1. PURPOSE OF THE REPORT:

The Report of the Morecambe Bay Investigation (Kirkup Report) was published in March 2015. The report was 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.

Issues Addressed in the Report
The 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 which 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.

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 the responses to them by the Trust and by the wider National Health Service (NHS), including regulatory and other bodies.

The independent investigation covered the period from 1 January 2004 to 30 June 2013. The main theme was that serious problems did not develop overnight and numerous opportunities were missed to prevent harm and
improve patient safety.

**Background to Report**
The independent investigation covered the period from 1 January 2004 to 30 June 2013. The main theme was that serious problems did not develop overnight and numerous opportunities were missed to prevent harm and improve patient safety.

The timeframe provides a useful overview:

- The first sign of problems occurred in 2004, when a baby died from the effects of shortage of oxygen, due to a mismanaged labour.
- Between 2004 and 2008 there were a series of missed opportunities to identify problems, including five serious incidents that occurred between 2006-2007.
- A cluster of five further incidents followed in 2008 – these incidents clearly signalled to the Trust Board and Executive Directors that all was not well. At the same time consultant obstetricians began raising concerns.
- By the end of 2009 there was clear knowledge of a dysfunctional maternity unit at Furness General Hospital (FGH) but the Trust response was flawed, clinical governance systems throughout the Trust were inadequate and there was an inadequate flow of information (the 2008 incidents were treated as unconnected).
- Early in 2009, the Trust was focused on achieving Foundation status and this played a significant part in what transpired. The application for Foundation Status led to the Trust reporting 12 serious incidents 5 of which were at FGH. 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. Monitor looked to the CQC as the arbiter of clinical quality, including patient safety. The CQC investigation team declined a referral from Monitor stating that the incidents were unrelated, however 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.
- In 2009 the Parliamentary and Health Service Ombudsman (PHSO) was considering a complaint. 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 opportunity.
- 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.
- 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.
- Monitor approved the Trust for FT status in September 2010.
- In 2010 the Fielding review was produced in draft but took until August 2010 to finalise. The report contained significant criticism and 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.
- In 2011 – four events brought the Trust to wider attention: CQC and Monitor obtained the suppressed Fielding Report, Coroners verdict on the death of a particular baby was strongly critical of failing care, a
police investigation was commenced to look into other deaths and lastly, families came forward in response to the police investigation

- 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.

**Conclusion**

The conclusion of the report is that these events represented 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

There were 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 had 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. The report has 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.

- There was poor practice though staff were reported to be trying hard. What was inexcusable is the repeated failure to examine incidents properly.
- Barrow in Furness was an isolated town with an isolated hospital. There were recruitment problems and some staff had never worked anywhere else, this contributed to low standards.
- When the size of the problem was identified, the Trust’s response was flawed and inadequate; there was a culture of denial and cover up in the maternity unit.
- The drive to achieve Foundation Status diverted attention from the day to day running of the organisation and fostered a reluctance to disclose problems.
- The monitoring of the quality of services delivered by Trusts has varied over time. The frequency of organisational change has introduced uncertainty - loss of corporate memory and expertise.
- It is clear that the accountability for the quality of patient services lies with the Trust, however there is little point in an elaborate system of overview and scrutiny if it cannot detect failures.
- The report acknowledged effort of families to bring issues to light, however this was against a backdrop of a flawed complaints system.
- There was no evidence that the ethnicity of families played a factor in the incidents.

**Recommendations**

There were 44 recommendations in total. These were as follows:

**University Hospitals of Morecambe Bay Foundation Trust should:**

- Admit the nature of the problem
- Review competencies, skills and knowledge of all clinical staff
- Draw up plans to deliver training and development
- Identify requirements of CPD for staff
• Promote effective multi-disciplinary working
• Protocol for risk assessment in maternity services
• Audit the operation of maternity and paediatric services
• Identify a retention and recruitment strategy
• Identify an approach to better joined up working regarding policies, systems and standards
• Forge links with a partner Trust by Sept 2015
• Identify a programme to raise awareness of incident reporting and the processes behind this. Review Open and Honest policy. Duty of Candour
• Review structures to investigate incidents – carry out RCA, report and disseminate results
• Review complaints process
• Review arrangements for clinical leadership in obs, paeds and midwifery
• Prioritise work commenced in response to the review of governance systems already in place
• Middle and senior managers should have the requisite clarity over roles and responsibilities in relation to quality
• Improve the physical environment of the delivery suite – should be completed by Dec 2017
• Implement these recommendations with the involvement of the CCGs, CQC and Monitor. NHS England should oversee this process and provide necessary support in order that all parties remain committed to the outcome.

For the wider NHS the recommendations are as follows:

• Professional regulatory bodies to review findings and take action for registrants involved
• There should be National review of maternity care and paediatrics in challenging circumstances
• NHS England considers the wisdom of extending the review of requirements to sustain safe provision of other services. The challenge of providing safe health care in isolated settings is not restricted to maternity and paediatrics
• There should be a review of the challenges of educational opportunities in smaller units
• Clear standards need to be drawn up for incident reporting
• There should be a Duty of Candour for all NHS professionals
• There should be a duty on NHS Boards to report openly the findings of any external investigation into clinical services, governance or other aspects of the operation of the Trust
• There needs to be a clear national policy on whistleblowing
• Professional regulatory bodies should reinforce the duty to report concerns
• There needs to be clear national standards setting out professional duties and expectations of all clinical leads
• There needs to be clear national standards setting out the responsibilities for clinical quality for other managers
• There needs to be a national protocol setting out duties of all Trusts and their staff in relation to inquests
• Complaints systems - There needs to be a fundamental review of the NHS complaints system which needs external scrutiny
• LSA for midwives was ineffectual. There needs to be an urgent response needed both to this report and to the Kings Fund review of midwifery regulation in the UK
• The report carefully considered roles of CQC and Monitor but were persuaded that there was more to be gained than lost by keeping these two regulators separate.
• A Memorandum of Understanding (MOU) must drawn up between CQC, PHSO.
• NHS England needs to draw up a protocol setting out the responsibilities of all parts of the oversight system
• 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 DH to review how it carries out impact assessments of new policies to identify the risks as well as the resources and time required
• Organisational change that alters or transfers responsibilities and accountability carries significant risk, which can be mitigated only if well managed. There is a need for a national policy to set out how processes should be managed in future especially re: electronic and paper documents
• There needs to be a review of recording systems to improve recording and tracking of perinatal deaths and
maternal deaths. Legislative preparations have already been made to implement a system based on medical examiners – this is not yet implemented in full and that this system is extended to include stillbirths.

- There is a need for an appropriate framework for external reviews as currently this undertaken in an ad hoc and variable way at present.
- All reviews of suspected failures should always be registered with CQC and Monitor.
- The report identified concerns that the scale of recent NHS reconfiguration could result in new organisations and post-holders losing the focus on this priority. As a result the report recommends 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.
- Investigation hampered by the lack of established framework covering matters relating to documents and the legal basis for handling evidence. There is a need to establish a proper framework for future investigations.

2. STRATEGIC OBJECTIVES SUPPORTED BY THIS REPORT:

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<th>Objective</th>
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<td>Continue to improve the quality of services</td>
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<td>Reduce unwarranted variations in services</td>
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<td>Deliver the best outcomes for every patient</td>
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<td>Improve patient experience</td>
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<td>Reduce the inequalities gap in North Lincolnshire</td>
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3. ASSURANCES TO THE CLINICAL COMMISSIONING GROUP

NLCCG commissions maternity services from North Lincolnshire and Goole NHS Foundation Trust [NLAG]. A request has been made to review NLAG’s response to the Kirkup report. They have assured the CCG that a report will be submitted once it has been through their own Governance and Board processes.

4. IMPACT ON RISK ASSURANCE FRAMEWORK:

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<td>Assurance that the report has been recognised and any relevant lessons learnt locally are important to the assurance of Quality services.</td>
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5. IMPACT ON THE ENVIRONMENT – SUSTAINABILITY:

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6. LEGAL IMPLICATIONS:

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7. RESOURCE IMPLICATIONS:

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<td>Nothing Identified at this stage - Provider would need to identify any resources issues identified as a result of the report recommendations to improve services.</td>
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8. **EQUALITY IMPACT ASSESSMENT:**

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9. **PROPOSED PUBLIC & PATIENT INVOLVEMENT AND COMMUNICATIONS:**

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10. **RECOMMENDATIONS:**

The CCG is asked to:
- Note the report.