

Shared Insights: Update on the Early Notification Scheme and the role of HSIB

For this session, we were delighted to be joined by **Sangita Bodalia**, Head of Early Notification (Legal) at NHS Resolution who discussed the changes to improve and streamline the investigation process for cases under the Early Notification (EN) Scheme (changes which came into effect from 1 April 2021).

We were also delighted to be joined by **Sandy Lewis**, Associate Director of Maternity Investigation Programme and **Amanda Morgan**, Regional Lead for Maternity Investigations (South) from HSIB who provided an update on the process for HSIB maternity investigations.

Together, Sangita, Sandy and Amanda discussed the interface between the HSIB and EN investigations.

Kelly Buckley, Senior Associate at Browne Jacobson also provided a Panel perspective and an overview of the process for those EN cases where it is appropriate for Panel to be instructed.

The Shared Insights were:

HSIB

- HSIB undertakes maternity investigations in accordance with the following criteria:
 - Where a baby was thought to be alive at the start of labour and was born with no signs of life
 - When a baby died within the first week of life (0-6) days of any cause
 - Where there has been severe brain injury diagnosed in the first 7 days of life
 - Death of a mother while pregnant or within 42 days of the end of the pregnancy, from any cause related to or aggravated by the pregnancy or its management, and not from accidental or incidental causes.

- From April 2020, HSIB no longer routinely investigate all maternity incidents involving cooled babies where there is no apparent neurological injury confirmed following therapy. This is assessed in multiple ways such as MRI reporting and other neurological investigations.
- From 1 April 2020, HSIB has been the notification portal for Trusts for all cases meeting the criteria for HSIB investigations and the NHS Resolution Early Notification Scheme (ENS). This is to continue, and Trusts are required to refer all cases via the HSIB portal as per the criteria in the HSIB Directions 2018.
- HSIB will triage the cases referred to it and, in addition to those where harm has been confirmed, will also investigate events where a family or Trust have specific concerns (even if there is no evidence of harm).
- HSIB share the details of all referrals relating to severe brain injury with NHS Resolution via a monthly report.
- The majority of HSIB investigations will take no more than 6 months and HSIB will share the final investigation report with NHS Resolution. Where the 6 month time frame is exceeded the Trust and family will be fully informed.

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NHS Resolution

- For anyone not familiar with NHS Resolution, they are an NHS organisation that operates in a similar way to an insurer by providing indemnity cover to NHS hospitals.
- The Early Notification scheme is an innovative approach to handling these rare but devastating cases of avoidable brain injury at birth. The scheme epitomises NHS Resolution's strategic shift to do more closer to the point of incident.
- The scheme intends to provide families with the support they need when they need it most and further improve the safety of maternity services within the NHS.
- Following on from the changes in reporting during Covid-19, from 1 April 2021, NHS Resolution will not take steps to investigate eligibility for compensation, under the EN scheme, until HSIB has completed a safety investigation. This will reduce duplication and enable Trusts to focus on liaison with HSIB and the family.
- On receipt of the HSIB report on relevant cases, NHS Resolution will overlay an investigation into legal liability for eligible cases. Where families have declined an HSIB investigation, no EN investigation will take place, unless the family requests this.
- From April 2021, the criteria for an investigation by NHS Resolution will be narrowed to those cases where there is evidence of or the potential for a hypoxic brain injury, defined as "Babies who have an abnormal MRI scan where there is evidence of changes in relation to intrapartum hypoxic ischaemic encephalopathy (HIE)". This will ensure that the scheme is focused on those cases where there is potential for a high value compensation payment.
- Babies whose MRI findings fall outside of the clinical definition of a brain injury could still be accepted by the EN scheme. For these babies, a multidisciplinary clinical review will take place to understand the extent of the MRI changes. If necessary, further information may be sought from the Trust to help NHS Resolution decide whether an investigation into compensation entitlement should proceed.
- The statutory duty of candour requires Trusts to inform families of all investigations into their care and it is vital that families involved in HSIB and EN investigations are fully informed by NHS Trusts of all processes underway and of the outcome reached.
- NHS Resolution will write to families directly regarding babies born after 1 April 2021 and HSIB investigation completed.
- Trusts are encouraged to continue with their initial 72-hour reviews to ensure that any learning is identified and actioned in a timely manner. 72-hour reports and investigations can be shared with NHS Resolution should a liability investigation take place.