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Background

This Review has been established in light of significant concerns raised regarding the quality and safety of maternity services at Nottingham University Hospitals NHS Trust (NUH) and concerns of local families. This Review replaces a previous regionally-led review after some families expressed concerns and made representations to the Secretary of State for Health and Social Care.

This nationally-commissioned Review will focus on identifying areas of concern within maternity care at NUH and will provide information and recommend actions to help improve the safety, quality and equity of maternity care and the handling of concerns at NUH when they are raised by women and/or their families and staff members.

The Care Quality Commission report (RX1RA Queen's Medical Centre – 2022-05-20 [002] (https://cqc-newsroom.prgloo.com/resources/ins2-11385749621-rx1ra-queen-s-medical-centre-2022-05-20-002) and RX1CC Nottingham City Hospital – 2022-05-20 [002] (https://cqc-newsroom.prgloo.com/resources/ins2-11385749621-rx1cc-nottingham-city-hospital-2022-05-20-002)) which highlighted the inadequacy of the current maternity services provided to the local community is noted in supporting the need for a review at this point.

Governance

The Review has been commissioned by the NHS England national team, and its sponsor and senior responsible officer (SRO) is the chief nursing officer (CNO), who will receive periodic (bi-monthly) updates from the Review chair. The Regional Director of NHS South East will, as executive lead, support the SRO. This Review replaced the regionally commissioned review, the work of which ended on 10 June 2022.

The Review will be led by an independent chair, Donna Ockenden, and will be supported by a wider review team including:

- 1. an administration team
- 2. a diverse multidisciplinary team of clinical and governance experts
- 3. independent legal advice sourced through the NHS Procurement Framework
- 4. experts in research and evidence, for example an academic, midwife, doctor or nurse

On a day-to-day basis the Review will liaise with the NHS England CNO's directorate.

Timeframe and duration

The Review began on 1 September 2022 following preparatory work including the development of Terms of Reference (ToR) and early engagement with families and NUH from June 2022.

Learning and recommendations will be shared with NUH as they become apparent to allow rapid action to improve the safety of maternity care.

The only and final report will be published and presented to families, NUH, DHSC and NHS England on or before Tuesday 30 June 2026. There will be no further extension to this date.

Grading of cases and family feedback

Clinical care in cases considered by the Review team will be graded using an established grading of care scoring system (see table below) developed by the Confidential Enquiry into Stillbirths and Deaths in Infancy (CESDI).

The purpose of the review remains to ensure timely learning, action and improvements in the safety and quality of the maternity care provided. A grading of care score does not provide a standalone basis for determining clinical negligence.

Existing processes including, but not limited to, Coronial inquests and investigations by the Healthcare Safety Investigation Branch (HSIB) may draw different conclusions from those reached by the Independent Review Team.

Table 1: CESDI grading

Grade	Summary description of care	Detailed description of care
0	Appropriate	Appropriate care in line with best practice at the time
1	Minor concerns	Care could have been improved, but different management would have made no difference to the outcome

2	Significant concerns	Sub-optimal care in which different management might have made a difference to the outcome
3	Major concerns	Sub-optimal care in which different management would reasonably be expected to have made a difference to the outcome

<u>Family feedback (https://www.ockendenmaternityreview.org.uk/family-feedback/)</u> will be completed within 6 months of the publication of the report, and no later than 31 December 2026. Closedown of the Review will also be done within 6 months of the publication of the report and completed as soon as possible following completion of family feedback.

In closing down the Review, account must be taken of any request or instruction from the Operation Perth investigation with regards to the retention and/or disclosure of documentation and information held by the Review.

Scope

The Review will consider cases between 1 April 2012 and 31 May 2025 inclusive, where the Review criteria (outlined in the Methodology section) are met.

The total number of cases to be included in the Review will be confirmed by the Review team to NUH and NHS England by Thursday 31 July 2025. This timeframe will enable the Review team to contact affected families, allowing them the choice to opt-out should they wish to do so.

Incidents which occur after 31 May 2025 will not form part of the Review. Any such incidents will be recorded and responded to in line with national and local policy requirements – including, but not limited to, the <u>Patient safety incident response</u> <u>policy and plan (PSIRF) (https://www.england.nhs.uk/patient-safety/patient-safety-insight/incident-response-framework/)</u>.

Cases in the scope of the Review will include clinical incidents where mothers and/or babies have suffered severe harm or death (the term 'severe harm' will be defined and agreed). The Review will clearly and concisely set out to NUH an understanding of the elements of maternity care that have failed over the period of the Review relating to:

- clinical care
- governance and incident reporting and investigation and response to families
- leadership and organisational culture including staff voices and staff wellbeing, including responses to staff whistleblowing and consideration of local Workforce Race Equality Standards (WRES) and other workforce data
- consideration of the commissioning and oversight of maternity services and any actions taken to improve the safety of maternity services by the thenprimary care trust (PCT)/clinical commissioning group (CCG) or other external bodies

The Review will consider whether NUH has had, and continues to have, robust governance and oversight arrangements in place to ensure appropriate identification, learning and action related to themes emerging from incidents, complaints, and concerns regarding maternity care at all levels in the trust from patients, families, and staff (current or former).

Methodology

The approach to the identification of cases will be based on the 'open book' approach as used in the review of maternity services at Shrewsbury and Telford Hospital NHS Trust, in the following 5 categories:

- Stillbirths from 24 weeks gestation.
- Neonatal deaths from 24 weeks gestation that occur up to 28 days of life; the Review team will also consider neonatal serious incident reports and neonatal never events.
- Babies diagnosed with hypoxic ischaemic encephalopathy (Grade 2 & 3) and other significant hypoxic injury
- Maternal death up to 42 days post-partum.
- Severe maternal harm to include cases such as:
 - all unexpected admission to ITU requiring ventilation
 - major obstetric haemorrhage for example, cases where blood loss exceeds 3.5L

- peripartum hysterectomy and other major surgical procedures arising from the maternity episode
- o cases of eclampsia
- clinically significant cases of pulmonary embolus requiring further treatment

The Review will consider the governance and learning from cases by:

- listening to the experiences inclusive of those from diverse ethnic backgrounds of families and identifying common themes
- considering the learning for current clinical practice along with any relationship to common themes in families' experiences and the clinical care provided
- ensuring that the cases considered are appropriate and reflective of local demographics to ensure that lessons and learnings for NUH reflect the experience of families, staff and all sections of local Nottingham communities

The Review will undertake engagement with:

- families including those from diverse backgrounds that are representative of the local population
- current and former staff from a wide range of cultural and professional backgrounds
- · local, regional and national stakeholders
- professional regulators

The Review will consider the latest clinical practice in relation to NHS maternity care and available local and national guidance to identify areas of learning for NUH going forwards. Cases will be considered with reference to the local and national policies and guidance in place at the time of the incident / case

During the course of the Review, if issues are identified that require referral to an appropriate professional body, the Review team should in the first instance raise the concern with the provider (if it is about a doctor the concern must be raised with their Responsible Officer and the provider).

The Review team may also wish to refer the matter directly to the professional body (regulator) in line with the process identified by the professional body, in those instances the Review Team will ensure that the provider is made aware of this referral. The Review team should maintain a record of all referrals made. The number and themes arising should be shared with the commissioner of the inquiry at agreed intervals.

The Review will share key findings with NUH and NHS England formally on a bimonthly basis. This will support NUH to continuously learn and improve the safety and quality of maternity care (enhancing the trust's current improvement plan where appropriate).

Where cases are included in the Review and elements of care have been provided by different organisations other than NUH, the Review team may feel it necessary to consider the care carried out by the other organisation(s) as part of the Review process and may therefore request relevant case notes from these organisations where this is the case.

The care delivered by these organisations will not be graded by the Review team. However, to ensure learning is shared and improvements made where needed, any themes or concerns identified by the Review team about care provided by organisations other than NUH will be reported by the Review Chair to the chief nurse and medical director of the organisation, the regional chief nurse, and SRO at NHS England.

This will allow the organisation to address the issues, including contacting the family in line with Duty of Candour obligations; oversight will be with the regional chief nurse who will report to the SRO on appropriate and timely action taken.

<u>Family feedback (https://www.ockendenmaternityreview.org.uk/family-feedback/)</u> for the neonatal care at NUH will be delivered in the same way as all cases included in the Review.

As the Review is focused on the care provided by NUH, any such themes or concerns identified which relate to the care provided by other organisations other than NUH may form part of the Review report; however, those organisations will not be identified.

Engaging with families who joined the previous review

Families who have already taken part in the previous Review will be offered the opportunity to join the Donna Ockenden Review if they wish.

Where families have already had a 'listening session' or have shared information with the first review they will be asked for permission for this information to be shared with the current review.

Families may wish to speak to Donna Ockenden's team afresh or may not wish to participate in this Independent Review. The decision of individual families will be respected.

Donna Ockenden and her team will make every effort to reach out to and engage with families who participated in the previous review.

Families will also be sign-posted, and can be referred to, trauma-informed care, if they require it.

Family support

The local NHS will ensure culturally appropriate specialist psychological support continues to be available to families who are part of this Review for its duration and throughout the family feedback and closedown processes, and that where necessary, they are subsequently transitioned into mainstream services who will be responsible for providing ongoing support.

Staff support

The Review team will be responsible for managing liaison with members of NUH staff, both current and former, who will be provided with appropriate support by the Trust. The Review will ensure appropriate support mechanisms are in place to encourage these staff members to voice their perspectives and experiences freely and without fear.

Ways of working

Resources

The Review will agree a financial plan for the duration of the Review with NHS England based on a formal agreement set out in writing between NHS England and the chair regarding resourcing.

The Review chair will consult NHS England prior to the Review putting in place any contractual arrangements. All contractual arrangements will need to have been deemed compliant with the NHS Procurement Framework by NHS England.

Information sharing and governance

The Review will keep in regular contact with NHS England via its sponsor and their team. Should the Independent Review team identify areas of concern relating to current patient safety in NUH maternity services, it will contact the sponsor's team and the executive team at NUH at the earliest opportunity to allow action to be taken to address issues.

All relevant NHS organisations and regulators are expected to co-operate with the Review as is normal, professional practice, including supplying documentation, as and when requested by the Review team. If the chair of the Review has any significant issues regarding non-co-operation which cannot be resolved, this will be escalated to the sponsor's team.

The inclusion of individual cases in the Review will be based on an opt-out methodology. Explicit consent will not be sought from the families for their information to be shared by the Trust with the Review team. Instead, information relating to individual cases will be included in the Review where families have not explicitly stated that they do not wish to be involved in the Review process.

Where families have chosen to opt-out of the process, their individual details may have been provided to the Review for the purposes of those families being informed of the opt-out process, but once families have opted out, their information will not be included in the Review, save in instances where, in the public interest, a minimum amount of information may be considered in the circumstances where it is contained in NUH corporate documents.

All records and data relating to the Review will be processed according to the agreed information sharing agreements. The Review will have information management and privacy policies that will set out the approach the Review takes to managing information that complies with information legislation.

The policies will include the approach to managing information and documentation upon completion of the Review, which must take into account the Operation Perth investigation and any request or instruction from that investigation that may be received with regards to the retention and/or disclosure of documentation and information.

Publication of findings

Should the Review team propose to include any significant criticism of individuals or organisations in the final report, the Review team will notify those individuals and organisations and provide them with a timely opportunity to respond to any such proposed criticism before the final report is prepared. All such information will be anonymised/pseudonymised.

The precise process, known as Maxwellisation, and timings to be used, will be agreed between the NHS England SRO and the chair of the Independent Review following appropriate professional advice. Prior to publication, families and staff will have opportunity to see and feedback on pseudonymised 'vignettes' or excerpts from interviews regarding their case. Where families or staff decline inclusion of 'their' excerpt this will be respected.

Publication of the final report (including an easy read summary) will be preceded by disclosure jointly to families, NUH, the DHSC and NHS England at a timescale to be agreed, so that they are aware of the content of the report to be published.

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