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Co-National Medical Director
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12 June 2025

[redacted]

Dear Coroner,

Re: Regulation 28 Report to Prevent Future Deaths – Ida Jean Lock who died on 16 November 2019

Thank you for your Report to Prevent Future Deaths (hereafter "Report") dated 21 March 2025 concerning the death of Ida Jean Lock on 16 November 2019. In advance of responding to the specific concerns raised in your Report, I would like to express my deep condolences to Ida's parents and family. NHS England are keen to assure the family and the Coroner that the concerns raised about Ida's and Sarah's care have been listened to and reflected upon.

I am grateful for the further time granted to respond to your Report, and I apologise for any anguish this delay may have caused to Ida's parents and wider family. I realise that responses to Coroners' Reports can form part of the important process of family coming to terms with what has happened, and I appreciate this will have been an incredibly difficult time for them.

Your Report concludes that "Ida was a normal child whose death was caused by a lack of oxygen during her delivery that occurred due to the gross failure of the three midwives attending her to provide basic medical care to deliver Ida urgently when it was apparent she was in distress and contributed to by the lead midwife's wholly incompetent failure to provide basic neonatal resuscitation for Ida during the first 3 1/2 minutes of her life that further contributed to Ida's brain damage from which she died on 16 November 2019 at the Royal Preston Hospital neonatal intensive care unit."

In your Report you listed several concerns about Ida's death, and listed the organisations you expected to respond to each concern:

A. Culture of Candour (Trust, ICB, DHSC)
B. Clinical Governance and Maternity Governance (Trust, ICB and DHSC)
C. Mandatory Training, expired training and remedial training (Trust and ICB)
D. Grading of harm for incident reporting: Babies who have sustained hypoxic brain injury and undergo cooling (Trust, ICB, DHSC, NHSE, Mr Streeting)

E. Funding for Maternity and Newborn Safety Investigations (MNSI) (DHSC and Mr Streeting, NHSE and ICB)

My response therefore focuses on concern D and E. I note that you have also addressed this report to University Hospitals Morecombe Bay NHS Foundation Trust (UHMBT) and NHS Lancashire and South Cumbria Integrated Care Board (LSC ICB). These organisations will address specifics as to the changes being implemented as a result of the Report. NHS England's response to you is also made on behalf of the Department of Health and Social Care (DHSC), and I understand that they will not therefore be issuing a separate response to the Coroner. With DHSC input, I have also addressed in this response some of your concerns regarding A and B.

Grading of Harm

You concluded that in terms of grading of harm, the Trust graded Ida's level of harm as 'moderate', even after Ida's death, and this grading should have been adjusted to 'severe' as the consultant paediatrician at the time identified Ida had a severe hypoxic ischaemic encephalopathy when transferred to Royal Preston Hospital. You also reference the 2024 Learn from Patient Safety Events (LFPSE) guidance which replaced the National Reporting and Learning System (NRLS) and the significant risk that if reporting is graded on harm alone, clinical care that resulted in hypoxic brain damage during delivery, and which was prevented by therapeutic cooling, would not adequately identify the problems that caused the harm during the delivery. Finally, you also mention that evidence was given of inconsistency nationally in the application of categorisation of harm for babies who sustain hypoxic injury due to fetal bradycardia, particularly where cooling has occurred. You confirm that clarification would assist in the prevention of further maternity deaths and ensure full and proper investigations are carried out.

At the time of Ida's birth in 2019, the older patient safety systems of NRLS and the Serious Incident Framework (SIF) were in place in the majority of Trusts across England. LFPSE's full implementation to Trusts occurred in 2024 shortly after the Patient Safety Incident Response Framework (PSIRF) which was introduced on a transitional basis across NHS Trusts between August 2022 and Autumn 2023. The application of PSIRF principles is mandatory for all health services contracted under the NHS Standard Contract. The new system and framework represent a significant shift in the way the NHS responds to patient safety incidents and marks a shift towards more compassionate, learning-focused approach, which is a key part of The NHS Patient Safety Strategy.

The introduction of LFPSE sought to move away from a focus on purely categorical fields and provide greater opportunity for organisations to review the content of narrative description in their patient safety reporting and explore all aspects of care that may contributed to harm. Whilst harm grading is present as an important indicator by the reporter, strong governance processes within a Trust should provide multiple

points at which this grading can be challenged and changed by others outside of the department.

To support the new system and framework, NHS England has published guidance on recording patient safety events and levels of harm (updated in October 2024) - NHS England » Policy guidance on recording patient safety events and levels of harm. For example, severe physical harm is defined as when at least one of the following apply:

- permanent harm/permanent alteration of the physiology
- needed immediate life-saving clinical intervention
- is likely to have reduced the patient's life expectancy
- needed or is likely to need additional inpatient care of more than 2 weeks and/or more than 6 months of further treatment
- has, or is likely to have, exacerbated or hastened permanent or long term (greater than 6 months) disability, of their existing health conditions
- has limited or is likely to limit the patient's independence for 6 months or more.

If we were to apply the new guidance and new framework from 2024 to the information reported at the time of Ida's birth in 2019, as she required resuscitation immediately after birth, this should have been categorised as 'severe harm' as she required "immediate life-saving clinical intervention". I therefore confirm that under the new framework and reporting system, Ida's grading of harm would be recorded as 'severe'.

As you will be aware, national maternity investigations were established in 2018 as part of the Healthcare Safety Investigation Branch (HSIB). From October 2023, this is now the Maternity and Newborn Safety Investigations (MNSI) programme hosted by the Care Quality Commission (CQC). The criteria for an MNSI investigation in early neonatal deaths of term babies (within the first week of life), of any cause, includes: -

- Severe brain injury: diagnosed as occurring in the first 7 days of life, when the baby— (i) was therapeutically cooled (active cooling only), or (ii) has been diagnosed with moderate to severe encephalopathy, consisting of altered state of consciousness (lethargy, stupor or coma) and at least one of the following: (aa) hypotonia; (bb) abnormal reflexes including oculomotor or pupillary abnormalities; (cc) absent or weak suck; (dd) clinical seizures)

This means that if similar circumstances to what happened with Ida occurred today, an independent investigation by MNSI should be triggered separate to any local Trust patient safety investigation or assessment.

This will be further supported by the roll-out of the new Maternity Outcomes Signal System (MOSS). This system will use Trust Electronic Patient Records to show term stillbirths, neonatal deaths up to 28 days from birth and term Hypoxic Ischaemic Encephalopathy (HIE) at grade 2/3 for all maternity providers, to be used as a signalling system for Trusts when there are clusters or an increased number of

incidents. MOSS is currently in the pilot phase, but is due to be launched in November / December 2025.

Funding for Maternity and Newborn Safety Investigations (MNSI)

You concluded that MSNI is currently hosted by CQC with funding secured for the next two years and without assurance that funding will continue beyond 2027, you were concerned that significant harm events to mothers and babies and deaths such as Ida's will go unrecorded and lessons that should be learned to prevent future maternal and baby deaths would go unnoticed, and there will be a risk of future maternity deaths.

NHS England acknowledges the importance of, and rigour required, when undertaking these investigations and the specialist skills of the investigators. As you may be aware, the Prime Minister recently announced his intention for the abolishment of NHS England, and a transfer of many of our functions into the DHSC. It is expected that this process will be completed within a two-year timeframe. The DHSC have engaged with us on the concerns raised in your Report and have advised us to share the following with you:

'The Government is committed to ensuring that all women and babies receive safe, personalised and compassionate care. A key part of this is ensuring we have a strong and robust approach to investigations which ensures both the appropriate level of scrutiny into individual cases and that learning is fed back into the system to prevent future harm to mothers and babies. The work of organisations such as the Maternity and Newborn Safety Investigations Programme (MNSI) is therefore critical.

The MNSI programme forms part of a wider maternity investigatory landscape, with maternal and perinatal deaths also being investigated by Perinatal Mortality Reviews (supported by the Perinatal Mortality Review Tool (PMRT)) and the MBRRACE-UK Programme. MNSI was initially established for a time-limited period, with a review planned to identify opportunities for improvement and assess whether the programme's existing investigatory scope is fit for purpose.

To support this review, the DHSC has commissioned an evaluation of the PMRT and MNSI programmes via the National Institute for Health and Care Research (NIHR). The evaluation is exploring whether MNSI investigations and PMRT reviews have resulted in system-level quality improvements in maternity care and improved outcomes for parents and families. Further detail on the evaluation can be found at Maternity Investigations and Review Tools process evaluation (MATREP) - NIHR Funding and Awards. The Department will also take into account other feedback, for example from families and from this and other PFD reports.'

Duty of Candour

Whilst you have not asked NHS England to address this matter of concern in your Report, you have indicated that a response from DHSC is welcome. DHSC have commissioned a response from NHS England, who confirm:

As you will be aware, the statutory duty of candour organisationally places a direct obligation upon NHS Trusts and all other health and social care providers registered with the CQC to be open and honest with patients, service users and their families, when a notifiable patient safety incident occurs. The Government supports the review on the duty it inherited from previous administration and will consider the findings, published on 26 November 2024. The Government will consider these findings alongside findings from the ongoing NHS manager regulation consultation as it continues to develop policy on candour in healthcare. The Department's aim is to ensure the NHS can better meet the objectives of the statutory duty of candour and work with patients as partners to support a culture of learning and continuous improvement.

Maternity Governance

Whilst you have not asked NHS England to address these matters of concern in your Report, you have indicated that a response would be welcome from DHSC. As this response is to incorporate DHSC's response to your Report as well, I would also like to provide some assurances to the Coroner regarding maternity governance following engagement with and input from my regional clinical quality colleagues in the North West.

At Trust level

The Trust has been receiving support from the National Maternity Safety Support Programme (MSSP) and has been part of the MSSP programme following a Care Quality Commission (CQC) inspection of maternity services in 2021.

In regard to the Trust improvements of maternity services, the MSSP completed a full diagnostic assessment, which identified several areas for improvement including governance, maternity strategy and vision and leadership. Having delivered required improvements, the Trust entered a sustainability phase of the MSSP (which aims to ensure improvements can be sustained) in October 2023. A reset and review meeting was held in May 2025 and it was agreed that assurance visits were required to test the sustainability and ensure that changes have been embedded. These assurance visits are planned for July 2025, and exiting of the programme will be based on the findings of these site visits. With regard to next steps, once the Trust exits the MSSP they will enter enhanced oversight and gain support from LSC ICB's Local Maternity and Neonatal Systems (LMNS) (subject to change based on the current ICB restructure). The details of the level of support and oversight is currently in development.

Internally, the Trust have also undertaken a review of maternity governance, which has included the following:

- An organisation reconfiguration in July 2024. Maternity, neonatal and gynaecology services have moved to the Surgical Care Group, to strengthen support mechanisms.

- The Director of Midwifery continues to have a direct line to the Chief Nurse and will continue to report to the Board.
- A number of recent leadership changes within maternity have taken place and they now have a substantive leadership team.
- The maternity governance architecture has been further strengthened by the establishment of a Maternity/Neonatal Improvement Group to monitor the MSSP improvement plan. The reporting structure ensures the Trust's board receive regular reports and contact with the Director of Midwifery.
- Embedding a culture of openness and humility evidenced through the improvement in their National Education and Training Survey results for both midwifery and obstetrics and engagement with the national maternity score survey.
- All elements of the improvement journey and exit criteria will be further tested in all maternity settings via a MSSP quality visit which is planned over three days in July 2025.

At Regional/National Level

NHS England North West (NW), has developed a Management of Patient Safety Incidents Standard Operating Procedure (April 2024), which ensures escalation of the maternity incidents of serious concern to the NW Regional Maternity Team. The ICB are responsible for escalating concerns, which are shared directly with the regional maternity team. The regional maternity team receive, monitor, and share escalation through the regional governance architecture. By extreme exception (s), the significant concerns are escalated to the National Chief Midwifery Officer and the National Obstetric Lead within NHS England.

In addition, the region has Perinatal Surveillance Group in place, which is attended by multi-stakeholder group such as the LMNS and external arm's length bodies, which enables to provides a timely identification and escalation of concerns and subsequent action(s).

Regional escalation of maternity risks and concerns to the NHS England national team takes place through the maternity-specific Quality and Performance Committee, and into the National Executive Quality Group. Any Trust requiring additional support, such as UHMBT, can access a Recovery Support Programme meeting where improvement and challenges are discussed, and further support requirements are agreed.

In March 2023, NHS England also published its Three year delivery plan for maternity and neonatal services, setting out how we would make care for babies, women and their familiar safer, more personalised and more equitable. An update on the first year of the plan was published in May 2024. The plan is supported by the work of the Maternity and Neonatal Safety Improvement Programme which aims to reduce the rates of maternal and neonatal deaths, stillbirths and brain injuries that occur during or soon after birth by 50% by 2025.

I would also like to provide further assurances on national NHS England work taking place around the Reports to Prevent Future Deaths. All reports received are discussed by the Regulation 28 Working Group, comprising Regional Medical Directors, and other clinical and quality colleagues from across the regions. This ensures that key learnings and insights around events, such as the sad death of Ida, are shared across the NHS at both a national and regional level and helps us to pay close attention to any emerging trends that may require further review and action.

Thank you for bringing these important patient safety issues to my attention and please do not hesitate to contact me should you need any further information.

Yours sincerely,

[redacted]

[redacted]
Co-National Medical Director
(Secondary Care)