.197 Throughout the period of the Investigation, information was passed to the DH from various sources but predominantly from the NW SHA. This information related mainly to the FT process but also to complaints and correspondence from concerned individuals. Consistent within the briefing reviewed is the assumption that the cases were not linked and indicators of systemic failure. Primary sources of information were not passed to the DH through the NW SHA – which was consistent with practice at the time. However, if the evidence had been seen by the DH the view of the DH might have been different. The NW SHA provided assurances that the maternity issues were isolated incidents and not indicative of any wider quality concerns at the Trust.

5.198 We found no evidence that officials at the Department of Health sought to hide the issues at UHMBT from Ministers or the media. Rather, they were appropriately briefed about the extent of them. Their source of information on events, and appraisal of the Trust's response to them, was the NW SHA; that was the standard procedure, and UHMBT was no different in this to any other Trust. As we have seen, however, the NW SHA's view was crucially shaped by two perceptions, both sincerely but mistakenly held: that the untoward incidents had been "*coincidental*" and that action plans were being implemented to address the service issues that they had separately uncovered.

5.199 In view of the concerns that we know have been expressed previously by family members, we asked all of those we interviewed from the Department of Health about the possibility of any political imperative to suppress 'bad news', which may have affected how these events were handled, particularly in the run-up to the 2010 general election. What we heard consistently expressed to us was a general awareness amongst senior staff in all health organisations that news of such stories must be carefully managed at a time of heightened political sensitivity and intense press scrutiny, but nobody gave any credence to the notion that this would be extended to falsifying assessments or denying service failures; nor did we hear, or see in documentary evidence, any suggestion of any such instructions being given in writing or in conversation.

5.200 Dame Christine Beasley, the former Chief Nursing Officer, described the environment to us most clearly in these terms:

¹⁷⁶ Una O'Brien interview.

"Nobody ever said to me, 'Don't print a story.' But there is never any doubt that people don't want bad stories as you run up to an election. But to be fair I think it was more about, 'So do we think there are going to be bad stories? What are they? And what can we now do about it to stop them being a bad story?' Rather than, 'Don't let's do it.' So if A&E is going wrong will money help?"

She was clear that no-one ever suggested to her that they should deny that something was happening.¹⁷⁷

5.201 On the basis of the evidence that we have seen, it is clear that the Francis Inquiry reports into events at Mid Staffordshire NHS Foundation Trust caused a significant amount of effort to be put into identifying poorly performing hospitals, including a series of intensive visits commissioned by Sir Bruce Keogh into 14 hospitals that were outliers on mortality statistics (which did not include UHMBT). This was, in our opinion, a clear and commendable initiative to identify problems, not to hide them; the subsequent changes to the CQC and the hospital inspection regime have further strengthened this approach.

5.202 The reason that UHMBT did not feature on the Department of Health's list of concerns was, we believe, very clear: the briefing system from the NW SHA obscured the true picture and gave false reassurance. Sir David Nicholson told us that, upon reading the Fielding Report, it was clear to him that there were systemic issues, but he did not read it at the time.¹⁷⁸ He had been briefed that the Fielding Report "*independently reviewed*" the cluster of incidents in 2008 and "*found that the incidents were coincidental but the report raised governance, facilities, leadership/mutual trust and team working issues*", which were, it was believed, being addressed.¹⁷⁹

5.203 The judgments made by the Department of Health relied heavily on the assurances it received and the DH did not triangulate information received through the various routes into the organisation. It did not take an active line on its concerns on the Trust and whether it should proceed towards authorisation as an FT, relying on Monitor to make a judgment on the Trust. It accepted assurances that the position was being managed, and trusted that the information it was receiving was sound. It did not initiate a new set of enquiries based on available primary sources of information.

Secretary of State for Health and Ministerial team

5.204 The Secretary of State for Health is required to decide whether or not to permit an NHS Trust to apply for Foundation Trust status. In relation to UHMBT, this decision was made on his behalf by MS(H) on 5 February 2009. The submission recommended that permission be granted and identified as issues the Trust's MRSA performance, A&E performance and information governance. There were no issues around maternity services identified in the briefing. Once those issues had come to light, in July 2009 the DH officials considered whether there was scope to request Monitor to reject the application, but there is no evidence that Ministers were made aware of this issue.

5.205 On 6 January 2010, a briefing was prepared for a meeting between the Secretary of State for Health and a Cumbria MP. The subject of the meeting was cancer services at Westmorland General Hospital; the briefing ran to 23 pages, mostly on cancer services, but included in a section on "Current Issues" was the following:

"There were five reported incidents during 2008 concerning neonatal, maternity and gynaecological services at Furness General Hospital, Barrow. These included two neonatal

¹⁷⁷ Dame Christine Beasley interview.

¹⁷⁸ Sir David Nicholson interview.

¹⁷⁹ Maternity Services at University Hospitals of Morecambe Bay NHS Foundation Trust 2011; Police Investigation of Maternity Services at University Hospitals of Morecambe Bay NHS Foundation Trust.

deaths (Baby T and Baby B), two maternal deaths and one unexpected death after routine gynaecological surgery.

All cases occurred within ten months and included the same medical/clinical teams service wide. All are subject to complaints and possible litigation using the same legal firm.

An internal investigation into the death of Baby T (26 November 2008) highlighted a number of underlying contributory factors to the death around multi-professional team working, communication, clinical skills, clinical protocols, staffing handover/named carer arrangements and record keeping.

The investigation into death of Baby B has not yet reported, however, initial findings suggest that there were issues in terms inter-professional communication between the midwifery and obstetric teams, which are similar to the concerns raised in the Baby T case.

Inquest dates have not been set for the maternal deaths. Internal investigations are already underway but will not conclude finally until after inquest.

The North West SHA reports that there is a new leadership team in the Trust and they are addressing the practice and organisational issues. Action has already been taken to address issues highlighted in response to the Baby T investigation and the Trust is strengthening the action plan to ensure the longer-term issues of team and multidisciplinary working, are addressed and embedded. The SHA is working closely with the PCT and Trust on incident management and submission of the action plan. The Trust is considering a further review of the investigation by an independent reviewer. The SHA is closely monitoring the Trust in collaboration with CQC and will be agreeing the way forward following the CQC review visit and on receipt of the latest incident reports and other ongoing reviews.

Line to Take: I am aware of the incidents affecting maternity, neonatal and gynaecological services that have been reported at the Trust in the last 12 months. I am assured that these incidents are being taken very seriously and I expect that any recommendations made are acted upon quickly to ensure that services remain safe and of high quality.¹⁸⁰

5.206 This note is obviously intended to be reassuring, indicating clearly that, while there appear to be problems in the Trust's services, the NW SHA is taking appropriate action to ensure that problems are being addressed, including "a further review of the investigation" that must refer to the Fielding review. This was in accordance with the information available to the DH at that time; without the benefit of hindsight, there is nothing to suggest that the SHA, PCT and Trust would not between them be able to restore safe working.

5.207 On 12 September 2011, the Secretary of State for Health was briefed, at his request, on matters relating to the police investigation into events at the Trust, following media interest. He was advised that:

"There were a cluster of incidents relating to maternity services at Furness General Hospital in 2008. This included a stillbirth, a neonatal and maternal death and a second maternal death which were reviewed by Dame Pauline Fielding on behalf of the Trust. She concluded that the incidents were coincidental but the report raised governance, facilities, leadership/mutual trust and team working issues. Many of the issues had already been identified in

¹⁸⁰ Briefing for Secretary of State meeting with Tim Farron MP, 13 January 2010 Cumbria PCT – NW SHA.

the original investigations of the incidents. An action plan has been implemented by the Trust.”¹⁸¹

5.208 The briefing noted that the Trust had identified failings in the care of JT, apologised, and made a settlement in the case. It also noted that the coroner had raised concerns about collusion between the midwives and also that the observation chart may have been destroyed. We have noted above that by this time officers in the CQC and Monitor were concerned about the lack of timely responses in the Trust and in particular that issues identified in the Fielding Report in 2010 seemed not to have been resolved by the time of the CQC visit in July 2011. If this was known by the DH, it was not communicated to the Secretary of State.

5.209 On 13 July 2012, following his request for a specific briefing on the Fielding Report, the Secretary of State was informed that:

“3. The Report concluded the incidents were unconnected but raised issues around governance, facilities, leadership/mutual trust and team working issues. These echo the overarching problems identified in CQC’s investigation of the Trust published today. Although the Trust produced an action plan at the time to implement the Report’s recommendations it is clear that an opportunity was missed to make improvements.”¹⁸²

5.210 Although this was based on the understanding of the NW SHA at the time, it was not in fact the case that the Fielding Report had reached any conclusion on whether the incidents were connected, as this issue had been excluded from its terms of reference. It was also misleading to state that the action plan to address the Fielding Report had been produced “*at the time*”, as the action plan was not drawn up until much later and did not in fact address all the recommendations as a number were stated to be inapplicable. The briefing also recorded that, in February 2010, the NW SHA advised that it had been satisfied with the actions the Trust was taking.¹⁸³

5.211 Ministers also spoke in debates in the Houses of Parliament. These included a debate on 5 February 2013, prompted by John Woodcock, MP for Barrow and Furness, which discussed configuration issues and the challenges of providing services in the area.¹⁸⁴ The House of Commons debated issues arising from the Care Quality Commission’s oversight on 19 June 2013.¹⁸⁵

5.212 Briefings provided to Ministers were consistent and accurately reflected the judgments of the NW SHA and regulators; there was no mechanism by which DH officials could have known that these judgments were flawed.

Parliamentary and Health Service Ombudsman

5.213 The powers of the Health Service Ombudsman derive almost wholly from the Health Service Commissioners Act 1993. Amendments to the Act have now limited its powers to health services in England. Amendments have been made through a variety of Acts since then, expanding and refining the powers of the Health Service Ombudsman. The Ombudsman’s role is to investigate complaints that individuals have been treated unfairly or have received poor service from government departments and other public organisations and the NHS in England.

¹⁸¹ Police Investigation of Maternity Services at University Hospitals of Morecambe Bay NHS Foundation Trust.

¹⁸² University Hospitals of Morecambe Bay NHS Foundation Trust, Fielding Report and Learning and Implications Report for Monitor.

¹⁸³ University Hospitals of Morecambe Bay NHS Foundation Trust, Fielding Report and Learning and Implications Report for Monitor.

¹⁸⁴ Briefing for Secretary of State meeting with Tim Farron MP, 13 January 2010 Cumbria PCT – NW SHA.

¹⁸⁵ Briefing for Secretary of State meeting with Tim Farron MP, 13 January 2010 Cumbria PCT – NW SHA.

5.214 The validity of decisions taken by the PHSO fall outside our terms of reference. However, they are important for our work in two respects. First, a number of decisions by bodies that do fall within our terms of reference were affected by the decision of the PHSO not to investigate a complaint. Second, the availability of the jurisdiction of the PHSO is an important component of the system by which those who suffer mishaps within the NHS can seek investigation and redress. We cannot consider how effectively that system served the needs of the families without understanding the role of the PHSO.

5.215 Around April 2009 a family asked the PHSO to consider a complaint. The complaint fell broadly into two categories: first, the quality of clinical care experienced and the disappearance of medical records relating to the first 24 hours of care, and second, discrepancies between the statements of midwives and the events as recalled by the family.

5.216 Kathryn Hudson, former Deputy Ombudsman, in her interview described the events in the following way:

*"It was assessed in the normal way through our processes and we were aware at that time that CQC and Monitor had an interest and that made it unusual. We did not usually have contact with them at that particular time."*¹⁸⁶

5.217 The complaint went through the PHSO's review process and the outcome of that review went to an assessment panel on 12 August 2009. The recommendation to the panel was that an investigation was undertaken.¹⁸⁷ Up to 30 cases might go before the panel at a time, but a small proportion would receive detailed discussion. Ms Hudson told the Investigation:

*"Most of those would be going forward as fairly straightforward. Usually, somewhere between six and ten that we would need to discuss in detail. This particular case was one that was there for discussion."*¹⁸⁸

5.218 Ann Abraham, the Ombudsman at the time, confirmed that this panel was the first time the case was presented in its entirety. She told us:

*"The assessment panel was the time I would have seen any paperwork and I think my shorthand really for what those assessment paperwork was intending to do was to be – well, answer the question of can we investigate, is it within remit? Should we? And it was the 'should we' question that would be the subject of the discussion."*¹⁸⁹

5.219 The decision at the meeting was for further discussions to be held between the CQC and the PHSO office. Ms Abraham stated:

"I can tell you what was going through my mind, I think, when I was discussing Mr Titcombe's complaint and what was going through my mind is I could not see how an Ombudsman investigation was going to add anything significant to what was already known. The Trust had accepted the standard of care was unacceptable and it was obvious to me that the failings were systemic and I was concerned that if we took on the case for a formal investigation that could actually delay matters because what was urgently needed was for CQC to do its job as a regulator to ensure that improvements were secured. What I had understood from the assessor was that Mr Titcombe obviously wanted to understand what had happened here but that his primary concern was to prevent this happening to anybody else. I thought that as long as we could be sure that CQC knew about these

¹⁸⁶ Ann Abraham and Kathryn Hudson interview.

¹⁸⁷ PHSO Assessment Panel, 12 August 2009.

¹⁸⁸ Ann Abraham and Kathryn Hudson interview.

¹⁸⁹ Ann Abraham and Kathryn Hudson interview.

systemic failings, that they were taking appropriate action, then we did not need to carry out a formal investigation in order to prove something that was self-evident and we did not need to make formal recommendations to secure improvements in care quality at the Trust. So I was minded not to accept the complaint for investigation but because at that point CQC's position was unclear, and that was something very specific that was in the assessment papers, we had this very vague statement that CQC had delayed taking their relevant action in relation to the Trust pending PHSO's decision. I didn't understand what that meant at all. So I wanted to understand what CQC's position was and I needed more information about CQC's understanding of the situation at the Trust and what it planned to do about it. Without that information I could not safely make a decision on this case about what we should do. So I asked Kathryn to obtain the information and I asked Cynthia Bower who Kathryn should talk about in order to obtain the information.”¹⁹⁰

5.220 There followed a conversation between Ms Hudson and Mr Jefferson from the CQC, which confirmed that the CQC had concerns that ranged wider than maternity and that:

“What he then said to me was he expected that rating to remain at that level for some time and that that would affect the registration of the hospital from April and might mean that the hospital be registered with conditions and what he said to me at that time was and it would mean that they could not at that time apply for Foundation Trust status and they would need to reapply in due course.”¹⁹¹

5.221 Ms Hudson's note of the conversation states:

“The larger question also remains. If this is happening in maternity and children's services what is happening in the rest of the Trust? CQC raised the risk rating of the hospital to red for an initial period. They consider the situation to have improved slightly and have reduced the rating to amber. Mr Jefferson expects the rating to remain at that level for some time until positive actions can be seen from work currently being implemented. The hospital are unhappy about this as in the meantime they will not be able to satisfy Monitor that they should achieve Foundation status until there is sustained improvement. There will be a progress meeting on 17 September 2009. NHS Trusts are in the process of registering with CQC for April 2010. The Chief Executive at Morecambe has been told that CQC will consider their application very carefully to ensure that standards are appropriate. If not, their registration may be limited.”¹⁹²

5.222 On 10 September, Ms Hudson briefed the PHSO on the CQC's current activity and thinking in the form of a note of a conversation she had had with Mr Jefferson. That briefing made it clear that Ms Hudson understood that a decision from the PHSO was pending and raised questions as to whether an investigation by the PHSO might raise expectations that could not be met about answering the family's outstanding questions, suggesting that it *“would be unlikely to alter what the Trust are currently being requested to do by the CQC”* so that *“it may be that there is little to be gained by an investigation”* by the PHSO.¹⁹³

5.223 On 11 September 2009 the Ombudsman, Ms Abraham, confirmed in an email to Ms Hudson her conclusion that she should not accept the case for investigation, stating:

¹⁹⁰ Ann Abraham and Kathryn Hudson interview.

¹⁹¹ Ann Abraham and Kathryn Hudson interview.

¹⁹² Memo from Kathryn Hudson to Ann Abraham, 10 September 2009.

¹⁹³ Memo from Kathryn Hudson to Ann Abraham, 10 September 2009; memo from Ann Abraham to Kathryn Hudson, 11 September 2009.

*"I agree that there is little to be gained by an investigation into this case given that the CQC is clearly taking very seriously indeed the concerns that **** have raised."*¹⁹⁴

5.224 It was on that basis that the PHSO made its decision, reassured that appropriate action was to be taken by the CQC. There is evidence of conflicting information from the CQC, but the understanding of the PHSO was based on this conversation with Mr Jefferson, who was deemed to be representing the views of the CQC. Ms Abraham said to us that:

*"Kathryn [Hudson] and I then had a conversation, so we would have met regularly, we talked about casework issues and on the following day I wrote a memo to her to say that I, in effect, agreed with her assessment and confirming my decision that we should not take the case on for investigation. I did that because at that stage we had clear and documented assurances from CQC that they knew there was systemic failing in maternity services at the Trust and possibly beyond maternity services; that there would be close oversight by CQC of the Trust's action plan to secure the necessary improvements and that progress by the Trust against their action plan would be taken into account in their registration and would also play out in their application to Monitor for FT status. So I suppose I thought that we had secured what we needed to secure in order to actually deliver what needed to happen next to secure improvements in the quality of care at this Trust and, therefore, an Ombudsman investigation was not going to add anything to that. So I then said to Kathryn, will you – I was very concerned that this decision would not be well received by the family. I asked Kathryn to do something which was quite unusual for me to do, which was to ask her to go and visit the family to actually explain our decision before we confirmed it in writing. That took a while to arrange, I think, and, therefore, it was, I think, early February by the time the decision letter came to me for signature."*¹⁹⁵

5.225 Ms Hudson had a further telephone conversation with Mr Jefferson to obtain an update on progress before meeting the family to discuss the PHSO's conclusions, prior to the decision being communicated. She was told of a meeting with the Chair and chief executive of the Trust at which Mr Jefferson made it clear that the CQC expected further progress before it would be satisfied. He also indicated that the *"Trust (along with many others) may be subject to an improvement notice in relation to their registration"*.¹⁹⁶ Ms Hudson then met with the family and further exchanges of correspondence followed. On 3 February 2010 the Ombudsman wrote formally to the family, communicating her decision and outlining her reasons for not undertaking an investigation.¹⁹⁷

5.226 The Investigation is satisfied that the motivation for the decision not to investigate was made with the best intentions and based on the evidence available at the time. It was made on the full expectation that actions were already under way and redress already made would be supported by the CQC looking carefully at the widespread failings it was aware of. The CQC position, however, changed markedly over the next few months moving the Trust from 'Amber' to 'Green' and registering it without restrictions. This was not what was anticipated by the PHSO when its decision was made. Ms Abraham was asked in her evidence to this Investigation:

*"How important in your thinking was the fact that you had reasons to think that there was regulatory action under way?"*¹⁹⁸

¹⁹⁴ Memo from Ann Abraham to Kathryn Hudson, 11 September 2009.

¹⁹⁵ Ann Abraham and Kathryn Hudson interview.

¹⁹⁶ Telephone conversation between Kathryn Hudson and Alan Jefferson, 12 November 2009.

¹⁹⁷ Letter from Ann Abraham, 3 February 2010.

¹⁹⁸ Ann Abraham and Kathryn Hudson interview.

She replied:

“Central and fundamental... Without that I would have done something different and I do not know what because, you know, it is speculation and I am not sure how helpful it is to anybody and particularly to the families.”¹⁹⁹

5.227 In summary, the PHSO decided not to investigate, based on the evidence supplied to it, primarily through the CQC and the Trust, that there was active change under way within the Trust to address the issues raised and that the CQC would address the wider systemic issues. Furthermore, there were not likely to be any remedies that the PHSO could recommend that would go beyond what the Trust had already offered.

5.228 Questions have been raised with the Investigation as to whether there was any agreement between the PHSO and the chief executive of the CQC over which agency was best placed to conduct enquiries. We had the opportunity to ask each of them about their discussions concerning UHMBT during their interviews. We have reviewed the available documentation. We have also heard from the Deputy Ombudsman, Ms Hudson, and from the staff at the CQC with whom she communicated about the case.

5.229 There is documentary evidence that the Ombudsman reached a tentative conclusion at a meeting in the morning of 12 August 2009 that an investigation by her Office would not be undertaken. This was prior to a meeting with the chief executive of the CQC later that day on other matters, at which there was a brief conversation between them about the Trust. We are satisfied that this conversation was intended to identify which officers within the CQC were best placed to liaise with the PHSO in relation to its consideration of a potential investigation into UHMBT. We do, however, accept on the balance of probabilities that Ms Abraham attempted to convey to Ms Bower that the complaint demonstrated systemic problems that the CQC were the appropriate body to address, although this was denied by Ms Bower. There was considerable dialogue between the PHSO and the CQC subsequent to this meeting before the Ombudsman reached her final decision, and the records of this make it clear that the matter remained open for many months. We do not believe that it is plausible that this would have occurred if an agreement had already been reached. We have identified no evidence that there was discussion on this matter between the Ombudsman and the chief executive of the CQC on any other occasion.

5.230 Although it is evident from documentation and from what we heard that there was significant divergence in the understanding of this conversation, the actions that followed make it apparent that the Ombudsman was seeking clarity about the CQC’s position before making her final determination. There were a number of contacts between Ms Hudson and Mr Jefferson about the CQC’s approach and the notes and correspondence contain no suggestion that any agreement had been reached about the way forward.

5.231 We have also found evidence that various officers of the CQC were aware of the thinking of the PHSO at different points in this history and that they considered its implications for its own decisions. This seems inconsistent with the existence of an agreement as to who should take the issues forward. Ms Sherlock told us:

“At around end of August 2009, I was advised – and I believe it was either through Alan Jefferson and the conversation he had with Monitor or through a conversation I’d had directly with Monitor – that the Ombudsman were minded not to investigate and, at around the end of August, we sent a letter to Monitor, saying that, again, we would revisit the CQC decision in light of a formal Ombudsman decision.”²⁰⁰

¹⁹⁹ Ann Abraham and Kathryn Hudson interview.

²⁰⁰ Amanda Sherlock 2nd interview.

5.232 Each organisation reached separate conclusions. However, each was aware of the other's plans. What remains uncertain is not why the PHSO made its decision but why the CQC so rapidly changed its assessment of the organisation and why the views shared with the PHSO changed so markedly so soon afterwards.

5.233 We do, however, retain a degree of disquiet about the PHSO decision not to investigate the complaint. First, whatever the form of the "*robust action*" that it was supposed the CQC was going to take, it would not have addressed Mr Titcombe's concerns that his complaint had not been properly dealt with. Ms Abraham did explain to us that the PHSO process could not add anything further, and why, but it is clear that Mr Titcombe remained dissatisfied. With the knowledge we now have of the extent of the poor practice involved in the investigation of incidents and communication with relatives in the aftermath, this is not surprising, and the lack of investigation does represent another missed opportunity. Second, it does seem to us that if the decision was based in large measure on the understandable view that the CQC should have been better placed to investigate systemic issues, it is disappointing that there was then no attempt to see that it had done so, and that therefore the basis of the decision remained sound. If the system was sufficiently joined up to make a decision conditional upon action by others, it seems to us that it could be sufficiently joined up to follow up.

The Nursing and Midwifery Council

5.234 The Nursing and Midwifery Council is the UK regulator for nurses and midwives. The Council sets the standards for nurses and midwives to meet in their working lives and has developed a code of conduct that states how they must work and behave. It also sets the standards for education and conduct to make sure that midwives have the right skills and qualities when they start work. The education standards set by the Council are for nurses' and midwives' entire careers, post-qualification. Nurses and midwives must continually train and take part in learning activities to show that their skills and knowledge are up to date.

5.235 The NMC also maintains a register of all nurses and midwives in the UK who are entitled to practise and investigates allegations that registrants are unfit to practise when they are referred to them. Referrals may be made by individuals or by employers.

5.236 In addition, the legislation under which the NMC operates sets out the arrangements for midwives to be supervised, a system that is unique to midwifery.²⁰¹ The purpose of supervision of midwives is to protect women and babies by actively promoting safe standards of midwifery practice. Supervision is a statutory responsibility that provides a mechanism for support and guidance to every midwife practising in the UK and is a means of promoting excellence in midwifery care. This role is the responsibility of Local Supervising Authorities. In England, the Local Supervising Authority is NHS England, the functions having been transferred from the former Strategic Health Authorities following their abolition, and the establishment of NHS England, by the Health and Social Care Act 2012. The NMC sets the rules and standards for the functions of the LSAs and these are carried out for the LSA by supervisors of midwives. The Nursing and Midwifery Council (Midwives) Rules 2012 govern the framework in which midwives, SoMs and LSAs meet the requirements of the Nursing and Midwifery Order 2001.

5.237 The SoM role should be entirely different to a midwifery manager, who is responsible and accountable to the employer for making sure that maternity services run effectively. However, in small units the proper separation of roles is difficult. In UHMBT the maternity risk manager was also a supervisor of midwives. In relation to one of the cases examined by the PHSO the two SoMs who decided that there were no midwifery issues to warrant an investigation had in fact been present during the mothers' labour, albeit in a supporting role. While this was not inconsistent with guidance,

²⁰¹ NMC Review of Midwifery Regulation, 28 January 2015.

it is unlikely to give confidence to families.²⁰² In the context of a unit such as that at Furness General Hospital, where significant cultural problems were present, there is a substantial risk that supervisory investigations will be insufficiently independent to identify poor practice when this arises from a lack of awareness within the unit of standards of care provided elsewhere. This appears to have been a significant factor in reinforcing the isolation of midwifery practice at FGH and the apparent independence of supervision gave false reassurance.

5.238 All midwives have a named supervisor whom they are required to meet with at least once a year. The LSA requires that SoMs are experienced, practising midwives who have undergone education and training in the knowledge and skills needed to supervise midwives. SoMs act as an impartial monitor of the safety of midwives' practice and they should encourage midwives to develop their skills and knowledge. SoMs also have a role in relation to women. Part of this role is to support them if they have problems accessing care or a choice of care, for example the place of birth.

5.239 The LSAs are obliged to verify to the NMC that the standards for supervision of midwives are being met across the UK. Every LSA is required to submit an annual report that provides an opportunity to inform both the NMC and the public of its activities relating to the statutory supervision of midwives. These annual reports will also highlight the main challenges faced throughout that year.²⁰³

Role of the Nursing and Midwifery Council – external review

5.240 In response to the incidents that occurred at the Trust, the NMC commissioned its review of UHMBT. The purpose of the review was to assess that all requirements regarding the statutory supervision of midwives were in place and that they were effective in supporting safe midwifery practice, and identifying and responding to poor and unsafe practice. The review was undertaken in July 2011 and followed up in June 2012, with a report published the following month.²⁰⁴

5.241 The review found that statutory supervision was effective with a motivated and increasingly confident group of midwives. The NMC found that progress had been made to define the role of the SoM and to clearly distinguish it from midwives' substantive roles within the unit, although there were still challenges to this. Of the 15 recommendations made by the NMC, eight were met, six were partially met and one – relating to the Trust's governance systems and processes – was recorded as not met, as it had to be addressed by the Trust Board and not solely by midwifery managers.

5.242 Following the publication of the PHSO's investigations into three cases arising from failures in maternity care at the Trust,²⁰⁵ and their findings that the role of supervision of midwives be reviewed, the NMC commissioned an independent review of midwifery regulation by the King's Fund.²⁰⁶

5.243 The King's Fund review has only recently been published and its core recommendation is that the NMC, as the professional healthcare regulator for midwives, should have direct responsibility and accountability solely for the core functions of regulation, and the legislation pertaining to the NMC should be revised to reflect this. This would mean that the additional layer of regulation currently in

²⁰² Midwifery Supervision and Regulation – A report by the Health Service Ombudsman of an investigation into a complaint from Mr M about the North West Strategic Health Authority.

²⁰³ *Supervision, Support and Safety: Report of the quality assurance of the local supervising authorities 2012–13*. NMC, 2013.

²⁰⁴ *Nursing and Midwifery Council review of University Hospitals of Morecambe Bay NHS Foundation Trust*. NMC, 2012.

²⁰⁵ Midwifery Supervision and Regulation: Recommendations for change; Midwifery Supervision and Regulation – A report by the Health Service Ombudsman of an investigation into a complaint from Mr L about the North West Strategic Health Authority; Midwifery Supervision and Regulation – A report by the Health Service Ombudsman of an investigation into a complaint from Mr M about the North West Strategic Health Authority; Midwifery Supervision and Regulation – A report by the Health Service Ombudsman of an investigation into a complaint from Ms Q and Mr R about the North West Strategic Health Authority.

²⁰⁶ www.nmc-uk.org/media/Latest-news/The-Kings-Fund-to-undertake-independent-review-of-midwifery-regulation/

place for midwives, and the extended role of midwifery supervision exercised by the NMC, should end.

5.244 Although this Investigation was concerned with supervision in a single Trust, it has seen some evidence that related to the issues raised in the King's Fund report. There was evidence of confusion of managerial and supervisory roles and SoMs in UHMBT seemed to regard their role as supportive rather than regulatory. There was no evidence that supervision as practised in this Trust provided any significant protection for women. It is not clear that the LSA function, described above, was effective in this regard either. There is evidence that the chief executive of the Trust felt that the LSAMO made his relationship with the families more difficult.²⁰⁷ Although the LSAMO spent some considerable time with one of the families, which was initially perceived as constructive, it is not clear that they ultimately found this helpful.

The General Medical Council

5.245 The GMC maintains the register of those licensed to practise medicine in the UK. It also considers the suitability of practice settings for medical graduates who are new to full registration, agreeing the status of 'approved practice settings' (APS) in which they can work. To obtain this status, organisations must have systems in place to:

- provide doctors with appropriate supervision and regular appraisal;
- identify and act upon concerns about a doctor's fitness to practise;
- support the provision of relevant training and continuing professional development for doctors;
- provide regulatory assurance.

5.246 UHMBT had APS status from the introduction of the new registration framework in November 2007. In 2007, recognition of NHS hospitals in England was based on a self-declaration from the Trust confirming that it satisfied the APS criteria alongside information provided by the then Healthcare Commission (HCC) about the Trust's performance against standards. The APS status of UHMB FT was subsequently reviewed following the CQC investigation of 2012, and in July 2012 the GMC wrote to the Trust outlining a number of concerns in relation to Furness General Hospital and Westmorland General Hospital, both of which had not met three main aspects of the APS criteria, and in relation to the Royal Lancaster Infirmary, which had not met ten main criteria.

5.247 In August 2012, the Trust submitted to the GMC comprehensive action plans addressing all concerns raised around the non-compliance areas. The GMC decided to delay its approval until the completion of the North Western Deanery's visit, due on 25 October, and its report, as the visit may have highlighted further concerns that should be taken into account. The report was received in November 2012, and detailed no immediate concerns, as trainees generally reported a good experience, although there were some issues with access to education, lack of senior support, induction and handover. The Deanery set a number of conditions in response to the visit. The general picture from Deanery visits over the period 2007–2013 was that they identified good practice at the Trust, with notable areas that still required improvements, but that the number of recommendations made to the Trust during all the visits was no greater than for other Trusts; therefore the Trust was not perceived as an outlier.²⁰⁸

5.248 Taking this into consideration, the GMC agreed for the Trust to retain its APS status with an early review scheduled for 2013. In January 2013 Westmorland General Hospital was reported as fully compliant with CQC outcomes and a subsequent CQC report in March 2013 identified that the

²⁰⁷ Email from Tony Halsall to Chris Dent, 29 October 2010.

²⁰⁸ GMC University of Morecambe Bay NHS Foundation Trust Internal Review, November 2013.

Royal Lancaster Infirmary was non-compliant in relation to complaints. In April 2013 a further review was undertaken of the Trust and action plans were requested and submitted with continued APS approval given to the Trust on 31 July 2013.

5.249 In 2013, the GMC commissioned an independent review to assess what internal information it held and had acted on between 2007 and 2013 in relation to the cluster of infant and maternal deaths at the Trust.²⁰⁹ The review systematically searched the GMC databases and identified 5,217 records within the GMC document management system in which the Trust or one of its sites was mentioned. It also identified 150 complaints in its fitness to practise database. Each of these records was reviewed individually to see whether there may have been a pattern of cases that could have alerted the GMC to wider organisational issues. Of these, 44 related directly to the Trust. Thirteen related to the serious clinical issues and poor standards of care, including infant and maternity services, at the Trust between 2007 and 2013.

5.250 The review determined that each of the 13 reviewed complaints concerning the fitness to practise of individual doctors was conducted in accordance with GMC guidelines. While some of the reviews did include complaints against doctors, especially in obstetrics and gynaecology and paediatrics, in a number of cases it was difficult for the GMC to establish concerns about the individual doctor's fitness to practise. In further instances it was difficult to establish the individual doctors responsible at the time of an incident. There are a few complaints that remain open and are part of an ongoing police investigation; the GMC will not proceed further with its own investigations until the police have completed their work. The review has underlined the difficulty in highlighting any serious concerns with the Trust through the fitness to practise data.

5.251 However, the review noted that each complaint made about a doctor's fitness to practise could include other contributory factors about an incident which may have had an impact on the patient outcome. These contributory factors (known as human factors) could include staffing resources, workload, job stress and anxiety; lack of training, teamwork and in some cases the breakdown in communication between clinicians. The 13 complaints were reviewed with this in mind and a number of factors were identified that contributed towards a serious outcome or death including:

- mother had been given antibiotics for an infection but the clinical staff failed to recognise the signs and symptoms that indicated the baby also had an infection;
- inappropriate comments relating to the clinical care of a baby representing a significant departure from the guidance set out in *Good medical practice*;
- incorrect diagnoses of chest x-ray and bullying of a junior clinician who queried the abnormality;
- delays obtaining and interpreting scans had a direct impact on the patient outcome;
- poor communication between clinical staff including midwives;
- poor handovers between all healthcare practitioners;
- on-call consultant could not be identified for a high-risk maternity delivery;
- medical equipment not in good working order;
- clinical staff being unfamiliar with medical records of patients until patients clarified the issues;
- clinical records not updated appropriately.²¹⁰

²⁰⁹ *Recommendations of the University Hospitals of Morecambe Bay NHS Foundation Trust Internal Review*. GMC, 2013.

²¹⁰ GMC University Hospitals of Morecambe Bay NHS Foundation Trust Internal Review, November 2013.

5.252 While the review concluded that the GMC did discharge its duties appropriately in relation to individual complaints about doctors working at the Trust, it made recommendations about ways that the GMC could better use the information it gathered in the course of its work to assess potential problems in the future:

“The GMC must use its wealth of knowledge, experience and its capacity as a regulator to approach patient safety from a wider, more holistic perspective to ensure that it maintains its focus on protecting the public while continuing to maintain standards within the medical profession.”²¹¹

5.253 The review recommended that the GMC consider making changes to develop a strong model for improved services and standards in relation to data surveillance, doctors' service history, and regular surveys. These were to ensure the data held by the GMC was exploited in order to support quality surveillance and those responsible for promoting patient safety, including Boards. A programme of work to take this approach forward was agreed by the GMC at its meeting on 22 July 2014.²¹²

The Health and Safety Executive

5.254 The HSE is an enforcing authority responsible for the regulation of health and safety at work in Great Britain and was established by the Health and Safety at Work etc. Act 1974 (HSWA). Its mission is the prevention of death, injury and ill health to those at work and those affected by work activities. It also investigates incidents and complaints about health and safety practices. It is the only regulator that has duties towards employee health and safety, and it therefore pays particular attention to issues relating to staff. However, the HSWA section 3 places general duties on employers to ensure, so far as is reasonably practicable, that persons other than themselves or their employees are not exposed to risks to their health or safety.

5.255 Whilst certain incidents to patients are reportable to the HSE under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR), the vast majority of deaths that occur due to failures in the healthcare system are not. In particular incidents that occur under medical treatment or supervision are not reportable. Detail is given on the reporting criteria on the RIDDOR pages of the HSE website.²¹³ The Trust reported 269 cases to the HSE under RIDDOR between 2006 and June 2013, the majority of which related to injuries to staff.²¹⁴ The HSE only received one RIDDOR report that falls within the Investigation's terms of reference. This related to an incident in October 2011, involving the birth of a baby at Royal Lancaster Infirmary, during which the failure of some ventouse equipment occurred. The baby died on 12 October 2011 but the incident was not reported until 17 February 2012 and was not investigated. A copy of this RIDDOR report (Report No. 222E4F3F93) was sent to the police on 20 September 2012 along with a number of others. None of the five cases referred to the HSE by the police in May 2012 were reportable under RIDDOR,²¹⁵ and none was in fact reported by the hospital.²¹⁶

5.256 The HSE has the power to investigate accidents in order to determine their causes, whether action has been taken or needs to be taken to prevent a recurrence and to secure compliance with the law, identify lessons to be learnt and to influence the law and guidance, or what response is

²¹¹ GMC University Hospitals of Morecambe Bay NHS Foundation Trust Internal Review, November 2013.

²¹² GMC Strategy and Policy monitor summary from meeting, 22 July 2014.

²¹³ RIDDOR in health and social care: www.hse.gov.uk/healthservices/riddor.htm

²¹⁴ Submission from the Health and Safety Executive in response to the request for information and documentary evidence by the Morecambe Bay Investigation.

²¹⁵ Operation Scarf – Section 3 analysis of information provided by the police.

²¹⁶ Email from Mark Dawson to Jack Alan Montague, 20 September 2012.

appropriate to a breach of the law. In selecting which complaints or reports of incidents to investigate, and in deciding the level of resources to be used, the HSE takes account of the following factors:

- the severity and scale of potential or actual harm;
- the seriousness of any potential breach of the law;
- knowledge of the duty holder's past health and safety performance;
- the enforcement priorities;
- the practicality of achieving results;
- the wider relevance of the event, including serious public concern.

5.257 There is specific guidance on the regulation of healthcare, which indicates that the HSE might investigate incidents where a death has occurred, or where the harm was so serious that death may have resulted, that have clearly been caused by well-established standards not being achieved and the failure to meet them arising principally from a systemic failure in management systems. In general, it will not investigate where the incident arises from poor clinical judgment (rather than a failure to implement the actions flowing from clinical judgments); or is associated with 'standards of care', such as the effectiveness of diagnostic equipment or the numbers and experience of clinicians, or the quality of care, such as hydration and nutrition; or it arose from the disease or illness for which the person was admitted – unless the prime cause was inadequate maintenance of or training in the use of the equipment needed to treat the disease or illness.²¹⁷

5.258 The HSE gives a worked example of how this might apply to incidents arising in the course of the care of patients, as follows.²¹⁸

10. Drug error causing death or serious injury

HSE does not investigate deaths or illness that occur due to a failure to diagnose and effectively treat a medical condition, if the cause of death was that medical condition. However, HSE may, subject to other criteria being met, investigate deaths where the direct cause was not the medical condition being treated, but was caused by failure of some aspect of the medical treatment process such as a drug error or related equipment failure.

Some factors tending towards investigation

- a) The incident was directly caused by inadequate training in the use of equipment, such as syringe drivers used to administer drugs; or
- b) The error was directly caused by poor storage of similarly labelled drugs; or
- c) The error can be directly linked to a failure to implement known and communicated actions set out in MHRA, NPSA or other safety alerts.

Some factors tending away from investigation

- a) The drug error was due to an incorrect clinical decision – a clinician prescribed the wrong drug, wrong dosage or drug formulation; or
- b) The drug error was due to a prescription being wrongly fulfilled by a pharmacist; or
- c) The person administering drugs (or making associated measurements and calculations such as a patient's weight) was a properly trained, authorised healthcare professional and the error made was a genuine mistake by that individual; or
- d) The error was due to design failure of medical equipment, which was unknown or had not been made known to the organisation through appropriate channels such as MHRA or other safety alerts.

²¹⁷ www.hse.gov.uk/healthservices/arrangements.htm

²¹⁸ www.hse.gov.uk/enforce/hswact/docs/situational-examples.pdf

5.259 In December 2008, the HSE was asked by one of the affected parents to investigate the death of their baby. The family was told that the HSE's role was limited, but that it would ensure the relevant organisations were aware, and make enquiries to ensure that any health and safety issues uncovered during the SUI process were being properly managed.²¹⁹ The HSE therefore contacted the Trust:

*"Although I think most of the issues are outside of HSE's remit, I need to be assured that any matters that are possibly relevant to HSE have been looked at by the SUI team; that your team has been properly involved and that any necessary action has been taken."*²²⁰

5.260 Mr Stephen Garsed, Field Operations Directorate Inspector at the HSE, had conversations with the Trust's Health and Safety Manager, Anna Smith, and the Chief Executive, Mr Halsall, and ascertained that the Healthcare Commission had been informed of the SUI electronically and that two independent clinicians had been brought in to investigate the events. The HSE records indicate that Mr Garsed was satisfied that:

*"The issues were clinical and involved particularly training and communication. The unit was busy, but there was no causal link between staffing levels and the death... [he] would be discussing issues of management competence and staff engagement when [he] discussed the Management Standards with the Trust's Steering Group on Friday and that some of the benefits of the MS approach might be applicable to clinical performance. No further action."*²²¹

5.261 The position was explained to the family in a letter and the HSE regarded the matter as closed in February 2009. The letter indicated that the HSE was engaging with the Trust on matters within its remit:

"Having looked at the papers, I am satisfied that there are no specific health and safety matters to take forward. However, as part of my continuing work with the Trust, I am liaising with a Working Group which is looking at how the Trust can implement HSE's Management Standards. There are three main strands to the Management Standards: (i) leadership from the top; (ii) management competence and (iii) employee management.

Although the Management Standards arose from HSE's work on stress, they provide a framework for improving management, not just in health and safety, but also in clinical and support areas...

*I visited the Trust on 20 February, amongst other things to provide support and advice to the Working Group. I made it very clear that the benefits of the Management Standards extended to managing clinical and other risks, a point that was clearly understood."*²²²

5.262 The case was re-opened briefly in January 2010 on further communication from the family. In June 2011, it was re-opened following the inquest into the baby's death and a formal request was made to the HSE to investigate in August 2011. The HSE declined to investigate, stating that it did not generally investigate "matters of clinical judgment or relating to clinical care".²²³

5.263 Subsequently, the HSE received further information from the police investigation in 2011, and are still considering its response.

²¹⁹ Cases Report, 31 January 2014.

²²⁰ Email from Stephen Garsed to Anna Smith, 23 January 2009.

²²¹ Cases Report, 31 January 2014.

²²² Letter from Stephen Garsed to Mr and Mrs Titcombe, 26 February 2009.

²²³ Letter from Geoffrey Podger, HSE, to James Titcombe, 24 August 2011.

Relationships between organisations and coordination of responsibilities

5.264 One of the features of the picture that has emerged from our Investigation is the complexity of the regulatory context and the extent to which organisations relied on assessments made by others or assumptions about the intentions of other organisations to use their powers.

Care Quality Commission, Monitor and Department of Health liaison

5.265 Ms Sherlock explained the system for sharing intelligence between the CQC and other organisations. She would have weekly telephone conversations with counterparts at the Department of Health, and at Monitor (Assessment Director Miranda Carter and Portfolio Director Adam Cayley). There was a monthly face-to-face meeting. These meetings were not minuted, and there was no shared action plan from them, but they would be used to inform the CQC's risk log. She was not involved in any regular meetings with the PHSO, but she thought that there was an agreed memorandum of understanding. There were also memoranda of understanding with the professional regulators (the GMC and NMC), with whom the CQC's head of regulatory risk (Louise Dineley) had meetings.

The Health and Safety Executive

5.266 The HSE has clear and publicly available memoranda of understanding about liaison with other regulators and provides guidance on the different functions of regulators on its website.²²⁴ It responded fully to police requests to consider referrals and sought to make sure that the other regulators were aware of relevant matters. For example, Carol Forster, HSE Inspector, wrote to both Monitor and the CQC on 19 February 2013 to make contact with a view to sharing relevant information.²²⁵ The HSE told us that Monitor did not respond to this communication.²²⁶ Beverley Cole, the CQC's former Compliance Manager for Cumbria, responded in a general email of 21 February 2013.²²⁷ Mrs Forster replied to Ms Cole in an email on 27 February 2013 outlining matters referred to in CQC reports for the Trust that may have been potential health and safety issues over which the HSE may have had a remit.²²⁸ On 15 March 2013, there was a telephone conversation between Mrs Forster and Ms Cole. The CQC outlined its contact with the Trust but indicated that there were no issues identified that were of relevance to the HSE.

5.267 The evidence presented to the Investigation by the HSE indicated the steps that it had taken to cooperate with and inform colleagues. It also identified what the HSE sees as a regulatory gap:

"The regulatory gap in healthcare

HSE recognises that the lack of a comprehensive set of powers by other regulators, who may otherwise be better placed to act, often leaves it as the 'regulator of last resort', to whom those affected by provider failures look to secure justice.

Because HSE can only enforce where there has been a breach of the legislation it enforces, and because HSE needs to follow its policies and procedures as to when it should investigate, there is effectively a 'regulatory gap'. Providers may escape prosecution, even

²²⁴ www.hse.gov.uk/healthservices/arrangements.htm

²²⁵ Letter from Carol Forster to Adam Cayley, 19 February 2013; letter from Carol Forster to Joanne Wildman, 19 February 2013.

²²⁶ Submission from the Health and Safety Executive in response to the request for information and documentary evidence by the Morecambe Bay Investigation.

²²⁷ Email from Beverley Cole to Carol Forster, 21 February 2013.

²²⁸ Email from Carol Forster to Beverley Cole, 27 February 2013.

if their failures and the consequences have been very serious, because of this regulatory gap.

HSE has expressed concerns about this situation for some time, for example in a Memorandum to the Health Committee dated 16th September 2008. These concerns were also expressed in HSE's evidence to the Mid Staffordshire NHS Foundation Trust Inquiry.

The Government's response to the Francis Inquiry Hard Truths²²⁹ states that the regulatory gap will be closed in England by CQC acquiring powers to prosecute registered providers where there have been serious failures to provide safe or satisfactory care.

New registration regulations for CQC (giving them enhanced powers) are currently out to consultation. These new regulations should enable the vast majority of patient harm cases to be taken by CQC, with HSE only taking cases where it has more specific powers (or where CQC has none). HSE believes that it is right that the specialist regulator has this investigatory role and that it will be best placed to secure necessary improvement both locally and more widely.”²³⁰

Gold Command

5.268 On two occasions within the period covered by the Investigation, the NW SHA called a Gold Command to coordinate management of what it perceived to be crises. The most important of these covered a significant period of time from late 2011 and concluded with a stock-take in 2012.

5.269 The proliferation of interest in the Trust around the time that Gold Command was called was intense. Dr Bewick, Medical Director and Chair of Gold Command at Cumbria PCT, expressed some sympathy for Mr Halsall:

“There were so many people looking at Morecambe Bay at that particular time, and I think the SHA had been one day, and he said ‘How many times do we have to be beaten up and told we’re crap? Surely once or twice is enough, and we’ll do something about it.’ So there was a sense of drowning in the number of people coming in and criticising them, and what we hoped Gold would do was actually to minimise, well, to bring it together for them, so that they were just clear about what the actions they needed to do to make sure that there was transformation.”²³¹

5.270 There was other evidence of a siege mentality. Peter Clarke, the PCT-nominated Governor to the Trust told us:

“I’d link that with a cultural issue, because, again, there’s a sense that for years they had felt themselves to be battered for one thing or another, and had developed a coping mechanism which was about sort of batting that off rather than getting down underneath it. And as a governor during that period, there was no sense that the governors were being presented with anything other than the... I would almost say it was seen as a kind of irritation, as opposed to the fact that there was something significant in it.”²³²

²²⁹ *Hard Truths: The Journey to Putting Patients First*. Vol 2 of the Government Response to the Mid Staffordshire NHS Foundation Trust Public Inquiry: Response to the Inquiry's Recommendations, January 2014.

²³⁰ Submission from the Health and Safety Executive in response to the request for information and documentary evidence by the Morecambe Bay Investigation.

²³¹ Mike Bewick, Peter Clarke, Neela Shabde interview.

²³² Mike Bewick, Peter Clarke, Neela Shabde interview.

5.271 From the PCT's perspective, the calling of Gold Command brought a number of benefits, including making the Trust face up to its problems and giving it an opportunity "to call a halt; just to say 'This is a moment in time when we are taking stock and looking critically at the whole Trust and its environment around it'." ²³³ Mr Clarke continued:

"The definition of why you called Gold incidents includes that threat to the wider economies, and so we felt we had a very substantial case for doing so, and that in itself would bring in a supportive mechanism to the Trust, who we felt were in the headlights a bit, and trying to persuade themselves it was only a bit that was going wrong, when in fact there were things that we were really concerned were more widespread, and our view was the SULs and things like this were demonstrating it wasn't just one part of the Trust that had a problem but others. And so the first one was how can we support this to improve it..."

We realised at the time that the reputation of the Trust was just being destroyed, either extremely by the media or because the staff, we just couldn't get people to go and work there, and they were struggling with it, so there was a whole host of things that we were concerned about, that the Trust would just carry on going downwards, and we had to try and help them get back on a route that was at least stabilising at first, and then improving. So we – John Ashton and myself – actually at that time said to Sue Page that we thought the best way of doing this was to call an incident. Cumbria at the time had a good experience of calling incidents, we've had shootings and floods and rail crashes and various other things, and it struck us as being an unusual way of doing it, perhaps, but a good way in the sense that it would bring everybody to the table, and you got a much greater honesty when that happened." ²³⁴

5.272 Mr Halsall, Chief Executive of the Trust, did not see this as a supportive step. He was described by Dr Bewick as taking it:

"... through gritted teeth, I think, would be a fair way of saying it. He was very disappointed to have come to this, and he must I suppose have felt that it was a level of personal failure, to have come to this. He was... I think it took him a little, a few weeks to acclimatise, because he had so many investigations recently, and inputs and negativity that I think he found this as a negative event rather than what I was trying, and I met him several times to persuade him..."

His senior team too; they saw it as an added burden, and an unwelcome added burden, as opposed to an assistance or support or benefit. Initially." ²³⁵

5.273 It was also unclear whether Gold Command served to enable the Trust to learn how to address the problems or to undermine its ability to do so independently. Dr Bewick rejected the suggestion that Gold Command created a "learned helplessness" on the part of the Trust, but he then told us that it became a normal way of working:

"I think I said to them it'll be at least three months, and should that sort of buck CQC's position in a way, yes, at that time, and it was only when we realised particularly the complexity around the outpatient one, which took ages to do. I mean, to be honest I was always looking for an excuse to stand Gold Command down, don't get me wrong. I didn't want to make my days longer by this. You know, you were trying to find positive reasons to stop it, and we had to, but there were certain things that happened because of the organisations finding other problems, so it would have seemed very strange to the public

²³³ Mike Bewick, Peter Clarke, Neela Shabde interview.

²³⁴ Mike Bewick, Peter Clarke, Neela Shabde interview.

²³⁵ Mike Bewick, Peter Clarke, Neela Shabde interview.

when new problems were arising that you would have stopped prematurely. And in truth we got into a way of working together that I think became almost normal business for them, in altering the operations of the three hospitals.”²³⁶

5.274 Senior Trust leadership devoted time to responding to Gold Command requirements, including action plans, but it was not clear that this was connected to internal change so much as keeping external scrutinisers happy. Far from supporting sustainable change, it reinforced the disconnect between Board and wards by requiring senior Trust managers to be externally focused. It is possible that the use of Gold Command was understandable in the immediate context of Cumbria, which had recently used a similar mechanism to respond to crises caused by flooding and a mass shooting. However, it was not a suitable vehicle for resolving the underlying problems in the Trust. On one account it even contributed to the decision of the CQC not to investigate maternity services in 2012 because extra resources would have been in place during Gold Command, which would suggest that the Trust complied with relevant standards, but that would not have continued once Gold Command was stood down.

5.275 It seemed an unusual step to use such a technique to address what were essentially chronic management problems rather than a sudden emergency. It was not clear to the Investigation precisely what the purpose was and how if at all it would assist in reaching a sustainable solution to leadership problems at the Trust. In fact, the perceived need to call Gold Command seemed to the Investigation to reinforce the failure of the system to address the difficulties of the Trust through normal commissioning and performance management channels.

Chapter conclusions

1. *Complexity of system.* The review of external responses to the issues within our terms of reference demonstrates how many agencies had management or regulatory responsibilities that related to the issues we have examined. It was difficult for us to identify and trace through their interactions with the families and the Trust. It is not reasonable for the NHS to expect its users to face such a complex array of supervisory organisations without clear support in navigating the system and getting to the right people in a timely way.
2. *A system in transition.* A persistent feature of the material we have studied is that the health system was in some turmoil due to the transition to new governance or management arrangements. The NHS is a complex system with many organisations dealing with multiple agencies. Add to that a continuous set of restructuring and reorganisations, and the risk of things being missed, misunderstood and wrongly actioned increases massively. In this case, the Trust was moving to Foundation Trust status, dealing with a developing and changing authorisation process; the CQC was being established and its powers and methods of working were changing; the PHSO was changing and its responsibilities altering; Monitor was developing its ways of working; the SHAs were moving to new expanded geographies; and, as time went on, the whole system was grappling with the findings of the Francis Report. Such circumstances bring with them significant levels of risk.
3. *Missed opportunities.* We have identified a series of points at which there were contacts between the external agencies and the Trusts that might have prompted them to look closely at the maternity services that it provided. There were different, and often understandable reasons, for decisions not to do so, but at no point did any one of the agencies take on the task of examining the full picture.
4. *CQC failings.* The organisation that most clearly failed to deal adequately with the Trust was the CQC. It was newly formed in April 2009 from the merger of two large organisations and a smaller one, with a very broad remit for regulation of the whole health and social care sector.

²³⁶ Mike Bewick, Peter Clarke, Neela Shabde interview.

It is clear from the example of this Trust that the way it set about these tasks was wholly inadequate, and the results were the series of inconsistent judgments, communication breakdowns and misdirected visits that we have set out. As well as the organisational upheaval and size of the new task, the decision to make generic appointments to senior and inspector posts meant that many of the key individuals in the North West had little or no NHS experience or knowledge of the local Trusts.

5. *Over-reliance on the judgments of others.* There is a persistent pattern of external organisations and the Trust taking assurance from each other that there was not a fundamental problem with the maternity services at the Trust. Assumptions were made about the extent to which others had given detailed consideration to the evidence, when in fact they had not. There were also expectations that further consideration by others provided a safety net that matters were being kept under review, when in fact this did not happen. This is partly due to a lack of clarity over responsibilities and the alignment of the system to ensure that actions were taken and not assumed.
6. *False assurance.* In particular, the system took false assurance from the apparent consistency across organisations of the view that the incidents of 2008 were not linked, when in fact this was no more than the repeating of assessments made very early on without this being directly examined by others. Much was made of the Trust's failure to disclose the Fielding Report in a timely manner, as if it contained crucial new information. However, a much greater barrier to the external agencies' realisation of the issues was the mistaken belief that Dame Pauline Fielding had examined the incidents of 2008 and was satisfied that they were not connected. This became received wisdom and was the basis on which key decisions were made by the CQC, Monitor and the PHSO, as well as in Whitehall and Westminster. Had those giving briefings at this level read the report themselves, they would have seen that this was false assurance.
7. *Cover-up?* The overwhelming impression created by the evidence that we have uncovered shows that the external agencies that were contacted about issues at the Trust took them seriously and sought to respond appropriately. We did not find evidence that people intended to hide issues at UHMBT, but we did see a pattern that resulted in the failure of the system taken as a whole to investigate fully the problems at the Trust. The regulatory bodies had a strong sense of the limits of their jurisdiction and concerns about trespassing on the work of others. This led to a tendency to approach matters raised with them in terms of what their discrete role was, not how the system would get a clear picture of the issues. This has had the effect of obscuring the nature and extent of the problems and has left the families facing an incoherent and fragmented approach to their concerns.
8. *Overall responsibility.* There was insufficient clarity as to who was responsible for ensuring that the system operated effectively to understand the concerns of the families and establish what had occurred. Within the NHS, at regional level, this leadership responsibility clearly sat with the NW SHA. It was exercised through Gold Command but not consistently or effectively in relation to the concerns raised by families. With the abolition of SHAs there is no longer any NHS organisation with this role, although we were told that Quality Surveillance Groups might be the place where issues would be considered. There was no clear leadership responsibility or structure for the coordination of regulatory activity. Although arrangements were in place for communication and liaison between organisations, in relation to UHMBT there was no explicit plan that came out of these to ensure the overall work of those organisations comprehensively addressed the issues.

5.276 John Woodcock MP summarised the families' experience of the NHS systems for accountability in these terms during the House of Commons debate on 19 June 2013:

*"It is hard to imagine what it must be like to lose a child, but then to be faced with an almost impenetrable wall of bureaucracy, with one organisation and one group of people passing them over to another group, and with all of them ultimately washing their hands of accountability, is truly shocking."*²³⁷

5.277 While the responsibility for delivery of care sits with individual clinicians and the Board of UHMBT is accountable for its quality, the external regulatory system of the NHS failed to get to grips with the issues that the affected families were bringing to them.

²³⁷ www.publications.parliament.uk/pa/cm201314/cmhansrd/cm130619/debtext/130619-0002.htm

CHAPTER SIX: Questions raised about the scrutiny of perinatal and maternal deaths

Inquests into deaths of babies affected by perinatal events

6.1 An inquest is a legal process of very long standing that follows some deaths, and is conducted by a coroner, sometimes with a jury. It is generally described as a fact-finding exercise that is intended to establish who died, when, where, how and in what circumstances. It takes the form of an investigation of the facts, and is not based on contesting claims or pleas, described formally as inquisitorial not adversarial. Each coroner is responsible for a geographically defined jurisdiction, and for deciding which deaths occurring within that jurisdiction require investigation.

6.2 The death of a baby as a result of events in and around labour and delivery may show some features that are rather different to other, more common forms of death, and on occasions the coronial process does not appear well adapted to those features. This can lead to a concern amongst bereaved relatives that less rigour has been applied.

6.3 First, there may be significant doubt over whether a death should be subject to the coronial process at all. If a baby shows no signs of life after birth then it is said to have suffered a stillbirth and has not existed independently. Until recently, coroners generally held that their legal powers extended only to deaths that followed a live birth, excluding the possibility of holding an inquest into the death of a stillborn baby. As a result, although most families will receive an open and honest explanation of what has happened from the clinicians caring for them, there is no recourse to an inquest when there is controversy or a less than frank admission of what has happened.

6.4 Additionally, knowledge of the way that this cut-off is applied gives a subtle incentive for staff to record a death as a stillbirth where there is some doubt about whether there were signs of independent life, and to exclude signs of life that might be explicable on the basis of resuscitation alone. It also gives an incentive to Trusts to argue to the coroner that holding an inquest would be wrong in law following a stillbirth, as the University Hospitals Morecambe Bay Trust (the Trust) did following one of the 2008 deaths.

6.5 In reality, this cut-off is an artificial construct that does not accord with modern understanding of the physiology of childbirth. The transition of a baby from life in the womb to life in the outside world is a truly remarkable one that depends on drastic alteration mainly in the blood circulation and lungs, but it is not instantaneous. Nor are the root causes of death, principally shortage of oxygen to the baby during labour, greatly different according to whether death occurred before or soon after delivery; indeed, some babies so affected may survive for days or weeks before succumbing. This is a spectrum not a yes–no divide.

6.6 We believe that the exclusion of some deaths from inquest on the basis that they were stillbirths is both illogical and unhelpful. While the majority of stillbirths would not require an inquest, being both readily explicable and non-controversial, correcting this anomaly would, where there is uncertainty, bring the position into line with the rest of the coronial system and offer some families the prospect

of a more definitive account of what has happened. It does appear that some coroners are prepared to do this now, and there has been a high-profile case in Northern Ireland,¹ but we believe that this needs to be applied consistently. This would require expert review of the legislation.

6.7 Second, neonatal deaths not uncommonly occur to babies who were born in one coroner's jurisdiction but die in another's. This comes about because some aspects of the care of very sick newborn babies are specialised and best provided in larger neonatal units offering neonatal intensive care; some care that depends on very complex expertise and technology can only be provided in more centralised tertiary centres. Thus a baby born in poor condition in Barrow may be transferred to Preston, Manchester, Leeds or Newcastle and, when all efforts have failed, die there. The problem is that to the receiving paediatric team, the death is of course sad but not at all unexpected or inexplicable: it is due to the condition of the baby at the time of transfer. Thus the coroner in whose jurisdiction the death occurred sees no reason to investigate, and the coroner in whose jurisdiction the baby was born does not have the legal power to investigate.

6.8 Although in some cases this can be circumvented by the former coroner (in whose jurisdiction the death occurred) asking the latter coroner to investigate events around the time of the birth that may have led to the later death, this does not happen routinely. Where it does take place, it generally depends on parents with an unusual degree of persistence pressing their claim, as happened following one of the 2008 deaths at the Trust. We believe that this inconsistency should also be reviewed. As, however, this does not depend crucially on the framing or interpretation of the legal powers of coroners, it would best be done as part of the requirement for a more consistent approach to the recording, monitoring and investigation of neonatal deaths following transfer that we consider in the following section.

Scrutiny of perinatal and maternal deaths

6.9 Perinatal death, once sadly common, has become a relatively rare event. In 2012, seven pregnancies per 1,000 live births ended in a perinatal death, and this figure has declined by more than a third since 1982.² In order to ensure that the quality of maternity services remains high, it is important that both stillbirths and early neonatal deaths are adequately scrutinised, appropriately investigated and the correct lessons learnt.

6.10 Some stillbirths occur without warning, before the onset of labour and in the absence of any detectable problems affecting either mother or baby; as a result they are unpreventable with current knowledge. Others, however, occur as a result of conditions that can be detected and treated, or the baby's delivery expedited; it is important to review these to ensure that there were no missed opportunities to prevent the ensuing stillbirth. Most clear-cut of all are the deaths that occur during labour to a baby that had developed normally, described as intrapartum stillbirths; these should not happen, and their uncommon occurrence must be regarded as a serious incident requiring investigation. We were distressed to find that not only were intrapartum stillbirths a too-regular occurrence at Furness General Hospital (FGH), they seem to us to have been treated with far less concern than we expected, and as a result opportunities were missed to identify substandard practice. Although some of this is likely to have been particular to the unsatisfactory approach taken in the FGH maternity unit over this period, we cannot be sure that sufficient regard is paid to intrapartum stillbirths everywhere else. We therefore consider that intrapartum stillbirths should be recorded separately and each one reported mandatorily as a serious incident requiring investigation.

¹ Inquest into stillbirth of Axel Desmond. BBC website, 21 November 2013.

² Office for National Statistics: Childhood, Infant and Perinatal Mortality in England and Wales, 2012.

6.11 Some neonatal deaths are not likely to be preventable with current knowledge, particularly those associated with major abnormalities and extreme prematurity, although it is still important to review the care that was given. The neonatal death of a normally developed baby, however, should also be regarded as a serious incident requiring investigation. One of the reasons that this did not always happen at the Trust was the uncertain flow of information following the transfer of a baby requiring more specialist neonatal intensive care who then died in another centre. Although good practice demands that the receiving unit consultant notifies the outcome to the relevant obstetric and paediatric consultants in the referring unit, not least because they may well look after the parents in any subsequent pregnancy, it seems to us that this was not systematically recorded in the referring hospital, which was then unable to provide accurate figures for neonatal deaths that included deaths of babies transferred elsewhere. Further, in the case of the Trust, it appeared that at least sometimes neither the referral of a very sick baby nor the notification of a subsequent death was sufficient to trigger the reporting and investigation of a serious incident, which again resulted in missed opportunities to identify poor practice that required intervention. We believe that there should be a systematic notification of neonatal deaths following transfer that would enable the referring hospital to maintain accurate figures and to trigger an incident report and investigation where this had not already been done.

6.12 Maternal death is extremely rare in the UK, in common with nearly all developed countries, occurring in just 10 per 100,000 women giving birth in 2009–12.³ It should be self-evident that any such occurrence must be fully investigated to learn any lessons that would improve practice and minimise the risk of recurrence. We were distressed to hear and see evidence that the investigation of maternal deaths was also sometimes superficial and rudimentary, and failed to identify clear examples of substandard care. In some cases, this reflected an over-reliance on poorly completed records, when it would have been evident from a conversation with the relatives of the deceased that warning signs were missed some time in advance of the subsequent acute deterioration of the patient's condition. We were also taken aback to find that none of the unit clinicians, clinical director or executive directors appeared to have considered that there may have been a pattern to the occurrence of these extremely rare events in a small unit.

6.13 Whilst we believe that the great majority of Trusts that provide maternity services would take any maternal death very seriously and would investigate appropriately, the events at the Trust show that we cannot say that this applies to all. It is our view that the possibility of outlying behaviour such as this requires a failsafe system that would provide early warning of such problems by scrutinising the pattern of deaths of both mothers and babies. In view of the small numbers involved, it would make little sense to establish a mechanism solely for this purpose. However, a mechanism already in use in other countries has been put forward to scrutinise all deaths in this way that would by its nature pick up maternal and neonatal deaths. This is the appointment of medical examiners, initially proposed by Dame Janet Smith as a recommendation of the Shipman Inquiry,⁴ subsequently endorsed by the Luce review,⁵ put into enabling legislation in 2009 but not yet implemented. It is our view that implementing these proposals should be reactivated as the best means to provide the necessary scrutiny, not just of maternity-related deaths, but of all deaths. This would also provide an effective means of ensuring that in those cases where an inquest was considered into a death following neonatal transfer, as identified above, both coroners potentially involved had all of the relevant information.

³ *Saving Lives, Improving Mothers' Care*. MBRRACE-UK, 2014.

⁴ *The Shipman Inquiry: Third Report – Death Certification and the Investigation of Deaths by Coroners*. 2003.

⁵ *Death Certification and Investigation in England, Wales and Northern Ireland: The Report of a Fundamental Review*. 2003.

CHAPTER SEVEN: Assessment of current position

The Trust's ability to discharge its duties in delivering maternity services

7.1 The Investigation's terms of reference charged it with assessing and making findings as to the ability of the University Hospitals of Morecambe Bay NHS Foundation Trust (the Trust) to discharge its duties in delivering maternity services. To address this requirement, the Panel has adopted five lines of approach:

- i) We questioned interviewees currently working in the Trust about current practice and systems, and asked them where possible to compare these with how things were done previously.
- ii) We looked at Trust documentation that would show how incidents and complaints are dealt with now and what issues were arising.
- iii) Panel members made several visits to the maternity units at all three hospital sites and spoke informally with current staff.
- iv) We questioned the Trust Board on what lessons they had learnt from previous events, how they had sought to improve quality as a result and how they gained assurance that services are safe, effective and caring.
- v) We questioned relevant staff at the Care Quality Commission (CQC) and Monitor about how they currently fulfil their functions in relation to the Trust, and what their views are of service quality and governance there.

7.2 Taking first the clinical functioning of the maternity unit at Furness General Hospital (FGH), we consistently heard that steps had been taken to improve the knowledge and skills of clinicians and the way that they work together. New medical staff have been appointed in both paediatrics and obstetrics; new midwifery staff have been appointed with experience and training in other units, not just one unit within the Trust; regular multidisciplinary meetings take place to discuss incidents, practice and management; and a more systematic approach has been put in place to investigate incidents, identify root causes and disseminate lessons learnt. A new Head of Midwifery, Sascha Wells, is clearly offering enthusiastic and committed leadership to midwives across the Trust and particularly at FGH.

7.3 Nevertheless, we do have significant concerns. First, deep-rooted problems of organisational culture, like those we found had blighted the unit for years previously, take a long time to resolve. Second, we consistently heard that real change had effectively not begun until within the last year. Third, and consistent with the previous point, we saw and heard evidence that untoward incidents with worryingly similar features to those seen previously had occurred as recently as mid-2014. Fourth, there are limits to what one individual can achieve, however enthusiastic and committed, and we are not convinced that the change in midwifery leadership has yet been matched by a comparable improvement in medical leadership at divisional level. Finally, we remain concerned that, four years after the unsatisfactory physical accommodation of the FGH maternity unit was clearly pointed out, conditions remain poor, and the improvised 'fix' for the previous problem of getting patients to theatre for an emergency caesarean section remains unsatisfactory.

7.4 Overall, we were encouraged that steps have been taken that are changing the unit for the better. The difficult nature of the change, however, emphasises the need to maintain progress and make it sustainable, particularly by ensuring that the necessary quality of clinical leadership is in place and supported appropriately.

The Trust's governance and ability to function as an effective organisation

7.5 We also considered carefully the ability of the Trust as a whole, particularly its governance and ability to function as an effective organisation, through which safe, high-quality maternity services can be delivered.

7.6 A pattern emerged during the Investigation: of a Trust that has undertaken reviews, produced action plans and provided assurance to commissioners and regulators that appropriate action is in hand. However, on numerous previous occasions this assurance has proved false. Given this history, assessment of the current position has been approached with caution. We have been mindful of the need to consider whether improvements in actual ways of working have been delivered, alongside the systems and structures that have been put in place.

7.7 In reaching an assessment, the Investigation has reviewed a range of evidence, both that provided by the Trust, commissioners and regulators, and from direct observation and discussion with those in key positions.

7.8 A picture has emerged of an organisation that has moved from a very weak position to one that is stronger, but by no means complete.

7.9 Jackie Daniel, Trust Chief Executive, described the journey that the Trust had been on since her arrival:

*"So we began to describe the journey of improvement around three areas: of stabilisation, transition and transformation. That's the language we use in the Trust, and I think recognising that it would take years, not a year or two years, and my sense is that we're part way into that journey. I'm not sure we're even halfway into that journey. Changing culture, which was a significant element of what I think this is about, takes rather longer than a couple of years."*¹

7.10 Monitor staff described their first view of the Trust after it went into special measures as "*quite awful*". More recently, their assessment was of a Trust that had made real progress, particularly in the last year – but one with significant challenges to overcome.

7.11 The CQC was cautious in its assessment, seeing progress but aware of previous claims of improvement that had proved to be false. It saw encouraging signs but emphasised that its forthcoming May 2015 inspection of the Trust was a critical test of the organisation. In the CQC's view, this re-inspection would be crucial in determining whether there had been real and material change, or whether the signs were once again to be proved premature.

7.12 Commissioners were positive about the level of engagement they were getting from the Trust, and saw the dialogue over the future direction of services positively. However, they also recognised that there were significant challenges ahead before a viable, sustainable service would be in place.

7.13 The documentation provided to the Investigation confirmed to us that new systems and structures have been put in place, that there is a new leadership team which (with the medical director recently taking up post) is now complete, that efforts are being made to improve staffing levels and training, and that management is being strengthened at all levels.

¹ Trust Board interview.

7.14 We saw evidence that complaints are being handled better; however, we also heard of recent examples that suggested there was still considerable room for improvement. The complaints report for the third quarter of 2014 provides both an assessment of numbers, together with breakdown of where the incidents happened, and the learning that has been derived from the complaints. The additional section on learning was not routinely included during the period of the Investigation and is welcomed. Attention will still need to be placed on ensuring that the lessons learnt are fully implemented, both in the area where the incident occurred and, where appropriate, elsewhere within the Trust. Complaints within the Trust have increased in volume. The Trust may wish to investigate the reasons behind this to see if there are any underlying issues. However, we recognise that increasing numbers of complaints can be a sign of both positive and negative aspects of the Trust.

7.15 Everything that we saw and heard signalled significant recent improvement in the reporting and investigation of serious incidents, but we must stress that this has been from a very low starting position, and there is still a considerable way to go before learning from incidents reaches an acceptable level. In particular, whilst there have been undoubted improvements in root cause analysis, and indications that there are robust discussions when the Board committees are not satisfied with the information received, we retain significant concerns about the quality of analysis, the identification of the root cause and the action taken to rectify the problem.

7.16 Previous problems were recognised by the Board. One of the Trust's non-executive directors, Angela Denton, told us that:

"The quality of [incident investigations] when I first came and first started chairing the SIRI² Panel was not good. And having sent them back and talked through what we needed, and the governance lead having done the same, the quality of them has improved significantly, and the detail, the relevant detail. And certainly the Women and Children's Division have paid particular attention to that in terms of those minutiae of examining things in detail. And we have asked for independent people to look at things as part of the SIRI, where we weren't satisfied, but again, women and children's, with having that very close scrutiny of what they have been doing themselves have sometimes pre-empted that by having had that done already, which was a very positive sign from my point of view."

She went on to say:

"I'll go back to what I said before; the information that was presented to the SIRI Panel when I first started chairing it was poor. I'll be very fair, it was poor, and over the last 18 months we worked very hard to not accept anything that we didn't feel gave us the information that we needed to know from a governance point of view, which is then backed up by people attending the SIRI Panel, and for there to be a discussion with other clinical colleagues around the room as to what might have happened or what might be missing.

*And the use of information wasn't – the use of information to identify themes and trends wasn't good either. So we were getting a lot of pressure ulcers, a lot of falls, and it was only through, I suppose, questioning and demanding in terms of my background, to look at – to have somebody do pieces of work to identify themes and trends to be able to say, 'Right, so what do we need to do differently to get it right first time?' But having pushed and pushed on those things, they now happen as a matter of course, and there's a free from harm group which actually does regularly and routinely now from establishing it, and there's a whole series of things that have changed as a consequence of it."*³

² SIRI: serious incident requiring investigation.

³ Trust Board interview.

7.17 The reports to the Quality Committee that we have seen are much improved, with detailed explanations of the incidents and the actions being taken identified. We did, however, find it hard to track through the actions agreed and completed from report to report, and this must be considered a weakness. It is vital that this rich source of information is used to change process across the Trust and that the identified learning can be demonstrated as being implemented and effective. We saw clear instances of insufficient challenges to reports and findings, particularly where higher-level factors were still in some instances being recorded as 'root cause'. A bed sore is not a root cause: the reasons for the bed sore will lead back to the root cause, which will often lie in poor procedures or lack of training.

7.18 We saw and heard that the Trust's governance system has been completely overhauled by the Trust under the direction of Mary Aubrey, Director of Governance, and this is a welcome initiative.

7.19 Ms Daniel described their work:

*"In terms of governance, we have completely overhauled the Board governance structures and processes, the board assurance framework, but particularly maternity. I think they are leading the way in terms of a divisional approach to that. So I've talked about the new skills and expertise in the governance team in midwifery, but also around training and education. We put a lot of investment there, we safeguard our system for instant reporting, but making sure, importantly, staff feel that they can report incidents. And I think among North-West and national benchmarks we are now considered to be a high reporter of incidents, and I think that's a good thing and needs to continue to be encouraged."*⁴

7.20 It is the view of the Investigation that, whilst progress has been made, there is still significant work to be done in embedding a culture of good governance and clinical quality into the organisation. Some areas have embraced the need to change more strongly than others. The delivery of a culture of governance, supported by clear and consistent systems, is vital to the Trust's improvement. There are clear signs of improvement but we believe that it is likely to be at least two more years before the systems and culture are sufficiently established, and it is essential that impetus is maintained.

7.21 Key to delivering a culture of improvement is leadership, both clinical and managerial. We heard from regulators that the improvement of clinical leadership within the Trust was a priority. We heard that this is recognised within the Trust, but there are some significant challenges to be overcome. The strength of the clinical leadership at divisional level needs careful consideration, as does the identification and development of a cadre throughout the organisation who are supported in their development as leaders of the future.

7.22 Many of the problems the Trust experienced in the past related to the implementation of the systems and processes that were in place to ensure effective governance. The new systems seem robust and appropriate, but if they are not being uniformly implemented across the Trust, their utility will be limited.

7.23 The Risk Committee of the Board undertook a review of divisional governance in May 2013. This confirmed the issues of variability and lack of consistency in the divisions. In summary it said:

"There is no consistent structure of clinical governance and risk management across the divisions. There is no consistent use of names for committees, boards, meetings or forums. Terms of Reference whilst available for each committee, board, meeting or forum have been completed but again there is no consistency and there are distinct gaps in some. For example, reporting responsibilities, annual review of terms of reference. There is also no consistency in the format of the governance report or dashboard and in the format

⁴ Trust Board interview.

of the risk registers as presented at each divisional meeting. There are clear schedules of meetings for most meetings but there is a lack of rigour in actually holding the meetings with frequent cancellations or apologies being offered. There is a poor record of attendance.”⁵

7.24 Although we do not have the level of detail to be confident of the most up-to-date position, any persistence of this variability within divisions would be a concern.

7.25 The Trust has made real progress in terms of improving its governance. It has introduced new systems, and the Board has focused appropriate attention on ensuring that it has the information it requires. Reporting internally is improved, and reports are shared externally with regulators. Work to strengthen divisional tiers has begun and the Trust has recognised that clinical leadership must be strengthened as a priority.

7.26 However, the Trust is, in our judgment, still some way from where it needs to be in developing satisfactory governance and external relationships. We were told by the regulators that there is still a reluctance to be proactive in sharing information. Requests are responded to promptly but there needs to be a more proactive approach to openness with the regulators if confidence in the Trust is to be improved.

7.27 We heard and saw evidence that the delivery of services has been strengthened by the additional investment made by the Trust in staffing. This is a welcome development, but it is important that it is made sustainable. The Trust remains in financial deficit and it is vital that a strategy is developed, in agreement with the national NHS system, regulators and local commissioners, that will deliver stability – or the Trust will remain vulnerable.

7.28 Organisational culture is set by the top of the organisation, and has clearly changed at that level, but typically takes a long time to permeate through the rest of the organisation. In our view, it would be a mistake to think that this has happened yet, and we would emphasise the need to ensure that change becomes embedded more strongly within the clinical body in particular. This will require clinical leadership from the top but also at all levels of the organisation. We are encouraged by the engagement initiatives the Trust has started and the increased exposure of the Board to frontline staff. However, we heard reports of continuing poor practice and a reluctance to share concerns within the Trust, and this underlines the need to maintain progress for the significant period needed.

7.29 Both Monitor and the CQC have expressed caution to us in assessing progress by the Trust, and we concur with the need for this. Whatever the outcome of the forthcoming May re-inspection by the CQC, the Trust will need to demonstrate that it can learn, admit failures when appropriate, and continue to progress.

Capacity and capability of regulators and others

7.30 The Investigation has not been specifically asked to comment on the current ability of the healthcare system as a whole to identify significant service failures and intervene where necessary. Nevertheless, the comprehensive nature of the failure to do either in the case of the events described here places some onus on us to comment. Otherwise, we believe that our assessment of the current position would be incomplete.

7.31 It is clear to us that the biggest change has been in the CQC. From an organisation that manifestly had significant problems in its first few years, which greatly hampered it, it has become, we believe, capable of effectively carrying out its role as principal quality regulator for the first time. Central to this have been new leadership under a new chief executive, the introduction of a new inspection regime under a chief inspector of hospitals, and the use of teams with appropriate

⁵ University Hospitals of Morecambe Bay NHS Foundation Trust Risk Committee, 15 May 2015.

experience of the services they are responsible for, rather than generic inspectors. Although prime responsibility for the safety, effectiveness and responsiveness of NHS services rightly remains with the Trust or other organisation providing them, the CQC is now much better placed to act as the quality regulator.

7.32 The other major problems highlighted by our findings lay not so much in the failings of individual organisations as in the lack of clarity over roles and relationships and the poor communication between organisations. The number of organisations that became involved with the events we have looked at is remarkable, and it is likely that some or all would be involved in any future service failures elsewhere. Whilst we believe that improvements have been made in defining roles and responsibilities and in clarifying communications, it seems to us that there is still further work to do to avoid the potential for future difficulty. We have made recommendations to that effect.

7.33 These events should have been identified significantly earlier than they were through two routes that continue to cause concern nationally. Complaints raised by patients or relatives should be a valuable source of information on service quality and an early warning of potential problems, as well as a means of answering complainants' concerns and requests for information. We are not convinced that complaints are generally treated in this manner, or that the national system is well designed to ensure that they are, or to intervene effectively when they are not. Neither are we convinced that systems generally provide adequate protection to staff who use whistleblowing procedures, the second route to raise concerns, or that whistleblowing is used effectively to provide early warning of problems. We endorse the need for change in both these areas.

7.34 Finally, we are conscious that the impact of new policies and organisational change has been a recurring theme through this Report. In our view, the NHS is still currently getting to grips with these. That process is integral to continuing and sustaining the improvement that we believe is evident in the capability of systems to deliver and ensure the high quality of services, including their safety and effectiveness.

CHAPTER EIGHT: Conclusions and recommendations

Conclusions

8.1 Maternity care is almost unique amongst NHS services: the majority of those using it are not ill but going through a sequence of normal physiological changes that usually culminate in two healthy individuals. In consequence, the safety of maternity care depends crucially on maintaining vigilance for early warning of any departure from normality and on taking the right, timely action when it is detected. The corollary is that, if those standards are not met, it may be some time before one or more adverse events occur; given their relative scarcity in maternity care, it is vital that every such occurrence is examined to see why it happened.

8.2 We have set out the poor practice that developed in the Furness General Hospital maternity unit, the failure to maintain standards and the tragic consequences that resulted in some cases. That mistakes were made should not itself be subject to criticism: the great majority of staff, in the University Hospitals of Morecambe Bay NHS Foundation Trust (the Trust), as elsewhere, set out to help patients, not to harm them, and errors occur in every healthcare system. What is inexcusable, however, is the repeated failure to examine adverse events properly, to be open and honest with those who suffered, and to learn so as to prevent recurrence. Yet this is what happened consistently over the whole period 2004–12, and each instance represents a significant lapse from the professional duty of NHS staff.

8.3 Barrow-in-Furness is a relatively inaccessible town comprising a pocket of post-industrial deprivation on the edge of an area of scattered, rural, more affluent communities. Many of the non-medical staff were born and raised in the town, trained in the hospital and have worked there ever since. Medical staff have proved hard to recruit and there has been little opportunity for joint working or shared experience with other sites. All of this has contributed to the isolation of the hospital and its clinical practice. In such settings, practice can ‘drift’ away from the standards and procedures found elsewhere, and this can remain undetected until it has deviated a long way and obvious problems develop. In the maternity services at Furness General Hospital, this ‘drift’ involved a particularly dangerous combination of declining clinical skills and knowledge, a drive to achieve normal childbirth ‘whatever the cost’ and a reckless approach to detecting and managing mothers and babies at higher risk.

8.4 The prime responsibility for ensuring the safety of clinical services rests with the clinicians who provide them, and those associated with the unit failed to discharge this duty over a prolonged period. The prime responsibility for ensuring that they provide safe services, and that the warning signs of departure from standards are picked up and acted upon, lies with the Trust, the body statutorily responsible for those services. When the dysfunctional nature of the maternity services became obvious, in 2008, the Trust’s response was flawed and inadequate, and categorised for some years by instances of the same denial and cover-up that was evident in the maternity unit. At the time, the Trust was strongly focused on achieving Foundation Trust status, which both diverted capacity to manage day to day and surely fostered reluctance to disclose anything that may have jeopardised the bid. It may be that Trust officers believed that they were capable of resolving the

problem internally, but they were wrong, and the failure to share information with other parts of the NHS system was inexcusable.

8.5 The NHS has not left Trusts unmonitored since they were first established, but the system has varied markedly over time. Regional Health Authorities, Regional Offices and Strategic Health Authorities have all had overall monitoring responsibilities at one time or another, and all have come and gone; Primary Care Trusts exercised some responsibility as service commissioners, now replaced by Clinical Commissioning Groups; the Commission for Health Improvement, the Healthcare Commission and the Care Quality Commission (CQC) have had responsibility for various aspects of quality monitoring and regulation at different times; unresolved NHS complaints were the responsibility of the Healthcare Commission until its abolition, when the Parliamentary and Health Service Ombudsman (PHSO), previously a third tier above the Healthcare Commission, took on the role; with the creation of Foundation Trusts (FTs) another body, Monitor, took on responsibility for approval of would-be FTs and regulation of established FTs; and over all this the Department of Health (latterly with NHS England) set policy and occasionally intervened more directly. This is not only a complex and changing landscape to describe, the frequency of reorganisation has introduced uncertainty while roles, relationships and demarcation are being resolved, upheaval as staff must become accustomed to working with new organisations and colleagues, and loss of corporate memory of how to work effectively with widely variable NHS organisations and where the high-risk areas are. This repeated change to already complex systems has not helped them to function effectively.

8.6 Nearly all of those organisations had responsibility for oversight of at least some aspects of the Trust's operation at some stage. The North West Strategic Health Authority, the CQC, Monitor and the PHSO all had opportunities to identify the nature of the problem at the Trust and to prompt effective action. Each of those opportunities was missed, and it was not until late in 2011 that a proportionate response finally began to be mustered. The reasons behind each missed opportunity differed, as we have set out, but the effect of each was to delay further the recognition of the problem. This represents a collective and individual organisational failure to exercise an effective supervisory or regulatory function over the Trust's ability to provide safe and effective services. Whilst we are clear that the primary responsibility for assuring the quality of clinical services lies with the Trust itself, there is little point in having an elaborate system of overview and scrutiny if it cannot detect significant failure.

8.7 Without the persistent efforts of some bereaved families, these events would not have come to light when they did. Much attention has been given to reforming the NHS complaints system, but few people who have tried to use it speak well of the experience. The treatment of complainants at the Trust certainly exemplified the problems commonly reported, including defensive 'closed' responses, delayed replies, and provision of information that complainants did not find to be accurate. Nor did referral of complaints to the PHSO prove helpful in allaying concerns. As a result, many complainants went to litigation, principally as a means of getting at the truth in a way they did not feel that the response to their complaints did. It is not our brief to review the operation of the NHS complaints system nationally, but we believe that the evidence is now incontrovertible that it must be reviewed, expeditiously and comprehensively.

8.8 Some families raised the question with us of whether the care they experienced may have been influenced by the ethnicity of their family member. We took this question very seriously, and were careful to look for any confirmatory signs throughout the course of the Investigation. We found no evidence that ethnicity was a significant factor in those cases that we reviewed. The failures of care that we found were indiscriminate.

8.9 The problems that we have described within and around the maternity unit will, by their nature, take time to resolve fully. The Trust has begun to take steps to address what must be done, but

there is still significant work to do to complete the process. It is important that this time round, unlike previous attempts at action plans, the recovery is seen through and not abandoned prematurely as 'job done'. In this, the engagement of clinical staff is vital. Responsibility for overseeing the recovery rests with both Monitor and the CQC, the latter as quality regulator. Having seen the wholly inadequate attempts of the CQC in its early days to regulate the Trust, we were reassured by the approach now evident under new leadership. We believe that the Trust now has the capability to recover and that the regulatory framework has the capability to ensure that it happens.

8.10 When events such as these come to light, they raise understandable concerns about how widespread failures of this degree might be across the NHS. What happened at the Trust represents the simultaneous failure of a great many systems at almost every level from the labour ward to the headquarters of the national bodies. In the terms of the James Reason 'Swiss cheese' model of accident causation, there were a large number of slices of cheese, and in the case of the Trust every one of them was aligned so that one set of holes aligned perfectly. There will no doubt be many Trusts around the country that show one or two of these defects, and a few that show more, but the full set is very unlikely to be anything other than a rarity. Nevertheless, it is vital to learn all of the lessons so as to improve every layer of the system and eliminate the defects. If we were foolish enough to rely on the unlikelihood of the defects becoming aligned again in this way, sooner or later they would, with tragic and unnecessary repetition.

8.11 Our recommendations are set out below, in two sections. The first section is directed at the University Hospitals of Morecambe Bay NHS Foundation Trust. The Trust has made significant progress recently, but it is essential that this is maintained, and organisational culture is notoriously resistant to change. The second section is directed at the wider NHS, to minimise the chance that these events would be repeated elsewhere.

Recommendations

Recommendations for the University Hospitals of Morecambe Bay NHS Foundation Trust

Some of these recommendations will have been partially implemented already, but we set them out in full to show the range of action required, and completion dates.

1. The University Hospitals of Morecambe Bay NHS Foundation Trust should formally admit the extent and nature of the problems that have previously occurred, and should apologise to those patients and relatives affected, not only for the avoidable damage caused but also for the length of time it has taken to bring them to light and the previous failures to act. This should begin immediately with the response to this Report.
2. The University Hospitals of Morecambe Bay NHS Foundation Trust should review the skills, knowledge, competencies and professional duties of care of all obstetric, paediatric, midwifery and neonatal nursing staff, and other staff caring for critically ill patients in anaesthetics and intensive and high dependency care, against all relevant guidance from professional and regulatory bodies. This review should be completed by June 2015, and identify requirements for additional training, development and, where necessary, a period of experience elsewhere.
3. The University Hospitals of Morecambe Bay NHS Foundation Trust should draw up plans to deliver the training and development of staff identified as a result of the review of maternity, neonatal and other staff, and should identify opportunities to broaden staff experience in other units, including by secondment and by supernumerary practice. These should be in place in time for June 2015.
4. Following completion of additional training or experience where necessary, the University Hospitals of Morecambe Bay NHS Foundation Trust should identify requirements for

- continuing professional development of staff and link this explicitly with professional requirements including revalidation. This should be completed by September 2015.
5. The University Hospitals of Morecambe Bay NHS Foundation Trust should identify and develop measures that will promote effective multidisciplinary team-working, in particular between paediatricians, obstetricians, midwives and neonatal staff. These measures should include, but not be limited to, joint training sessions, clinical, policy and management meetings and staff development activities. Attendance at designated events must be compulsory within terms of employment. These measures should be identified by April 2015 and begun by June 2015.
 6. The University Hospitals of Morecambe Bay NHS Foundation Trust should draw up a protocol for risk assessment in maternity services, setting out clearly: who should be offered the option of delivery at Furness General Hospital and who should not; who will carry out this assessment against which criteria; and how this will be discussed with pregnant women and families. The protocol should involve all relevant staff groups, including midwives, paediatricians, obstetricians and those in the receiving units within the region. The Trust should ensure that individual decisions on delivery are clearly recorded as part of the plan of care, including what risk factors may trigger escalation of care, and that all Trust staff are aware that they should not vary decisions without a documented risk assessment. This should be completed by June 2015.
 7. The University Hospitals of Morecambe Bay NHS Foundation Trust should audit the operation of maternity and paediatric services, to ensure that they follow risk assessment protocols on place of delivery, transfers and management of care, and that effective multidisciplinary care operates without inflexible demarcations between professional groups. This should be in place by September 2015.
 8. The University Hospitals of Morecambe Bay NHS Foundation Trust should identify a recruitment and retention strategy aimed at achieving a balanced and sustainable workforce with the requisite skills and experience. This should include, but not be limited to, seeking links with one or more other centre(s) to encourage development of specialist and/or academic practice whilst offering opportunities in generalist practice in the Trust; in addition, opportunities for flexible working to maximise the advantages of close proximity to South Lakeland should be sought. Development of the strategy should be completed by January 2016.
 9. The University Hospitals of Morecambe Bay NHS Foundation Trust should identify an approach to developing better joint working between its main hospital sites, including the development and operation of common policies, systems and standards. Whilst we do not believe that the introduction of extensive split-site responsibilities for clinical staff will do much other than lead to time wasted in travelling, we do consider that, as part of this approach, flexibility should be built into working responsibilities to provide temporary solutions to short-term staffing problems. This approach should be begun by September 2015.
 10. The University Hospitals of Morecambe Bay NHS Foundation Trust should seek to forge links with a partner Trust, so that both can benefit from opportunities for learning, mentoring, secondment, staff development and sharing approaches to problems. This arrangement is promoted and sometimes facilitated by Monitor as 'buddying' and we endorse the approach under these circumstances. This could involve the same centre identified as part of the recruitment and retention strategy. If a suitable partner is forthcoming, this arrangement should be begun by September 2015.
 11. The University Hospitals of Morecambe Bay NHS Foundation Trust should identify and implement a programme to raise awareness of incident reporting, including requirements, benefits and processes. The Trust should also review its policy of openness and honesty

in line with the duty of candour of professional staff, and incorporate into the programme compliance with the refreshed policy. This should be begun with maternity staff by April 2015 and rolled out to other staff by April 2016.

12. The University Hospitals of Morecambe Bay NHS Foundation Trust should review the structures, processes and staff involved in investigating incidents, carrying out root cause analyses, reporting results and disseminating learning from incidents, identifying any residual conflicts of interest and requirements for additional training. The Trust should ensure that robust documentation is used, based on a recognised system, and that Board reports include details of how services have been improved in response. The review should include the provision of appropriate arrangements for staff debriefing and support following a serious incident. This should be begun with maternity units by April 2015 and rolled out across the Trust by April 2016.
13. The University Hospitals of Morecambe Bay NHS Foundation Trust should review the structures, processes and staff involved in responding to complaints, and introduce measures to promote the use of complaints as a source of improvement and reduce defensive 'closed' responses to complainants. The Trust should increase public and patient involvement in resolving complaints, in the case of maternity services through the Maternity Services Liaison Committee. This should be completed, and the improvements demonstrated at an open Board meeting, by December 2015.
14. The University Hospitals of Morecambe Bay NHS Foundation Trust should review arrangements for clinical leadership in obstetrics, paediatrics and midwifery, to ensure that the right people are in place with appropriate skills and support. The Trust has implemented change at executive level, but this needs to be carried through to the levels below. All staff with defined responsibilities for clinical leadership should show evidence of attendance at appropriate training and development events. This review should be commenced by April 2015.
15. The University Hospitals of Morecambe Bay NHS Foundation Trust should continue to prioritise the work commenced in response to the review of governance systems already carried out, including clinical governance, so that the Board has adequate assurance of the quality of care provided by the Trust's services. This work is already underway with the facilitation of Monitor, and we would not seek to vary or add to it, which would serve only to detract from implementation. We do, however, recommend that a full audit of implementation be undertaken before this is signed off as completed.
16. As part of the governance systems work, we consider that the University Hospitals of Morecambe Bay NHS Foundation Trust should ensure that middle managers, senior managers and non-executives have the requisite clarity over roles and responsibilities in relation to quality, and it should provide appropriate guidance and where necessary training. This should be completed by December 2015.
17. The University Hospitals of Morecambe Bay NHS Foundation Trust should identify options, with a view to implementation as soon as practicable, to improve the physical environment of the delivery suite at Furness General Hospital, including particularly access to operating theatres, an improved ability to observe and respond to all women in labour and en suite facilities; arrangements for post-operative care of women also need to be reviewed. Plans should be in place by December 2015 and completed by December 2017.
18. All of the previous recommendations should be implemented with the involvement of Clinical Commissioning Groups, and where necessary, the Care Quality Commission and Monitor. In the particular circumstances surrounding the University Hospitals of Morecambe Bay NHS Foundation Trust, NHS England should oversee the process, provide the necessary support, and ensure that all parties remain committed to the outcome, through an agreed plan with the Care Quality Commission, Monitor and the Clinical Commissioning Groups.

Recommendations for the wider NHS

Many of these recommendations are for other Trusts, but we have generally indicated the bodies responsible for leading and ensuring that action is completed.

19. In light of the evidence we have heard during the Investigation, we consider that the professional regulatory bodies should review the findings of this Report in detail with a view to investigating further the conduct of registrants involved in the care of patients during the time period of this Investigation. Action: the General Medical Council, the Nursing and Midwifery Council.
20. There should be a national review of the provision of maternity care and paediatrics in challenging circumstances, including areas that are rural, difficult to recruit to, or isolated. This should identify the requirements to sustain safe services under these conditions. In conjunction, a national protocol should be drawn up that defines the types of unit required in different settings and the levels of care that it is appropriate to offer in them. Action: NHS England, the Care Quality Commission, the Royal College of Obstetricians and Gynaecologists, the Royal College of Midwives, the Royal College of Paediatrics and Child Health, the National Institute for Health and Care Excellence.
21. The challenge of providing healthcare in areas that are rural, difficult to recruit to or isolated is not restricted to maternity care and paediatrics. We recommend that NHS England consider the wisdom of extending the review of requirements to sustain safe provision to other services. This is an area lacking in good-quality research yet it affects many regions of England, Wales and Scotland. This should be seen as providing an opportunity to develop and promote a positive way of working in remote and rural environments. Action: NHS England.
22. We believe that the educational opportunities afforded by smaller units, particularly in delivering a broad range of care with a high personal level of responsibility, have been insufficiently recognised and exploited. We recommend that a review be carried out of the opportunities and challenges to assist such units in promoting services and the benefits to larger units of linking with them. Action: Health Education England, the Royal College of Obstetricians and Gynaecologists, the Royal College of Paediatrics and Child Health, the Royal College of Midwives.
23. Clear standards should be drawn up for incident reporting and investigation in maternity services. These should include the mandatory reporting and investigation as serious incidents of maternal deaths, late and intrapartum stillbirths and unexpected neonatal deaths. We believe that there is a strong case to include a requirement that investigation of these incidents be subject to a standardised process, which includes input from and feedback to families, and independent, multidisciplinary peer review, and should certainly be framed to exclude conflicts of interest between staff. We recommend that this build on national work already begun on how such a process would work. Action: the Care Quality Commission, NHS England, the Department of Health.
24. We commend the introduction of the duty of candour for all NHS professionals. This should be extended to include the involvement of patients and relatives in the investigation of serious incidents, both to provide evidence that may otherwise be lacking and to receive personal feedback on the results. Action: the Care Quality Commission, NHS England.
25. We recommend that a duty should be placed on all NHS Boards to report openly the findings of any external investigation into clinical services, governance or other aspects of the operation of the Trust, including prompt notification of relevant external bodies such as the Care Quality Commission and Monitor. The Care Quality Commission should develop a system to disseminate learning from investigations to other Trusts. Action: the Department of Health, the Care Quality Commission.

26. We commend the introduction of a clear national policy on whistleblowing. As well as protecting the interests of whistleblowers, we recommend that this is implemented in a way that ensures that a systematic and proportionate response is made by Trusts to concerns identified. Action: the Department of Health.
27. Professional regulatory bodies should clarify and reinforce the duty of professional staff to report concerns about clinical services, particularly where these relate to patient safety, and the mechanism to do so. Failure to report concerns should be regarded as a lapse from professional standards. Action: the General Medical Council, the Nursing and Midwifery Council, the Professional Standards Authority for Health and Social Care.
28. Clear national standards should be drawn up setting out the professional duties and expectations of clinical leads at all levels, including, but not limited to, clinical directors, clinical leads, heads of service, medical directors, nurse directors. Trusts should provide evidence to the Care Quality Commission, as part of their processes, of appropriate policies and training to ensure that standards are met. Action: NHS England, the Care Quality Commission, the General Medical Council, the Nursing and Midwifery Council, all Trusts.
29. Clear national standards should be drawn up setting out the responsibilities for clinical quality of other managers, including executive directors, middle managers and non-executives. All Trusts should provide evidence to the Care Quality Commission, as part of their processes, of appropriate policies and training to ensure that standards are met. Action: NHS England, the Care Quality Commission, all Trusts.
30. A national protocol should be drawn up setting out the duties of all Trusts and their staff in relation to inquests. This should include, but not be limited to, the avoidance of attempts to 'fend off' inquests, a mandatory requirement not to coach staff or provide 'model answers', the need to avoid collusion between staff on lines to take, and the inappropriateness of relying on coronial processes or expert opinions provided to coroners to substitute for incident investigation. Action: NHS England, the Care Quality Commission.
31. The NHS complaints system in the University Hospitals of Morecambe Bay NHS Foundation Trust failed relatives at almost every turn. Although it was not within our remit to examine the operation of the NHS complaints system nationally, both the nature of the failures and persistent comment from elsewhere lead us to suppose that this is not unique to this Trust. We believe that a fundamental review of the NHS complaints system is required, with particular reference to strengthening local resolution and improving its timeliness, introducing external scrutiny of local resolution and reducing reliance on the Parliamentary and Health Service Ombudsman to intervene in unresolved complaints. Action: the Department of Health, NHS England, the Care Quality Commission, the Parliamentary and Health Service Ombudsman.
32. The Local Supervising Authority system for midwives was ineffectual at detecting manifest problems at the University Hospitals of Morecambe Bay NHS Foundation Trust, not only in individual failures of care but also with the systems to investigate them. As with complaints, our remit was not to examine the operation of the system nationally; however, the nature of the failures and the recent King's Fund review (*Midwifery regulation in the United Kingdom*) lead us to suppose that this is not unique to this Trust, although there were specific problems there that exacerbated the more systematic concern. We believe that an urgent response is required to the King's Fund findings, with effective reform of the system. Action: the Department of Health, NHS England, the Nursing and Midwifery Council.
33. We considered carefully the effectiveness of separating organisationally the regulation of quality by the Care Quality Commission from the regulation of finance and performance by Monitor, given the close inter-relationship between Trust decisions in each area. However, we were persuaded that there is more to be gained than lost by keeping regulation separated in this way, not least that decisions on safety are not perceived to be biased by their financial

- implications. The close links, however, require a carefully coordinated approach, and we recommend that the organisations draw up a memorandum of understanding specifying roles, relationships and communication. Action: Monitor, the Care Quality Commission, the Department of Health.
34. The relationship between the investigation of individual complaints and the investigation of the systemic problems that they exemplify gave us cause for concern, in particular the breakdown in communication between the Care Quality Commission and the Parliamentary and Health Service Ombudsman over necessary action and follow-up. We recommend that a memorandum of understanding be drawn up clearly specifying roles, responsibilities, communication and follow-up, including explicitly agreed actions where issues overlap. Action: the Care Quality Commission, the Parliamentary and Health Service Ombudsman.
 35. The division of responsibilities between the Care Quality Commission and other parts of the NHS for oversight of service quality and the implementation of measures to correct patient safety failures was not clear, and we are concerned that potential ambiguity persists. We recommend that NHS England draw up a protocol that clearly sets out the responsibilities for all parts of the oversight system, including itself, in conjunction with the other relevant bodies; the starting point should be that one body, the Care Quality Commission, takes prime responsibility. Action: the Care Quality Commission, NHS England, Monitor, the Department of Health.
 36. The cumulative impact of new policies and processes, particularly the perceived pressure to achieve Foundation Trust status, together with organisational reconfiguration, placed significant pressure on the management capacity of the University Hospitals of Morecambe Bay NHS Foundation Trust to deliver against changing requirements whilst maintaining day-to-day needs, including safeguarding patient safety. Whilst we do not absolve Trusts from responsibility for prioritising limited capability safely and effectively, we recommend that the Department of Health should review how it carries out impact assessments of new policies to identify the risks as well as the resources and time required. Action: the Department of Health.
 37. Organisational change that alters or transfers responsibilities and accountability carries significant risk, which can be mitigated only if well managed. We recommend that an explicit protocol be drawn up setting out how such processes will be managed in future. This must include systems to secure retention of both electronic and paper documents against future need, as well as ensuring a clearly defined transition of responsibilities and accountability. Action: the Department of Health.
 38. Mortality recording of perinatal deaths is not sufficiently systematic, with failures to record properly at individual unit level and to account routinely for neonatal deaths of transferred babies by place of birth. This is of added significance when maternity units rely inappropriately on headline mortality figures to reassure others that all is well. We recommend that recording systems are reviewed and plans brought forward to improve systematic recording and tracking of perinatal deaths. This should build on the work of national audits such as MBRRACE-UK, and include the provision of comparative information to Trusts. Action: NHS England.
 39. There is no mechanism to scrutinise perinatal deaths or maternal deaths independently, to identify patient safety concerns and to provide early warning of adverse trends. This shortcoming has been clearly identified in relation to adult deaths by Dame Janet Smith in her review of the Shipman deaths, but is in our view no less applicable to maternal and perinatal deaths, and should have raised concerns in the University Hospitals of Morecambe Bay NHS Foundation Trust before they eventually became evident. Legislative preparations have already been made to implement a system based on medical examiners, as effectively used in other countries, and pilot schemes have apparently proved effective. We cannot

- understand why this has not already been implemented in full, and recommend that steps are taken to do so without delay. Action: the Department of Health.
40. Given that the systematic review of deaths by medical examiners should be in place, as above, we recommend that this system be extended to stillbirths as well as neonatal deaths, thereby ensuring that appropriate recommendations are made to coroners concerning the occasional need for inquests in individual cases, including deaths following neonatal transfer. Action: the Department of Health.
 41. We were concerned by the ad hoc nature and variable quality of the numerous external reviews of services that were carried out at the University Hospitals of Morecambe Bay NHS Foundation Trust. We recommend that systematic guidance be drawn up setting out an appropriate framework for external reviews and professional responsibilities in undertaking them. Action: the Academy of Medical Royal Colleges, the Royal College of Nursing, the Royal College of Midwives.
 42. We further recommend that all external reviews of suspected service failures be registered with the Care Quality Commission and Monitor, and that the Care Quality Commission develops a system to collate learning from reviews and disseminate it to other Trusts. Action: the Care Quality Commission, Monitor.
 43. We strongly endorse the emphasis placed on the quality of NHS services that began with the Darzi review, *High Quality Care for All*, and gathered importance with the response to the events at the Mid Staffordshire NHS Foundation Trust. Our findings confirm that this was necessary and must not be lost. We are concerned that the scale of recent NHS reconfiguration could result in new organisations and post-holders losing the focus on this priority. We recommend that the importance of putting quality first is re-emphasised and local arrangements reviewed to identify any need for personal or organisational development, including amongst clinical leadership in commissioning organisations. Action: NHS England, the Department of Health.
 44. This Investigation was hampered at the outset by the lack of an established framework covering such matters as access to documents, the duty of staff and former staff to cooperate, and the legal basis for handling evidence. These obstacles were overcome, but the need to do this from scratch each time an investigation of this format is set up is unnecessarily time-consuming. We believe that this is an effective investigation format that is capable of getting to the bottom of significant service and organisational problems without the need for a much more expensive, time-consuming and disruptive public inquiry. This being so, we believe that there is considerable merit in establishing a proper framework, if necessary statutory, on which future investigations could be promptly established. This would include setting out the arrangements necessary to maintain independence and work effectively and efficiently, as well as clarifying responsibilities of current and former health service staff to cooperate. Action: the Department of Health.

APPENDIX 1: List of abbreviations

Abbreviation	Full title
A&E	accident and emergency
AoMRC	Academy of Medical Royal Colleges
APS	approved practice setting
BMI	body mass index
BP	blood pressure
CCG(s)	Clinical Commissioning Group(s)
CE	chief executive
CEMACH	Confidential Enquiry into Maternal and Child Health
CEO	chief executive officer
CEU	Clinical Effectiveness Unit
CHAI	the Commission for Healthcare Audit and Inspection
CHI	the Commission for Health Improvement
CMATS	Case Management and Activity Tracking Service
CNST	Clinical Negligence Scheme for Trusts
COSHH	Control of Substances Hazardous to Health
CQC	the Care Quality Commission
CTG	cardiotocograph/cardiotocography
DH	the Department of Health
FGH	Furness General Hospital
FT	Foundation Trust
GMC	the General Medical Council
GP	general practitioner
HASCAS	Health and Social Care Advisory Service
HCC	the Healthcare Commission
HDU	high dependency unit
HEE	Health Education England
HES	Hospital Episode Statistics
HM	Her Majesty's [Coroner]
HoM	Head of Midwifery
HSCIC	Health and Social Care Information Centre
HSE	the Health and Safety Executive
HSMR	hospital standardised mortality ratios
HSWA	the Health and Safety at Work etc. Act 1974
IP	Integrated Performance
KPMG	a professional services company
LSA	Local Supervising Authority
LSAMO	Local Supervising Authority Midwifery Officer
MBI	the Morecambe Bay Investigation

MBRRACE	Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries
MHRA	the Medicines and Healthcare Products Regulatory Agency
MP	Member of Parliament
MRSA	meticillin-resistant staphylococcus aureus
MSLC	Maternity Services Liaison Committee
NHS	National Health Service
NHS FT	NHS Foundation Trust
NHSLA	the NHS Litigation Authority
NICE	the National Institute for Health and Care Excellence
NMC	the Nursing and Midwifery Council
NPSA	the National Patient Safety Agency
NW SHA	the North West Strategic Health Authority
PALS	patient advice and liaison service
PCAS	Primary Care Assessment Service
PCT	Primary Care Trust
PEAT	Patient Environment Action Team
PHE	Public Health England
PHSO	the Parliamentary and Health Service Ombudsman
PNMR	perinatal mortality rate
PROM	premature rupture of membranes
PwC	PricewaterhouseCoopers
R&D	research and development
RCM	the Royal College of Midwives
RCOG	the Royal College of Obstetricians and Gynaecologists
RCPCH	the Royal College of Paediatrics and Child Health
RIDDOR	the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations
RLI	Royal Lancaster Infirmary
RM	risk management
SHA	Strategic Health Authority
SIRI	serious incident requiring investigation
SofS	Secretary of State
SoM	supervisor of midwives
SROM	spontaneous rupture of membranes
StEIS	Strategic Executive Information System
SUI(s)	serious untoward incident(s)
UHMB FT	University Hospitals of Morecambe Bay NHS Foundation Trust
Also referred to as:	
UHMBT the Trust	University Hospitals Morecambe Bay Trust
WGH	Westmorland General Hospital
WHO	the World Health Organisation

APPENDIX 2: Acknowledgements

I wish to place on record my thanks to those who have assisted me in undertaking the work required to carry out a thorough investigation and to publish our Report.

A number of people have helped us to develop the methodology for our clinical review and to undertake analysis. I am also extremely grateful to those responsible for putting in place, managing and maintaining the significant organisational arrangements required to underpin the Investigation's work.

The Panel of expert advisors has provided me with support and guidance since the Investigation was established. I am grateful for their willingness to undertake this important work on top of their significant existing professional commitments. Their specialist expertise, and the depth of their experience, has enabled us to work effectively as a wholly independent multidisciplinary team to address the terms of reference. I consider that it has also provided reassurance to the families and to interviewees that we were determined to bring robust challenge, impartiality and clarity of purpose.

Thanks are also due to the Investigation's secretariat. This small, dedicated team has effectively and efficiently supported me and the expert advisors throughout the duration of the Investigation. I would like to thank especially Paul Roberts, the Investigation's Documents and Evidence Manager, and his team for their diligence in managing the tremendous volume of evidence that was submitted to the Investigation; Nick Heaps, the Investigation's Deputy Secretary, for ensuring that all the Investigation's interviewees were supported appropriately, enabling the interview programme to run smoothly throughout; and, above all, Oonagh McIntosh, the Investigation's Secretary, for her leadership of the secretariat and her wise counsel on too many occasions to count.

Hannah Knight, the Investigation's Data Analyst, provided an invaluable contribution, and the results of her analysis helped shape some of the work of the clinical sub-group.

I should like to thank those who assisted in the development of the methodology (Leicester Team) and in the analysis of evidence. Elizabeth Draper, Professor of Perinatal and Paediatric Epidemiology, and David Field, Professor of Neonatal Medicine, at the University of Leicester provided helpful advice at the outset of the Investigation.

In scoping and carrying out these analyses, we sought a range of expertise and encountered a general willingness to assist the Investigation with its enquiries. We would like to thank the following individuals for their cooperation: Dr David Cromwell, Director of the Clinical Effectiveness Unit at the Royal College of Surgeons of England; Bernard Horan and his colleagues at the Workforce and Facilities Statistics Team at the Health & Social Care Information Centre; Tim Draycott, Senior Clinical Lecturer in Social and Community Medicine, University of Bristol; Helen Brown, Head of Analytical Services – Data Flows, NHS England (North); Jayne Wheway, Head of Patient Safety – Maternity, Children and Young People, NHS England; Professor Jason Gardosi, Director of the Perinatal Institute; and Professor Neena Modi and her colleagues at the Neonatal Data Analysis Unit at Imperial College London.

I am grateful to the Investigation's legal advisors for their advice and cooperation, and to all those involved in the proofreading, editing and printing of the Investigation Report.

Finally, I would like to pay tribute again to the families affected by these events, for their courage and persistence in bringing them to light, and for their patience with, and support for, the Investigation process.

APPENDIX 3: Ministerial statement

WRITTEN MINISTERIAL STATEMENT DEPARTMENT OF HEALTH

University Hospitals of Morecambe Bay Trust Thursday 12 September 2013

The Secretary of State for Health (Jeremy Hunt): University Hospitals of Morecambe Bay Trust (UHMBT) has been the subject of scrutiny for a number of years, following the high number of serious untoward incidents in its maternity and neonatal services. The families of those who were harmed or died under the care of the Trust have persistently and courageously sought a full and independent investigation into the circumstances surrounding these deaths. I am today announcing to the House the terms of reference for the independent investigation into the management, delivery and outcomes of care provided by the maternity and neonatal services of UHMBT from January 2004 – June 2013, under the chairmanship of Dr Bill Kirkup CBE. Dr Kirkup is a former associate medical director at the Department of Health, and served on the Hillsborough Independent Panel.

The investigation will primarily focus on the service provided by the Trust, and the response of the Trust to shortcomings previously identified. It will look at evidence relating to organisations external to the Trust where this will help shed light on the tragic events that occurred, and assist in producing recommendations for preventing such incidences in the future. The principal concern of this investigation is getting the answers the families have requested. Answers are required about what went so desperately wrong with the care they received, and the steps the Trust must take to ensure no other families suffer in the future.

This is not an investigation into the regulatory and supervisory systems of the NHS, as these issues have only recently been examined by the second Mid Staffordshire Inquiry, and the Department of Health will publish its full response in due course. Nor is it a Public Inquiry as the requirements for public evidence sessions are not considered suitable for the privacy and tact with which this investigation must be undertaken. To ensure that the investigation will meet the requirements of openness and transparency, all of its sessions will be open to family members.

The investigation is expected to report to me by next summer and a copy of the full terms of reference has been placed in the Library. Copies are available to hon Members from the Vote Office and to noble Lords from the Printed Paper Office.

Dr Kirkup plans to issue a method statement for the investigation in October 2013. I am grateful to him and the families for their significant contribution to the design of this investigation process. I sincerely hope that it will provide them with the answers that they seek.

APPENDIX 4: The Investigation's panel of expert advisors

Mr Julian Brookes, Deputy Chief Operating Officer at Public Health England

Dr Catherine Calderwood, Advisor to the Scottish Government and National Clinical Director for Maternity and Women's Health, NHS England

Mrs Jacquelyn Featherstone, Associate Director of Nursing and Midwifery at Princess Alexandra Hospital, Harlow, Essex

Professor Stewart Forsyth OBE, former Chair of the Scottish Government Neonatal Expert Advisory Group and the former Medical Director of NHS Tayside

Professor Jonathan Montgomery, Chair of the Health Research Authority and Professor of Health Care Law at University College London

Professor James Walker, Professor of Obstetrics and Gynaecology at St James's University Hospital, Leeds, and former Senior Vice-President of the Royal College of Obstetricians and Gynaecologists

Dr Geraldine Walters, Director of Nursing at King's College Hospital, London

APPENDIX 5: Morecambe Bay Investigation – Schedule of Panel meeting dates and venues

28 November 2013	Park Hotel, Preston
11 December 2013	Park Hotel, Preston
15 January 2014	Education Centre, Royal Lancaster Infirmary, Lancaster
13 February 2014	Park Hotel, Preston
5 March 2014	Park Hotel, Preston
3 April 2014	Park Hotel, Preston
8 May 2014	Park Hotel, Preston
12 June 2014	Park Hotel, Preston
10 July 2014	Park Hotel, Preston
11 September 2014	Park Hotel, Preston
9 October 2014	Park Hotel, Preston
6 November 2014	Park Hotel, Preston
14 January 2015	Park Hotel, Preston

APPENDIX 6: Membership of the Investigation Panel's sub-groups

Clinical

Stewart Forsyth – Chair

Bill Kirkup

Catherine Calderwood

Jacquelyn Featherstone

James Walker

Geraldine Walters

Trust management and governance

Geraldine Walters – Chair

Bill Kirkup

Julian Brookes

Jacquelyn Featherstone

Stewart Forsyth

Jonathan Montgomery

External response and governance

Jonathan Montgomery – Chair

Bill Kirkup

Julian Brookes

Catherine Calderwood

Geraldine Walters

APPENDIX 7: Invitation to families

THE MORECAMBE BAY INVESTIGATION

Chaired by Dr Bill Kirkup CBE

INVITATION FOR FAMILIES AFFECTED TO GET IN TOUCH

The Morecambe Bay Investigation has been set up to examine the historic standard of care received by mothers and babies in the maternity and neonatal service at the University Hospitals Morecambe Bay NHS Foundation Trust (UHMB FT), and in any hospital they were transferred to, between 1 January 2004 and 30 June 2013.

As Chairman of the Investigation I would like to invite any families who previously received unsatisfactory care from the maternity and neonatal services at Furness General Hospital, Lancaster Royal Infirmary and Westmorland General Hospital during this time period to contact the Investigation to talk about their experiences. The Investigation is looking at both the deaths of mothers and very young babies as well as cases of babies who were injured in childbirth during this period. It will also look at how the Trust managed serious untoward incidents.

I know the death of a child or mother, or their injury during childbirth, is a very distressing event in a family's life. I have therefore made arrangements for any families, if they would prefer, to provide evidence in private and remain anonymous.

If you would like to contact the Investigation, my team are available by emailing correspondence@mbinvestigation.org or by calling 01772 536382 during normal office hours but can make arrangements to call you back at a mutually convenient time if that would be helpful.

I would like to thank you in advance for your assistance.

Bill Kirkup CBE

Chairman of the Investigation

APPENDIX 8: Interview protocol

THE MORECAMBE BAY INVESTIGATION

Chaired by Dr Bill Kirkup CBE

INTERVIEW PROTOCOL

1. Background

The Morecambe Bay Investigation is an independent investigation into the maternity and neonatal services of the University Hospitals of Morecambe Bay NHS Foundation Trust (the Trust) and their governance and management.

The Investigation is chaired by Dr Bill Kirkup CBE and was commissioned by the Department of Health.

2. Who will the Investigation interview?

The Investigation Panel will draw up an initial list of individuals who will be invited to interview and be asked to provide oral information. The list will be kept under review and updated as necessary in light of further evidence emerging from documents and interviews. Additional interviews may be arranged at a later date in response to evidence seen or heard by the Panel.

Interviewees will be invited to attend the Investigation to give their own account and respond to questions from Panel members. The Investigation will not refer to 'witnesses' or to 'giving evidence' to reflect the collaborative approach the Investigation has adopted and the nature of the process, which is an investigation to establish the facts and make recommendations to improve care both locally and more widely. The corollary is that the Investigation expects full cooperation from staff as well as organisations, in line with their professional duty and employment responsibility. It is expected that this will extend to anyone no longer employed in the NHS, and considers that present or future receipt of an NHS pension carries a corresponding responsibility.

Interviewees who are registered with the General Medical Council (GMC) are reminded that the GMC's *Good medical practice guidance* 2013 states that "*You must cooperate with formal inquiries and complaints procedures and must offer all relevant information*".

Interviewees who are registered with the Nursing and Midwifery Council (NMC) are reminded that the NMC Code states "*You must cooperate with internal and external investigations*".

The Investigation intends to interview individuals who were:

- responsible for the leadership, management, governance and delivery of maternity and neonatal services at the Trust between 1 January 2004 and 30 June 2013;
- employed in any one of a number of related organisations, and responsible for the commissioning, oversight, monitoring, regulation and supervision of, and complaints made about, the services as well as the standards of those providing the operational delivery between 1 January 2004 and 30 June 2013;

- directly responsible for delivering care in the maternity and neonatal units between 1 January 2004 and 30 June 2013;
- directly affected by the services and care delivered primarily, but not exclusively, in the maternity and neonatal units at the Trust between 1 January 2004 and 30 June 2013; and/or
- responsible for the development of national policies and procedures in respect of maternity and neonatal care and governance for the period in question.

In addition the Investigation will interview:

- those who are currently responsible and accountable for the delivery of services and care, notably maternity and neonatal, at the Trust; and
- those who are responsible and accountable for supervising and regulating clinical and nursing staff and for monitoring data recorded by the Trust.

To ensure that the Investigation will meet the requirements of openness and transparency, all of its sessions will be open to family members. In practice many family members have recognised that their presence may inhibit some interviewees, and the Investigation will arrange one or more separate sessions for them to listen to recordings so that they can be assured that the process is thorough.

3. How will the Investigation make initial contact with those it wishes to interview?

The Investigation has already asked a number of interested organisations to advise their staff (serving and former) about the Morecambe Bay Investigation and its terms of reference.

The Investigation will compile a list of interviewees and potential interviewees.

The employer, former employer or, if appropriate, legacy organisation of each interviewee will be asked to make contact with the relevant individuals to advise them that the Investigation would like to interview them and thereafter communication will be directly between the Investigation and interviewees. This early notification to employers, former employers or legacy organisations should also assist them to plan for attendance of staff at the Investigation.

4. The storage of interviewee details

Once responses are received from interviewees, their contact details will be stored by the Investigation on a database. The database will be password protected and will only be accessed by a small group of staff within the Investigation for the specific purposes of liaising with the interviewee to arrange a schedule of hearings and to undertake the necessary administrative work that will be required to achieve this.

Contact details of individual interviewees will be retained by the Investigation for the duration of its work and until four weeks after the Report has been published.

Contact details will then be destroyed by the Investigation in accordance with Data Protection requirements.

5. Invitation to interview

As the Investigation is not part of a legal process, interviewees will not be legally represented and the Investigation will not deal with anyone other than the interviewee.

Interviewees will be advised that they are welcome to bring a relative, friend or colleague with them to the Investigation who will be able to remain with the interviewee but not to comment on the proceedings or to ask any questions during the interview.

The Investigation recognises that some individuals may wish to be accompanied by a Trade Union official or a legal representative. It will be made clear that that individual is free to accompany them to the Investigation but is attending as their colleague or friend and not in a representative capacity.

Appropriate refreshments will be provided for the interviewee and any relative, friend or colleague who accompanies them.

It is the expectation that interviewees will have any reasonable expenses they incur, as a direct result of attending an interview at the Investigation, met by their employer. If an employer will not reimburse an interviewee for their expenses, each interviewee will be entitled to claim reimbursement from the Investigation for reasonable travel expenses and the loss of earnings incurred as a direct result of their attendance at the Investigation (as set out in the Investigation's travel and subsistence policy). Receipts will be required for all claims and evidence will be required prior to reimbursement for any loss of earnings. A claim form will be provided on the day of interview.

Each Friday a list of the following week's interviewees will be posted on the Investigation website. This will enable families who may wish to attend to observe the interviews, to make practical arrangements and will provide information to those who are following the progress of the Investigation.

Once dates are confirmed for attendance at the Investigation, interviewees and their employer, former employer or legacy organisation will be advised what principal subject(s) or term(s) of reference they will be asked about by the Investigation Panel to enable them to undertake any necessary preparation. When possible the Investigation will advise both interviewees and their employer, former employer or legacy organisation, if any specific document(s) should be viewed prior to their attendance.

Interviewees will be advised to contact their current/previous employer to arrange to view those papers that may assist them provide the Investigation with detailed responses to questions they may be asked.

There may be specific instances where the Investigation wishes to ask an interviewee to comment on a particular document. If such a circumstance arises the Investigation will make appropriate arrangements for the interviewee to be made aware of the material.

Recognising that many interviewees may be operational NHS staff and have limited time or opportunity to prepare for their attendance, they will be given as much notice as possible of their interview by the Investigation. The Investigation will establish, at the earliest opportunity, what dates individuals are unavailable to attend for an interview. A minimum of one week's notice will be provided to confirm the arrangements for an interview.

Interviewees will be asked to confirm, in writing, that they will attend the Investigation on an agreed date(s) to ensure that everybody's time is used as effectively and efficiently as possible. They will also be advised what arrangements will be put in place should their interview over-run. Interviewees may be required to return either the next day or on another date to conclude their interview.

6. Attendance at the Investigation

All interviewees will be sent a brief factsheet giving them information about the practical arrangements for their interview.

All those attending (including the Panel, Secretariat, stenographers and those who are observing) will be required to hand their mobile telephone, laptop computer, tablet, camera and/or any recording device they may have with them to the Investigation's Secretariat for safe keeping whilst the interviews are taking place.

Interviews will take place at the Investigation's office in Preston or, if appropriate, at a venue in Barrow. Interviews will commence each day at 10.00am. There will be a suitable half hour for lunch and the afternoon session will conclude by 4.00pm.

Interviewees will be able to attend the Investigation for a brief introduction by the Secretariat and be given the opportunity to familiarise themselves with the Meeting Room. This will happen earlier in the day of their interview.

The Chairman will give a brief introduction to each interviewee, explaining which Panel members are present and how the interview will proceed and of the responsibility of all present to respect confidentiality. It is not anticipated that all of the Panel will be present at each interview.

The Investigation will make a recording of the interviews. The recording will be made to aid the production of the note of each interview and also so that those family members who are unable to attend interviews will have the opportunity to attend the Investigation's offices in Preston at a convenient time in the month following the interview, to hear the recording. Recordings of any closed sessions at which personal sensitive data is discussed will not be replayed to family members. The recordings of all interviews will be destroyed when the Investigation's Report is published.

It will be a matter for interviewees how they respond to the questions they are asked and it will be a matter for the Secretary of State and others what action is taken in response to the Investigation's findings and recommendations.

Many interviewees will previously have been interviewed about the events that occurred at the Trust. In the unlikely event that the Investigation should hear evidence from an individual about which they consider that they should take advice and/or take appropriate action, they will do so and the interviewee will be notified accordingly.

Should the Panel need to ask an interviewee about a specific patient or member of staff, and personal sensitive data will be referred to, all observers will be required to leave the interview room. Any evidence provided regarding personal sensitive data will be heard in a closed session by the Panel. Appropriate redaction will be made of the record of the interview. Observers will not be permitted to listen at a later date to the recordings of any closed sessions.

7. Following the interview

Following their attendance at the Investigation, interviewees will be shown a copy of the transcript of their interview as soon as is practicable. The transcript will be provided in hard copy or a PDF version can be provided by email. The interviewee will be asked to add any further clarification or other information that will help ensure their account is as complete as possible.

Records of all Panel meetings and interviews will be placed in the Department of Health's record office *after* the Investigation's Report has been published. At that stage they will be accessible through applications made under the provisions of the Freedom of Information Act.

Any subsequent or related question that the Investigation Panel may have following an interview will, when possible, be dealt with in correspondence between the Investigation and the interviewee. Every effort will be made to avoid having to recall any interviewee; however, this may have to be arranged in exceptional circumstances or when additional information of significance has arisen from interviews or documentary evidence.

A summary of each day's hearing – not the record of the interview – will be posted onto the Investigation website. The summary will detail who was interviewed and what their role/responsibility was, what term of reference they were interviewed about (or greater detail if appropriate to do so) and which Panel members were present.

8. Handling of media enquiries/interest in the oral hearings of the Investigation

The Investigation is aware that some interviews will generate media interest.

The media are not permitted to attend the interviews or to enter the building and the Investigation will make this clear on its website and to any member of the media who makes enquiries in advance of the interviews. A media protocol will be available and will be shared with interested organisations and placed on the Investigation website.

Interviewees may wish to avail themselves of the offer of an early arrival and a slightly later departure from Park Hotel on the day(s) they are attending the Investigation.

Interviewees will be accompanied by a member of the Secretariat throughout their attendance at the Investigation.

In addition the Investigation can make arrangements for interviewees to be collected by car from the main entrance of Park Hotel and this will reduce the time that any interviewee could be spoken to by a member of the media or a member of the public.

APPENDIX 9: List of interviewees

NAME	REASON INTERVIEWED
Ms Ann ABRAHAM	former Parliamentary and Health Service Ombudsman
Mrs Moira ANGEL	Director of Nursing and Quality, Cumbria Primary Care Trust
Dr Muhammad ASGHAR	Consultant Paediatrician, University Hospitals of Morecambe Bay NHS Foundation Trust (UHMB FT)
Professor John ASHTON	former Director of Public Health, Cumbria Primary Care Trust, and former Regional Director for Public Health North West
Ms Lisa BACON	Local Supervising Authority Midwifery Officer North West
Mr Vincent BAMIGBOYE	Consultant Obstetrician and Gynaecologist, UHMB FT
Dame Christine BEASLEY	former Chief Nursing Officer, Department of Health
Mr David BEHAN	Chief Executive, Care Quality Commission
Dr David BENNETT	Chief Executive, Monitor
Mr Tim BENNETT	former Director of Finance and Information and former Deputy Chief Executive, UHMB FT
Dr Mike BEWICK	former Medical Director, Cumbria Primary Care Trust, including Chair of Gold Command
Ms Lindsey BIGGS	Midwife, UHMB FT
Mrs Jo BORTHWICK	former Head of Business Planning, UHMB FT
Ms Cynthia BOWER	former Chief Executive, Care Quality Commission
Mrs Jennifer BOWNS	Senior Midwife, Supervisor of Midwives and Labour Ward Coordinator, Furness General Hospital
Ms Angela BROWN	Senior Nursing Officer, North West Strategic Health Authority
Mrs Julie BUCKLEY	former Head of Information, UHMB FT
Professor Andrew CALDER	co-author of the Fielding Report
Mr Fraser CANT	former Assistant Director of Operations, UHMB FT
Ms Miranda CARTER	Assessment Director, Monitor
Mr Adam CAYLEY	Regional Director, Monitor

Dr Michael CHESHIRE	former Medical Director, North West Strategic Health Authority
Mr Peter CLARKE	Public Engagement and Communication, Cumbria Primary Care Trust, member of Gold Command
Ms Jennifer CLAY	Public Health Intelligence Analyst, Cumbria Primary Care Trust
Ms Beverley COLE	former Compliance Manager for Cumbria, Care Quality Commission
Ms Karen CONNOLLY	Co-author of the <i>Diagnostic Review undertaken at University Hospitals of Morecambe Bay NHS Foundation Trust</i>
Professor Ian CUMMING	former Chief Executive, North Lancashire Primary Care Trust, and former Chief Executive, UHMB FT
Mrs Jane CUMMINGS	former Director of Nursing, North West Strategic Health Authority
Ms Jackie DANIEL	Chief Executive, UHMB FT
Ms Julia DENHAM	Area Manager, Care Quality Commission
Ms Louise DINELEY	Head of Regulatory Risk and Foundation Trust Assurance Team, Care Quality Commission
Ms Marian DRAZEK	former Local Supervising Authority Midwifery Officer North West
Mr Russell DUNKELD	former Senior Nurse, Royal Lancaster Infirmary
Mr Peter DYER	former Medical Director, UHMB FT
Mr Ian ELLIOTT	author of the PricewaterhouseCoopers governance review
Mr Stephen EVANS	former Head of Business and Performance (Family Services), UHMB FT
Mr Michael FARRAR	former Chief Executive, North West Strategic Health Authority
Professor Dame Pauline FIELDING DBE	author of the Fielding Report
Miss Denise FISH	former Head of Midwifery, UHMB FT
Ms Ann FORD	Senior Regional Manager, Care Quality Commission
Dr Owen GALT	Consultant Paediatrician, later Divisional Clinical Director, UHMB FT
Dr Saeed GHANIM	former Consultant Paediatrician, UHMB FT
Mr Paul GIBSON	former Consultant Paediatrician and Clinical Lead for Paediatrics, UHMB FT

Mrs Kay GILBEY	former Acting Director of Nursing and Deputy Director of Nursing, UHMB FT
Dr June GREENWELL	former Non-Executive Director, UHMB FT
Mr Julian GRIEVES	Business Manager Women's and Children's Division, UHMB FT
Mr Graham HALL	former Governance Manager, UHMB FT
Mr Tony HALSALL	former Chief Executive, UHMB FT
Mrs Kathryn HAMPSON	Midwife and Supervisor of Midwives, UHMB FT
Dr Susan HARDING	former Clinical Lead for Anaesthesia, UHMB FT
Mrs Vanessa HARRIS	former Divisional Manager, UHMB FT
Sir David HENSHAW	former Chairman, North West Strategic Health Authority, and former Interim Chair, UHMB FT
Mr David HOLDEN	former Interim Director of Governance, UHMB FT
Ms Jacqueline (Jackie) HOLT	former Director of Nursing, UHMB FT
Dr Ann HOSKINS	former Acting Regional Director, Public Health North West, and former Deputy Director, North West Strategic Health Authority
Ms Kathryn HUDSON	former Deputy Parliamentary and Health Service Ombudsman
Mr Ibrahim HUSSEIN	former Associate Medical Director, Consultant Obstetrician and Gynaecologist, UHMB FT
Dr Ruth HUSSEY	former Regional Director, Public Health North West
Mr Alan JEFFERSON	former North West Regional Director, Care Quality Commission
Dr Geoff JOLLIFFE	Medical Advisor, Cumbria Primary Care Trust
Professor Eddie KANE	former Chairman, UHMB FT
Sir Bruce KEOGH	former Medical Director, Department of Health
Mrs Ayshea KITCHIN	Labour Ward Coordinator, Furness General Hospital
Dr Sangeetha KOLPATTIL	Consultant in Radiology, UHMB FT
Dr Karnad KRISHNAPRASAD	Clinical Lead for Anaesthesia, UHMB FT
Mrs Judith KURUTAC	former North West Local Supervising Authority Midwife
Ms Catherine LUBELSKA	former Chair, Morecambe Bay Primary Care Trust, and former Non-Executive Director, UHMB FT
Miss Stella McDOWELL	Midwife, UHMB FT
Mr Patrick McGAHON	former Director of Commercial Developments, UHMB FT

Ms Joyce McGULLION	former Matron, UHMB FT
Ms Sue McMILLAN	Senior Regional Manager, Care Quality Commission
Dr Dhia MAHMOOD	Consultant Paediatrician, Royal Preston Hospital
Mr Prabas MISRA	Consultant Obstetrician and Gynaecologist, UHMB FT
Mrs Joan MOORBY	Midwife, UHMB FT
Mr Eric MORTON	Interim Chief Executive, UHMB FT
Ms Amanda MUSGRAVE	Compliance Manager, Care Quality Commission and section 48 investigation report
Mr George NASMYTH	former Interim Medical Director, UHMB FT
Sir David NICHOLSON	former Chief Executive, NHS and NHS England
Ms Una O'BRIEN	Permanent Secretary, Department of Health
Dr Anas OLABI	Consultant Paediatrician, UHMB FT
Mrs Angela OXLEY	former Head of Midwifery, Gynaecology and Obstetrics, UHMB FT
Mrs Susan (Sue) PAGE	former Chief Executive, Cumbria Primary Care Trust
Mr Kirk PANTER	Royal College of Nursing staff side representative, Theatre Nurse in Anaesthetics and Recovery, UHMB FT
Mrs Holly PARKINSON	Midwife, UHMB FT
Miss Jeanette PARKINSON	former Maternity Risk Manager (Senior Midwife), Furness General Hospital
Mrs Jayne PINKNEY	Modern Matron Community and Antenatal Clinic, UHMB FT
Ms Marie RATCLIFFE	Midwife, UHMB FT
Dr Hugh REEVE	former Medical Director and PEC Chair, Morecambe Bay Primary Care Trust/Cumbria Primary Care Trust
Mrs Geraldine ROBINSON	Maternity Ward Manager/Ward Sister B7, Furness General Hospital
Ms Lesley RYAN	Paediatric Nurse Practitioner and Paediatric Matron, UHMB FT
Ms Sarah SEAHOLME	Head of Investigations Team/Investigations Manager, Care Quality Commission
Dr Neela SHABDE	Medical Director for Children, Cumbria Primary Care Trust, and member of Gold Command
Dr Veena SHARAN	former Consultant Obstetrician and Gynaecologist, Furness General Hospital
Ms Kay SHELTON	former Non-Executive Director, Care Quality Commission
Ms Amanda SHERLOCK	Director of Operations, Care Quality Commission

Mr Andrew SIMPSON	Advanced Neonatal Nurse Practitioner, Royal Preston Hospital
Ms Jackie SMITH	Chief Executive and Registrar, Nursing and Midwifery Council
Ms Janet SOO-CHUNG	former Chief Executive, North Lancashire Primary Care Trust
Mr Sunando SUR ROY	Specialty Doctor in Obstetrics and Gynaecology, UHMB FT
Mr David TANSLEY	Deputy Director of Governance, UHMB FT
Dr Abdulmagid TAUFIK	former Paediatrician, UHMB FT
Dr David TELFORD	former Interim Medical Director, UHMB FT
Mr Steven VAUGHAN	former Director of Operations and Performance, UHMB FT
Ms Sarah VAUSE	Co-author of the <i>Diagnostic Review undertaken at University Hospitals of Morecambe Bay NHS Foundation Trust</i>
Dr Patrick WARD	former Consultant Paediatrician, UHMB FT
Mrs Karen WEAKLEY	Modern Matron Maternity Ward, Furness General Hospital
Professor Dickon WEIR-HUGHES	former Chief Executive and Registrar, Nursing and Midwifery Council
Ms Sascha WELLS	Head of Midwifery, Gynaecology and Obstetrics, UHMB FT
Mrs Ann WEST	former Matron, Children's Services, Furness General Hospital
Mrs Karen WESTALL	former Non-Executive Director, UHMB FT
Ms Angela WHITAKER	former Neonatal Matron, UHMB FT
Mr Roger WILSON	former Director of Human Resources and Organisational Development, UHMB FT
Mrs Valerie WILSON	Deputy Head of Midwifery, Gynaecology and Obstetrics/ Governance Lead, UHMB FT
Ms Fiona WISE	Improvement Director, UHMB FT
Mr John WOODCOCK	Member of Parliament for Barrow and Furness
Ms Victoria WOODHATCH	Senior Assessment Manager, Monitor

INVITED TO ATTEND FOR INTERVIEW BUT DID NOT

Dr W MOYES¹

¹ Former Executive Chair of Monitor. We attach by agreement as Appendix 10 the most recent letter from Dr Moyes setting out his reasons for declining to be interviewed.

APPENDIX 10: Letter from Dr William Moyes, former Executive Chair of Monitor, to the Investigation Chairman, Dr Bill Kirkup CBE

Dr Bill Kirkup CBE,
Chairman, the Morecambe Bay Investigation,
3rd Floor, Park Hotel,
East Cliff,
Preston,
Lancashire PR1 3 EA,

9, January, 2015

Dear Dr Kirkup,

Since I wrote to you on 22 December 2014 my former colleagues in Monitor have given me a copy of the letter of 30 December 2014 from the secretariat to the Investigation outlining the process they intend to follow to conclude the taking and analysis of evidence and the preparation of a report to the Secretary of State for submission in February. In the light of this I thought I should write to you to ensure you and your colleagues are properly aware of my position, and to seek once again your assurance that I will have the opportunity to comment on any reference to me in the final report before it is submitted.

I hope I have made clear in my correspondence with you and the secretariat I support the concept of a full investigation where NHS management or service quality or clinical performance appears to be unacceptably poor. I strongly believe that the performance of services funded by the taxpayer should be thoroughly scrutinised and lessons clearly learned from failures or mistakes. So, my unwillingness to be a witness should not be taken to imply a lack of support for the Investigation.

My position is simply that I do not believe my involvement would in any way assist the Investigation to understand what happened and why, given my peripheral involvement and the passage of time.

During my time as Executive Chairman of Monitor I attended around 200 board-to-board meetings with applicants to be authorised as Foundation Trusts. I also attended a similarly large number of meetings with Foundation Trusts which were in significant breach of the terms of their Authorisation, or were suspected of being so. I have no recollection of having had any contact with Morecambe Bay NHS Trust, although my former colleagues in Monitor tell me that I was involved in the earliest stages of Monitor's consideration of the Trust's application.

Apparently the sequence of meetings relating to Morecambe Bay's application was as follows:-

- 7 May 2009 – first Board-to Board meeting
- 27 May 2009 – Application considered by Monitor's Board, which decided to "pause" the application process
- April 2010 – Application "deferred" by Monitor's Board
- 8 September 2010 – second Board-to-Board meeting
- 29 September 2010 – Morecambe Bay authorised as a Foundation Trust

I retired from Monitor at the end of January 2010. I am told that I was involved in the meetings in May 2009, but obviously not thereafter. So, I played no part in the decision to authorise the Trust or in the subsequent monitoring of Morecambe Bay's compliance with the terms of its Authorisation.

2009 was a time of great difficulty for some NHS Trusts and Foundation Trusts, and contributing to the management of these problems consumed a lot of my time and energy. Although I would have considered carefully any issues put to me by the team assessing Morecambe Bay's application for authorisation, it would not have been high in my priorities during 2009. So, it should be no surprise that I have no recollection of the application and the issues it raised or of any internal or external conversations about the performance of the Trust or what it had to do to secure authorisation as a Foundation Trust.

Moreover, since I left Monitor I have undertaken a range of activities including board appointments and senior advisory roles. However, none of these have involved contact with Monitor or Foundation Trusts and therefore I have not kept up with developments in those areas.

For these reasons I do not believe I can assist the Investigation and I would be concerned that any evidence I might offer could not be regarded as reliable given my slight involvement with the authorisation of Morecambe Bay and the fact that this was nearly 5 ½ years ago.

Nonetheless, you and your colleagues have pressed me to attend to give evidence and have asserted that I would be the only person to refuse the invitation to attend. I do not believe this to be true. I understand, for example, that one former member of staff of Monitor, who had some operational involvement with Morecambe Bay's application for foundation trust status, refused the invitation to give evidence and appears not to have been pressed to reconsider. In addition, at Monitor's request some relatively junior members of staff, who had also been involved in assessing Morecambe Bay's application, were excused from giving evidence. One senior member of Monitor's team, who would have had oversight of the assessment of Morecambe Bay's application throughout and of the subsequent monitoring of Morecambe Bay's performance once authorised, has not been called. A request by Monitor for me to be excused, on the grounds summarised above, was swiftly rejected by the Investigation, without discussion or explanation.

I remain unclear as to what is it that the Investigation thinks I can uniquely help them with. This was the question I posed most recently in my letter to you of 22 December, and which remains unanswered.

In August 2014 the secretariat suggested that I might read the documents submitted to the Investigation by Monitor. However, since the vast majority of these would have been completely new to me, that did not seem a very sensible approach. I also understand that Monitor supplied the Investigation with a huge number of documents, so there would have been a very major practical hurdle to overcome as well. Subsequently you have suggested in successive letters to me that what the Investigation wants to understand is :-

“.....how interested organisations, such as Monitor, engaged with the Trust

“.....the perspectives of all of the relevant staff, past and present.

“..... you were Executive Chair of Monitor at the time of the initial application and its deferral, and, as such, led the organisation and its processes. My Panel would like the opportunity to hear at first hand how these operated.

I believe all of these are matters which could be dealt with more comprehensively and reliably by current staff of Monitor who were involved with Morecambe Bay’s application and who remain part of Monitor’s team. However, if I were to be provided with a specific statement of what the Investigation seeks from me, and why this cannot be better provided by others, I would be prepared to review my position.

In successive letters to me you have emphasised your intention to identify in your report individuals who were invited to give evidence and refused. You are clearly entitled to do that. However, the terms of any such references must be fair to me. In my letter to you of 11 November 2014 I sought your assurance that I would have a proper opportunity to comment on the terms of any reference to me in the draft report before it is submitted, and that my comments would be carefully considered. You have not yet responded to that. In the light of the process and the very tight timetable now being followed by the Investigation, as described in the secretariat’s letter of 30 December, I would be grateful to have the assurances and information I seek.

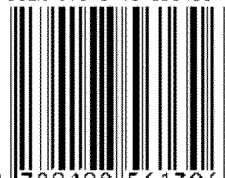
I look forward to an early response to this letter, which I have copied to the secretary to the Investigation.

Yours sincerely,

GRO-C

William Moyes (Dr.)

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