HSIB and NHS Resolution Early Notification Scheme update webinar – May/June 2021

Frequently Asked Questions

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Earlier this year, NHS Resolution held a number of regional webinars to update members on changes to the Early Notification Scheme (ENS), in partnership with the Healthcare Safety Investigation Branch (HSIB). The events were really well attended, and we'd like to thank those of you who took the time out of your busy schedules to attend.

In addition to publishing a recording of one of the regional webinars on our website, we've compiled a number of frequently asked questions from the events to help with any additional queries that you may have.

If you have any further questions that are not answered below, please contact the Early Notification Scheme team directly.

1. **Are the changes made to the process for reporting to HSIB and the ENS during Covid-19 to be made permanent?**

   HSIB – In order to minimise the impact our work has on NHS maternity services during the pandemic, we reviewed our approach and investigation criteria. As a result, from 1st April 2020 and until announced otherwise, we no longer routinely investigate maternity cases where there is no evidence of harm or brain injury following cooling therapy. All qualifying cases should, however, continue to be referred to us. These cases will be considered for investigation if the family or trust have concerns regarding clinical care. This decision is reviewed regularly with the Department for Health and Social Care (DHSC), and any change will be communicated.

   NHS Resolution – Under the previous reporting requirements, since 1 April 2017 trusts have been required to report all maternity incidents of potentially severe brain injury to us within 30 days.

   In line with the criteria used by the Royal College of Obstetricians and Gynaecologists' 'Each Baby Counts' programme, this applied to all babies born at term (greater than or equal to 37 completed weeks of gestation), following labour that had a potentially severe brain injury diagnosed in the first seven days of life and:
   - was diagnosed with grade III hypoxic ischaemic encephalopathy (HIE); or
   - was therapeutically cooled (active cooling only); or
   - had decreased central tone AND was comatose AND had seizures of any kind.

   In order to reflect the impact of the pandemic on trusts, we paused reporting requirements from 1 April 2020. Trusts have needed to continue reporting all cases that meet the criteria to HSIB to support learning investigations. In turn, HSIB report potential eligible Early Notification (EN) cases to us for further consideration from a legal perspective.

We've received positive feedback from trusts on the revised process, which has reduced the burden of reporting and enabled the adoption of a collaborative approach with our colleagues at HSIB to share learning from maternity investigations. The current reporting process has therefore been moved onto a permanent footing. This means that trusts will not need to report EN incidents separately to us. Reports should continue to be made to HSIB, who will continue to inform us of relevant incidents.

The flow chart provided on page 12 of the slide pack summarises the referral process and maps the path a case will take from initial referral to HSIB by the trust through to investigation by NHS Resolution.

2. What happens if a family declines a HSIB investigation?

HSIB – Trusts should continue to refer **all cases** that meet HSIB criteria to enable data capture. Where damage is suspected, details are shared with our colleagues at NHS Resolution.

We always seek consent for the sharing of records. If consent is not given, an investigation cannot progress.

As of April 2021, family engagement stood at 87 per cent, and this is monitored continuously. Work is ongoing to analyse this engagement and identify local opportunities to improve on this score, working in collaboration with service providers.

NHS Resolution - Where families have declined a HSIB investigation, no EN investigation will take place, unless the family specifically requests this. We expect trusts to have timely conversations with families about HSIB and NHS Resolution's involvement as part of duty of candour conversations after an incident. Trusts should continue to undertake a 72-hour review of an incident and communicate with families where the requirement for an investigation is identified.

3. What happens to EN cases reported to NHS Resolution before the change to the outcome first approach?

NHS Resolution – We're undertaking a retrospective review of all cases reported to the ENS, which includes those from 1 April 2017, and we'll apply the newly adopted clinical definition of hypoxic brain injury to ensure that only cases that meet the 'outcome first' approach are progressed. We'll be applying the following definition to cases:

"Babies who have an abnormal MRI scan where there is evidence of changes in relation to intrapartum hypoxic ischaemic encephalopathy (HIE)."

Babies whose MRI findings fall outside of the clinical definition of a brain injury may still be accepted by the ENS following a multidisciplinary clinical review to understand the extent of the MRI changes. A decision will then be made as to whether a liability investigation will take place.

We recognise that some cases previously reported to us will have already progressed, and we'll look at these on a case-by-case basis. We're planning to send an update to each trust over the coming months, summarising the position on each of their EN cases reported to the scheme with a view to progression and closure as appropriate.

4. **Do trusts need to share their 72-hour report and previous letters to the family with NHS Resolution and HSIB?**

NHS Resolution - We won't take steps to investigate eligibility for compensation under the ENS until HSIB has completed its learning investigation. This will reduce duplication and enable trusts to focus on liaison with HSIB and the family in the early stages. Trusts are encouraged to continue with their initial 72-hour reviews to ensure that any learning is identified and actioned in a timely manner.

Once HSIB has referred a case to us, and we've accepted the case for an EN investigation, the trust will need to share all documents with us for the liability investigation, including the 72-hour report and copies of all correspondence sent previously to the family. It's important that trusts hold this correspondence centrally between legal and maternity/governance teams so that both can access.

5. **What is the expectation on the trust in terms of family liaison?**

HSIB – Once a referral has been made, the trust should provide the family with some initial information explaining who we are and what will happen next. HSIB investigators will contact the family to discuss with them how they want to be involved. Referral to HSIB does not affect the responsibility of a trust in relation to their duty of candour.

We encourage a tripartite meeting at the conclusion of an investigation. This is arranged by the trust and is an opportunity for the trust, family and the HSIB team to discuss the findings and recommendations of the investigation and to consider any learnings arising from the case. This also provides an opportunity to build relationships between families and service providers to support future interactions.

NHS Resolution – It's important for trusts to be open and transparent with families about our role and involvement from the outset. Both the statutory duty of candour and safety action 10 of the Maternity Incentive Scheme require trusts to inform families of all investigations into the care received, so it's vital

that families involved in HSIB and EN investigations are fully informed by trusts of all processes underway and of the outcome reached. We've suggested the following wording, which should form part of the trust's maternity duty of candour process:

"We will also work with an NHS organisation called NHS Resolution to decide whether to proceed with a further review of the care provided, as part of NHS Resolution's Early Notification Scheme. If you would like to know more about the Early Notification Scheme, please visit NHS Resolution's website.

If families have any questions or concerns about this, they can be provided with our contact details.

We'll take direct responsibility for writing to the families of babies born on or after 1 April 2021. However, trusts still need to discuss with families the possibility of an EN investigation during the duty of candour process, as explained above. Families will hear from us at different points: once when the triage is undertaken by our in-house teams and a decision reached on whether or not to progress to an EN investigation; and then secondly once the investigation is complete.

Please note that 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 us should a liability investigation take place.

6. What support is available for families during the HSIB and EN investigations?

HSIB – Our family engagement approach underpins our investigation methodology. Maternity investigators will identify the degree of involvement a family wishes to have in the process. The frequency and means of updating that a family wishes to receive throughout the course of an investigation is agreed, and we provide contact details for them to use. Our investigators are also able to provide signposting information and consider safeguarding throughout their work.

We have a new video on our website to show a family perspective on being involved in a HSIB investigation.

NHS Resolution – It's really important that families receive information that is accurate and up to date, particularly as the ENS continues to evolve. Information for families is accessible via our webpages, which we keep under regular review.

We've also established a Maternity Voices Group, which is a collaboration with other patient facing organisations including AvMA, Baby Lifeline and Peeps

HIE, as well as families. This group aims to represent the voice of parents and help steer the ENS and its learning resources.