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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)) (<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-)) (<https://cqc-newsroom.prgloo.com/resources/ins2-11385749621-rx1cc-nottingham-city->

[hospital-2022-05-20-002](#))) which highlights 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.

Time 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 NUH, NHS England (as the Review's commissioners) and key stakeholders in September 2025. Any requested extension to this time period will be considered and may be granted following discussion and agreement between the NHS England SRO (the CNO) and the Chair of the Independent Review, Donna Ockenden.

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

Family feedback is anticipated to be completed within four months from the publication of the report. Closedown of the Review will follow completion of family feedback. An addendum will be published to the ToR by the end of January 2024 setting out the processes and provision for family feedback for the families within the Review.

Scope

The Review will consider cases from 1 April 2012 to a time anticipated to be four months before publication of the final report in September 2025 (i.e. up to the end of May 2025). This will enable the Review team to advise NHS England and NUH as to the safety and quality of maternity services just prior to completion of this Review. In an exceptional case, where the chair of the Review believes the consideration of a case from 1 April 2006 to 31 March 2012 may add significantly to the Review's findings, such a case may be accepted into this Review.

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; and
- consideration of the commissioning and oversight of maternity services and any actions taken to improve the safety of maternity services by the then-primary 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 five 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 brain 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 e.g. cases where blood loss exceeds 3.5L; peripartum hysterectomy and other major surgical procedures arising from the maternity episode; cases of eclampsia; and 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; and
- 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; and
- 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 bi-monthly 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).

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 at the earliest opportunity to allow action to be taken to address issues.

All relevant NHS organisations and regulators are expected to cooperate 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 upon completion of the Review.

Publication of findings

The Review Chair will lead on the publication process working together with NUH, NHS England, DHSC and other stakeholders including families. The Review team will notify individuals and organisations who are referred to in the final report and provide them with

a timely opportunity to respond to any significant criticism of them proposed for inclusion in the final report. 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 in its entirety (including an easy read summary) will be preceded by disclosure jointly to families, 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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