NHS
Cumbria
Clinical Commissioning Group

NHS Cumbria CCG Governing Body	Agenda Item
1 April 2015	6

The report of the Morecambe Bay Investigation – Dr Bill Kirkup

Purpose of Report:

- The Governing Body is asked to receive and consider the report of the Morecambe Bay investigation and agree the proposed governance arrangements.
- The report includes the executive summary and recommendations of the investigation. The full report is available at https://www.gov.uk/government/publications/morecambe-bay-investigation-report

Key Issues/Considerations:

Summary

The Morecambe Bay investigation report was published on 3 March 2015 and makes 44 recommendations for Morecambe Bay University Hospital Trust and the wider NHS.

Covering January 2004 to June 2013, the report concludes the maternity unit at Furness General Hospital (FGH) was dysfunctional and that serious failures of clinical care led to unnecessary deaths of mothers and babies.

The Investigation Panel also reviewed pregnancies at other maternity units run by University Hospitals of Morecambe Bay NHS Foundation Trust. It found serious concerns over clinical practice were confined to FGH.

The report's recommendations are far reaching, with 18 aimed at the Trust and 26 for the wider NHS and other organisations. Many contain specific target dates for completion.

The General Medical Council and Nursing and Midwifery Council are recommended to consider investigating the conduct of those involved in patient care. The report recommended a national review of the provision of maternity and paediatric care in rural, isolated or difficult to recruit to areas.

Other recommendations call for action from Trusts, professional regulatory bodies, the Care Quality Commission, Monitor, the Department of Health, NHS England, nursing and midwifery organisations and the Parliamentary and Health Service Ombudsman.

The report concludes that significant progress is being made at FGH and that the recommendations are intended to ensure they continue to be built on.

The investigation was established by the Secretary of State for Health in September 2013 following concerns over serious incidents in the maternity department at Furness General Hospital (FGH).

Response from MBUHT

MBUHT immediately issued an unreserved apology to all the families. The report has been received at a special board meeting and a preliminary action plan to address the trust recommendations has been produced.

Governance arrangements:-
MBUHT has elected to set up an additional sub-committee of its board to oversee the development and delivery of the action plan. Terms of Reference are in the process of being drafted. The two CCGs will be represented on the committee. Robust governance arrangements will be required to ensure the recommendations are monitored and implemented in full.

The sub-committee would be chaired by a non-executive director (Professor Anne Garden), with membership to include a public governor and an external expert.

The delivery of the action plan will be led by the Trust's Medical Director, Dr David Walker with the support of a 'delivery group'. The Women and Children's Division will be responsible for the day to day operational delivery of the plan. Additional resources will be made available by MBUHT to support administration and management of this programme of work

Ongoing engagement with families:-

A separate letter of apology is also being sent to a number of families affected by the findings in the Report.

The letter to families also makes the offer for the Trust Chair and Chief Executive to meet with any family members to discuss the findings of the report and their experiences with the Trust.

The local public and those families affected will have the opportunity to be kept informed of progress, should they wish to, and where possible, be involved in future decisions surrounding maternity services. A meeting has been arranged with John Woodcock MP to further discuss his suggestion.

The Trust is also exploring independent, expert support to facilitate engagement with families. This offer could include providing input to help shape future developments within the service.

Response from Cumbria CCG and Lancashire North CCG

In the light of these recommendations, both CCGs have agreed to respond together as part of a Bay-wide approach. This is consistent with the Better Care Together approach. In practical terms, Lancashire North CCG will take a coordinating lead for the work now required with UHMB, working closely with clinical and managerial colleagues from Cumbria CCG at all times.

The overarching monitoring of these arrangements will be undertaken through a monthly Quality Surveillance Group to include Care Quality Commission (CQC), Monitor and Health Education North West (HENW).
Recommendations:
The Governing body is asked to:- • Receive and consider the Kirkup report • Consider the governance arrangements to take forward the action plan (MBUHT with the Cumbria CCG and Lancashire North CCG). • Adopt the recommendations of the Kirkup report in full.
CCG Objectives:
Quality: Implement clear systems to improve clinical effectiveness, patient experience and safety **Performance and Outcomes:** Ensure continuous improvement in performance standards and outcomes **Plan on a Page and Commissioning Plans:** Ensure the effective delivery of our key commissioning plans
Statutory/Regulatory/Legal/NHS Constitution Implications
The Morecambe Bay Investigation was established by the Secretary of State for Health and has far reaching implications for the NHS both locally and nationally.
Assurance Framework:
There is a risk that maternity services cannot be provided in a way that is accessible, safe and sustainable for patients across Cumbria.
Finance/Resource Implications:
These will be evaluated through the development of the action plan.
Implications/Actions for Public and Patient Engagement:
Recent and future engagement with the families involved is of the highest priority. Arrangements are being made for ongoing involvement in the maternity sub-committee and the provision of specialist advice.

Equality Impact Assessment:
Not applicable

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THE MORECAMBE BAY INVESTIGATION - 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.

THE MORECAMBE BAY INVESTIGATION - 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. 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. 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.