HSIB

HEALTHCARE SAFETY INVESTIGATION BRANCH

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HSIB maternity programme year in review 2020/21

Summary of highlights, themes and future work

Independent report by the
Healthcare Safety Investigation Branch NI-003748

August 2021

Providing feedback and comment on HSIB reports

At the Healthcare Safety Investigation Branch (HSIB) we welcome feedback on our investigation reports. The best way to share your views and comments is to email us at **enquiries@hsib.org.uk** or complete our online feedback form at **www.hsib.org.uk/tell-us-what-you-think**.

We aim to provide a response to all correspondence within five working days.

About HSIB

We conduct independent investigations of patient safety concerns in NHS-funded care across England. Most harm in healthcare results from problems within the systems and processes that determine how care is delivered. Our investigations identify the contributory factors that have led to harm or the potential for harm to patients. The safety recommendations we make aim to improve healthcare systems and processes, to reduce risk and improve safety.

We work closely with patients, families and healthcare staff affected by patient safety incidents, and we never attribute blame or liability.

Considerations in light of coronavirus (COVID-19)

We have adapted some of our national and maternity investigations, reports and processes to reflect the impact that COVID-19 has had on our organisation as well as the healthcare system across England. For the period of this report, the way we engaged with staff and families was revised.

About this report

This report provides a review of the HSIB maternity investigation programme during 2020/21, including an overview of activity during this period, themes arising from investigations and plans for the future. It is intended for healthcare organisations, policymakers and the public to understand the work we have undertaken. For readers less familiar with medical and healthcare terms relating to maternity care, a glossary is included at the end of the review.

Our investigations

Our investigators and analysts have diverse experience of healthcare and other safety-critical industries and are trained in human factors and safety science. We consult widely in England and internationally to ensure that our work is informed by appropriate clinical and other relevant expertise.

We undertake patient safety investigations through two programmes:

National investigations

Concerns about patient safety in any area of NHS-funded healthcare in England can be referred to us by any person, group or organisation. We review these concerns against our investigation criteria to decide whether to conduct a national investigation. National investigation reports are published on our website and include safety recommendations for specific organisations. These organisations are requested to respond to our safety recommendations within 90 days, and we publish their responses on our **website**.

Maternity investigations

We investigate incidents in NHS maternity services that meet criteria set out within one of the following national maternity healthcare programmes:

- Royal College of Obstetricians and Gynaecologists' 'Each Baby Counts' report
- MBRRACE-UK 'Saving Lives, Improving Mothers' Care' report.

Incidents are referred to us by the NHS trust where the incident took place, and, where an incident meets the criteria, our investigation replaces the trust's own local investigation. Our investigation report is shared with the family and trust, and the trust is responsible for carrying out any safety recommendations made in the report.

In addition, we identify and examine recurring themes that arise from trust-level investigations in order to make safety recommendations to local and national organisations for system-level improvements in maternity services.

For full information on our national and maternity investigations please **visit our website**.

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1 Introduction

This report provides an overview of the operational performance, outcomes and achievements of the HSIB maternity investigation programme for the financial year April 2020 to March 2021. It also identifies themes in line with the requirement of our maternity Directions (secondary legislation that came into effect in 2018 that sets out our maternity investigation functions and responsibilities) and a high-level look at what we will focus on and hope to achieve during 2021/22.

Since April 2018, HSIB has conducted safety investigations in NHS maternity services in England into occurrences of stillbirths, neonatal deaths or suspected brain injuries that meet the criteria of the Royal College of Obstetricians and Gynaecologists (RCOG) Each Baby Counts programme. In addition, HSIB also conducts safety investigations into the death of any woman while pregnant or within 42 days of the end of her pregnancy, from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes and excluding suicides.

By April 2019, the HSIB maternity programme was fully established in all 130 NHS trusts and 11 ambulance services delivering and supporting maternity services in England.

The final RCOG Each Baby Counts programme report was published in March 2021 reflecting the important work RCOG has undertaken during the last five years. This work continues within the Each Baby Counts + Learn and Support programme, which is a collaboration between the RCOG and the Royal College of Midwives. This programme is currently supporting trusts to develop, test and evaluate new approaches to promote a more positive and supportive workplace environment.

HSIB's maternity investigation approach

The maternity investigation programme draws on HSIB's investigatory expertise to deliver a standardised, learning-orientated, and person-centred approach to safety investigations that produce insight to help reduce maternity safety incidents across the NHS.

HSIB maternity investigations:

- identify the factors that may have contributed towards death or injury
- use the perception of events from families and staff to establish what happened and why

- make safety recommendations to improve maternity care both locally and nationally
- identify safety themes of national significance to allow learning and implement change.

HSIB's investigations replace local trust incident investigations. Trusts are encouraged to complete an initial review (historically referred to as a review completed within 72-hours of the incident) to identify and act on any immediate safety concerns. Confidentiality of all staff and families is protected in line with our 'just culture' approach, which strives to supports a culture of fairness, openness and learning in which people feel confident to speak up when things go wrong, rather than fearing blame.

2 Highlights

- The HSIB maternity investigation programme commenced 760 investigations during 2020/21. At the end of March 2021 fewer than 5% of our investigations had exceeded the designated 6-month timescale.

- Where investigations exceed this timeframe, we have a detailed understanding of the reasons why and work closely with trusts and families to support their completion.

- When the COVID-19 pandemic was declared in March 2020, HSIB's maternity programme had almost completed one year of full operation. In line with NHS-wide efforts to reduce pressures on trusts, HSIB, in agreement with the Department of Health and Social Care, made amendments to the maternity programme criteria.

- Families are central to our work. Without good, effective family engagement, we would be unable to hear a family's story, reflect their voice and answer their questions. All families are invited to be part of their investigation and to date 87% have consented.

- Families have described how HSIB investigations have helped them to fully understand the circumstances of their case; to trust that the knowledge generated is fair, transparent, and independent; and to feel reassured that they have been an important part of the investigation.

- Non-English-speaking families have benefited from HSIB's inclusive approach – we have produced our information resources in 25 languages other than English, used interpreters and translated 57 investigation reports into the family's preferred language. We produce reports in other formats, such as audible, at a family's request.

- HSIB has adjusted the way we engage with families because of the pandemic. If appropriate and where technology allows, we will undertake trust, staff and family interviews remotely by phone or video rather than face-to-face visits. Where families feel unable to discuss their investigation or review a report using this approach a detailed risk assessment is completed to support a face-to-face meeting.

- Trusts tell us that HSIB investigations and recommendations are positively influencing safer maternity care. We support trusts to take ownership of the recommendations from our reports and instigate responsive changes. The regular information we produce for trusts about our maternity investigations has helped to improve the flow of patient safety communication across perinatal teams.

- The benefits of the HSIB maternity programme extend beyond learning and change for safer NHS maternity care. Improvements to NHS safety culture are being supported through HSIB's family engagement model. Our learning focus in safety investigations enables staff to speak freely about their experiences. Our approach provides a unique insight into the relationship between engaged leadership and a positive safety culture.

- HSIB works in collaboration with NHS England and NHS Improvement's Maternity Transformation Programme to support the national maternity safety ambition to reduce the rate of stillbirths, neonatal and maternal deaths and brain injuries that occur during or soon after birth by 50% by 2025.

- HSIB has been running a continuous survey of NHS staff who have been interviewed for maternity investigations, to drive improvement in the programme. The figures for April 2020 to March 2021 demonstrate that 86.8% of staff who responded strongly agree that HSIB investigations will help to improve the safety of maternity care at their trust.

- In addition to the individual reports we have provided to families and trusts, during the last year we have published four national learning reports. We worked in collaboration with the wider HSIB investigation team to highlight areas for national investigation.

3 HSIB strategic goals and objectives

HSIB Strategic Goal	Maternity investigation programme contribution
1. Undertake independent safety investigations with objectivity underpinned by competence credibility and integrity	We have commenced 760 maternity investigations. At the end of March 2021 fewer than 5% had exceeded the 6-month timeframe for completion. The completed investigations have provided families with a full account of what happened, and informed them of where we have made safety recommendations to trusts. All families are invited to be part of their investigation and to date 87% have consented. We receive positive feedback from staff involved in our investigations.
2. Value and prioritise professional development for staffing that includes internationally renowned safety investigation techniques and cutting-edge technology	All HSIB maternity investigators undergo a comprehensive training programme upon joining the organisation. HSIB offers maternity programme staff ongoing training and professional development from national experts in human factors, safety science and relevant clinical specialities for maternity services. In 2020/21 we trained 22 new maternity investigators to join our existing team. The teams work closely with trusts and our approach is influencing investigations outside the HSIB criteria.
3. Provide learning to the wider healthcare community and promote professional safety investigations by improving investigation skills and techniques throughout the NHS	The maternity programme has published four maternity-themed reports in 2020/21 and supported several national investigations, some of which are now complete and some ongoing. HSIB has piloted a regional newsletter in the London region with planned roll-out across England in 2021/22. We contribute to learning with local maternity systems and clinical networks. In addition, our learning is shared with NHS England and NHS Improvement as part of the perinatal quality surveillance model. HSIB's investigations, reports and family engagement approach are influencing the way trusts approach their local investigations

HSIB Strategic Goal	Maternity investigation programme contribution
4. Be financially sustainable, well governed and legally constituted to support our independence	The maternity programme remained within budget and has optimised innovative ways of working to support families, trusts and the wider maternity system. Governance structures have been strengthened through the development of the investigation directorate. The maternity programme has implemented a quality improvement process to support further developments in our work.
5. Support and uphold equality across all our work areas ensuring equitable and fair treatment, access and opportunities	HSIB maternity investigations provide information in multiple languages and formats to support families to be a central part of all the work we undertake. Our family engagement model ensures our teams are supported in all aspects of communication with families. Our investigators represent HSIB as equality and diversity champions and Freedom to Speak Up Guardians. Equality and diversity is integral to our approach to recruiting our teams.

4 Operational performance

Maternity care in England is provided and supported by 125 acute trusts (reduced from 130 due to trust mergers) and 11 ambulance services. These are covered by 14 HSIB regional maternity investigation teams. The trusts refer maternity incidents ('cases') which appear to meet the HSIB referral criteria.

Once a referral is received, an HSIB investigation team from the relevant region contacts the trust within 24-hours. This is to ensure the case meets HSIB's criteria for investigation and to obtain the family's contact details with their agreement. HSIB cannot commence an investigation without family consent to access the mother's and baby's healthcare records. We aim to initially contact families within five working days of the referral and provide them with detailed information about an HSIB investigation. This ensures they can make an informed decision when consenting for us to access medical records. The investigation team then scopes the case, working with the family and trust to establish the investigation's terms of reference.

Once the investigation has commenced, the team ensures that the family and the trust remain updated throughout. This enables the family and trust to be made aware of any delays. Ongoing communication with trusts during investigations ensures that any early learning is rapidly shared to support safer care.

Impact of the COVID-19 pandemic

When the COVID-19 pandemic was declared in March 2020, HSIB's maternity programme had almost completed one year of full operation. In line with NHS-wide efforts to reduce pressure on trusts, HSIB (with the agreement of the Department of Health and Social Care) made amendments to the maternity investigation programme criteria. Under the amended criteria, trusts would continue to refer all cases in line with the existing criteria, and HSIB would temporarily cease investigations of cases relating to babies who had received cooling therapy where there was no apparent neurological injury (brain damage). In these cases, if a family or trust reported concerns about care, the case would be individually reviewed, and an investigation progressed where appropriate.

Adjusting the criteria in this way reduced the overall investigation caseload by 15% during 2020/21. This also enabled HSIB to release some clinical staff to frontline duties in support of the response to the pandemic.

In addition, HSIB worked collaboratively with NHS Resolution to reduce the burden of reporting for trusts by becoming the main reporting portal for HSIB and NHS Resolution Early Notification scheme cases.

Involving families

Families remain central to our work. The time HSIB investigators take to develop relationships and provide support is reflected in the positive feedback we receive from families about their experience of an HSIB investigation. Without these relationships we would be unable to hear a family's story, reflect their voice and answer the questions they ask of us. An HSIB maternity investigation cannot proceed without a mother or family's consent to be contacted and allow us access to their healthcare records. In 2020/21, all families were invited to be part of their investigation and 87% consented.

HSIB is doing further work to understand the reasons behind families not wishing to be contacted by HSIB or progress an investigation. Table 1 demonstrates improvements in consent following HSIB contact. This ongoing work has identified themes relating to language, culture and faith, literacy, and age. Further ongoing work is being undertaken in 2021/22.

Table 1 Improvements in gaining family participation in investigations

Date range	Families not agreeing to be contacted by HSIB	Families agreeing to be contacted by HSIB but not agreeing to participate in an investigation	Families participating in an investigation
Quarter 1 2020/21	7.7%	8.1%	84.2%
Quarter 2 2020/21	7.3%	10.5%	82.2%
Quarter 3 2020/21	7.4%	7.5%	85.1%
Quarter 4 2020/21	7.9%	3.0%	89.2%

Because of the pandemic we have adjusted the way we engage with families. For example, we have conducted staff and family interviews via telephone and video conferencing, something we hadn't done extensively before the pandemic. This has enabled us to plan future working models to embrace a mix of IT solutions and face-to-face interactions with trusts and families post COVID-19.

Caseload statistics

During 2020/21 the HSIB maternity investigation teams completed 1,024 reports, a number of these reports were part of the dedicated work undertaken to reduce the number of investigations exceeding the 6-month timeframe.

HSIB received 1,269 maternity investigation referrals from trusts.

Of these referrals:

- 760 progressed to investigation
- 509 were not progressed for the following reasons:
  - 170 were duplicate referrals from trusts
  - in 124 cases the family did not give consent to access healthcare records
  - 80 cases did not meet HSIB's referral criteria
  - 135 were not progressed due to our COVID-19-related criteria adjustment.

Except in the case of duplicate referrals, to ensure opportunities for learning were not lost, trusts would be expected to conduct a local investigation into cases that did not proceed to an HSIB investigation.

Progress of referrals

Of the 760 referrals that progressed to investigation, 381 investigations have been completed, meaning that the final report has been provided to the family and the trust.

As at the end of March 2021, the remaining 379 ongoing cases were at varying stages of completion:

- 268 were live investigations
- 33 were undergoing internal quality assurance
- 78 were with the trust or the family for a review of factual accuracy prior to completion
- Over the course of the year we have reduced the number of active cases exceeding a six-month time frame from 283 (40 percent) to 15 cases (4 percent).

Categories of referrals

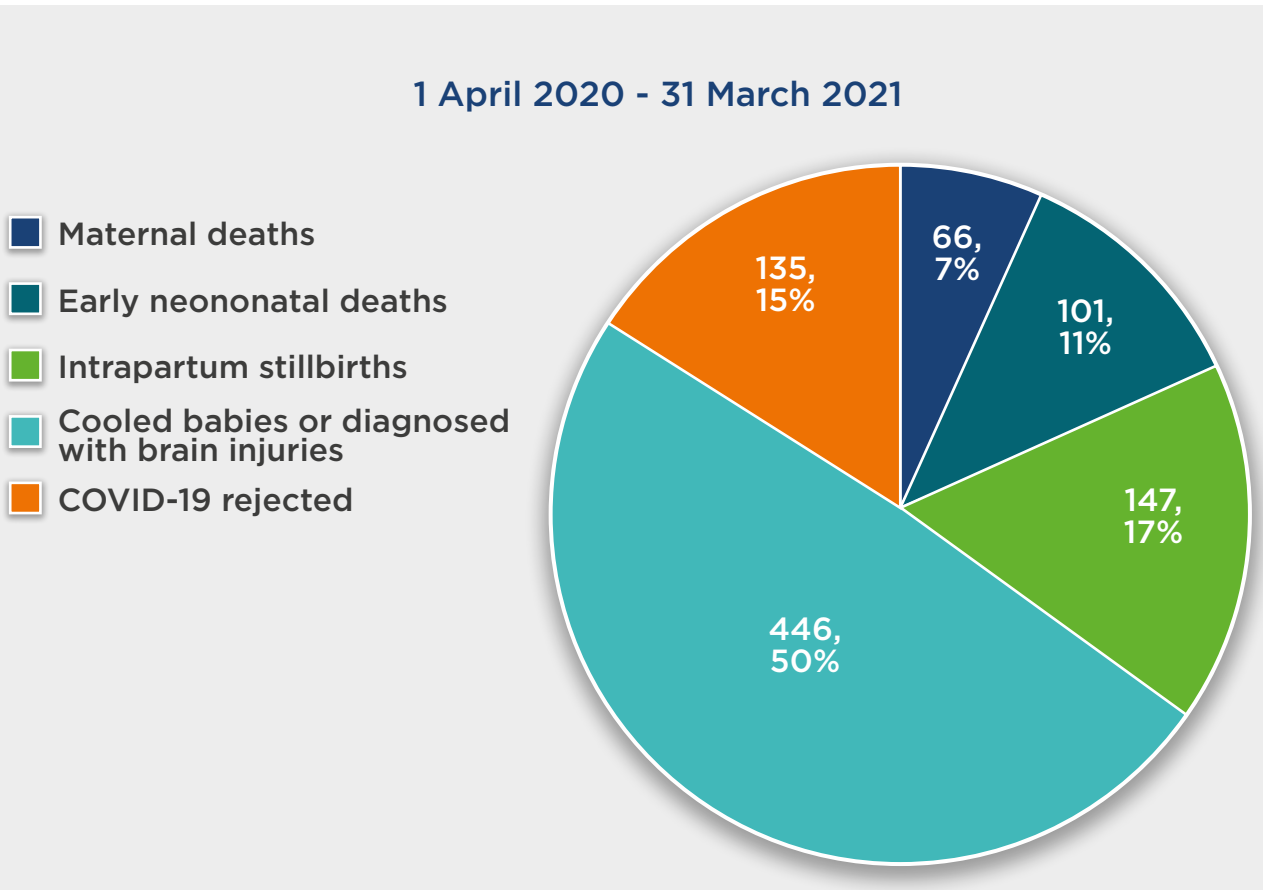
Referrals accepted for investigation across the four main criteria categories for the maternity investigation programme are set out in figure 1.

Referrals not investigated due to our COVID-19 criteria adjustment are shown, categorised as 'COVID-19 rejections'. The diagrams show that in the first two years of the programme, 'cooled babies or babies diagnosed with brain injuries' was the largest category.

The change in HSIB criteria has led to a change in the proportion of cases within each category. We also observed at the start of the pandemic an increase in intrapartum stillbirth and maternal death referrals, with both representing a greater proportion of referrals from April to July 2020 compared with previous years of the programme's operation.

In February 2021 HSIB published a national investigation report which highlighted the patient safety risks and contributory factors that emerged from our **review of maternal deaths** during wave 1 of the pandemic.

Figure 1: categories of accepted referrals to HSIB's maternity investigations programme



Investigation timescales

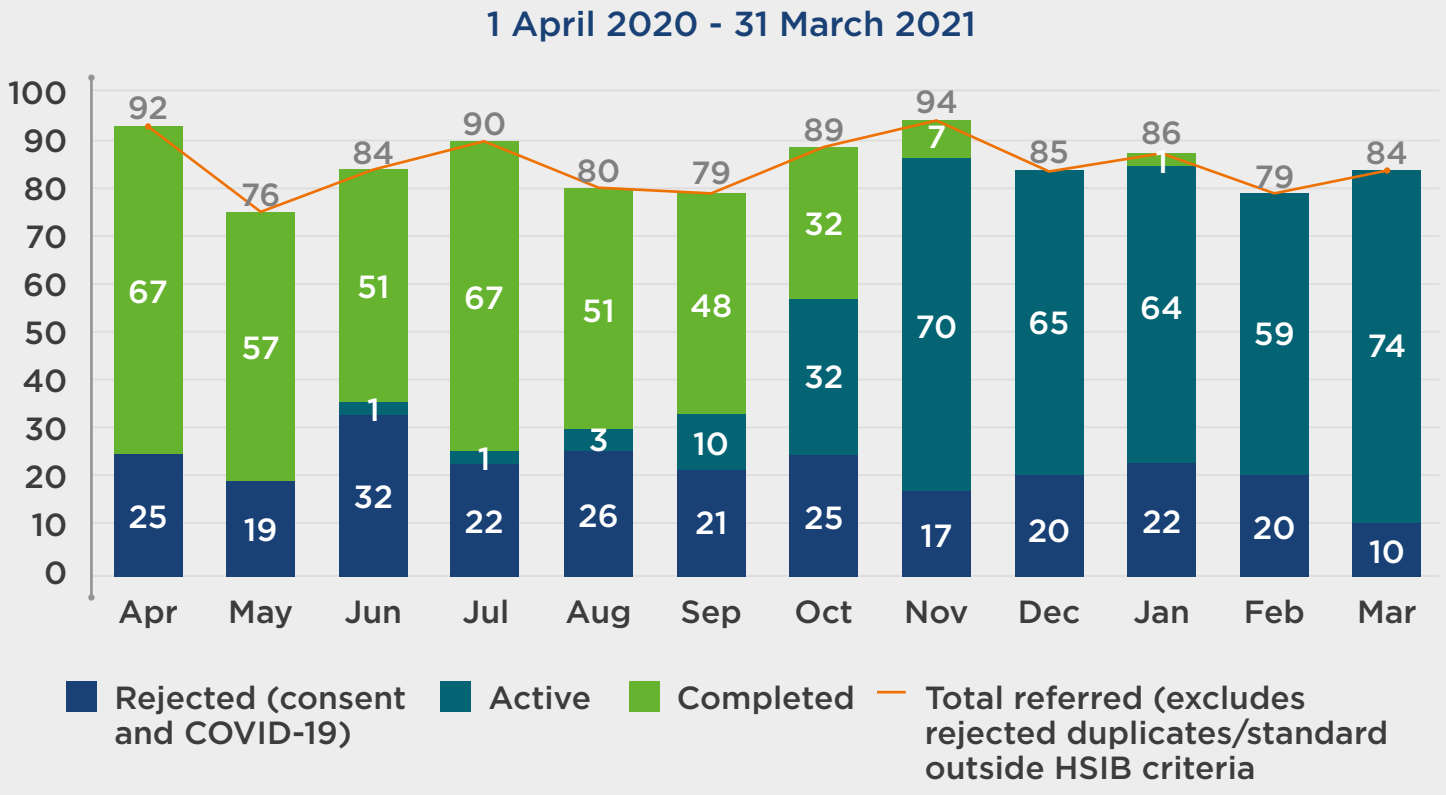
A key priority in the last year has been to resolve the number of investigations exceeding the 6-month timescale for completion, as set out in the 2018 maternity Directions. Investigation pathway development and close internal monitoring has led to the reduction in the number of cases exceeding this timeframe. At the end of March 2021 fewer than 5% of our live cases exceeded the 6-month timeframe.

Where cases have taken longer than 6 months to complete, this can be due to investigations being unable to progress because of:

- A requirement for another agency to complete an initial review
- investigations needing additional clinical information from trusts and staff
- the requirement to investigate care provision by a number of different healthcare providers.

In addition, some families require more time to feel ready to engage with the investigation. It is important that HSIB respects and accommodates these requests. The investigation team ensures that the family and the trust remain updated throughout.

Figure 2: Progress of active cases against the six-month timescale



At the point of publication the number of reports that remain active over 6 months has changed, this data is monitored and reported monthly to DHSC.

Operational engagement with trusts and local maternity systems

Ongoing communication with trust maternity service leaders is a key feature of HSIB's investigations. Close collaboration with trusts is necessary for the HSIB maternity investigation programme to be effective, and its operational structure ensures that every trust has regular, productive engagement with their local team of HSIB staff.

Each team includes a regional lead, team leader and a link investigator aligned to the trust. This is alongside the investigatory team. We share intelligence from our investigations with trusts through an ongoing programme of meetings and communications which are designed to facilitate a rapid response to safety concerns that require urgent attention. Awareness of emergent and recurring themes enables trusts to communicate effectively with frontline staff about risks and support their learning from HSIB's work.

We offer each trust a scheduled quarterly review meeting (QRM) with our HSIB team leader and link maternity investigator. We encourage the attendance of all clinicians involved in the provision of perinatal care, including obstetricians, midwives, neonatologists and obstetric anaesthetists (the perinatal team) to discuss the themes and possible actions being undertaken. We also encourage the attendance of staff from all levels of the trust, from the 'ward to the board'. There may be external representation from the regional chief midwife or commissioners.

At the QRM, the HSIB team presents referral data and reviews cases, identifying evolving and recurrent themes along with any evidence of safety improvement based on previous HSIB recommendations. This information remains with the trust for them to share with internal or external stakeholders including clinical commissioning groups (CCGs) and local maternity systems.

We also share national themes to allow trusts to learn from incidents that have occurred in other trusts. HSIB receives positive feedback on this approach. HSIB is in a unique position to influence and observe the changes implemented by a trust due to the ongoing engagement our teams have at trust level.

On occasion, including when there are serious safety concerns or when HSIB considers there to be insufficient urgency in a trust's response to previously identified issues, senior HSIB maternity team members also attend the QRM meeting. A member of the trust executive team and the board-level maternity safety champion are encouraged to attend.

A trust that is responding effectively to HSIB's investigations will keep their HSIB team informed and updated on actions being taken to address recommendations. Similarly, trusts will be open with their CCGs and use HSIB reports to reinforce their prioritisation of safety actions. For example:

A trust used the findings of an HSIB investigation to support a business case to acquire a piped (continuous) medical gas supply to neonatal resuscitaires, instead of reliance on oxygen cylinders. By addressing this issue, the trust reduced the future risk of interruption in the availability of medical gases during resuscitation, which had occurred and had impacted on a baby's care.

It is HSIB's experience that most trusts welcome our reports and act promptly to respond to our recommendations. For various reasons some trusts have taken longer to recognise or prioritise the actions necessary to address risks. We understand the many pressures on trusts and that maternity services are a product of systems not all within the full control of individual organisations; sometimes solutions do not appear easily achievable. In the event we are unable to resolve variation in opinion in relation to a safety recommendation we will ensure the trust board maternity safety champion is aware to support further discussion at executive board level.

HSIB has a duty under the 2018 maternity Directions to ensure that identified patient safety risks are known to relevant parties, including escalation to relevant regulatory agencies when there is evidence that the risks may, for whatever reason, be persisting. On the rare occasions HSIB has done this, it has only taken place after detailed consideration and discussion with the trust.

5 Staffing and recruitment

Maternity investigators

In November 2020, we welcomed 22 new maternity investigators. Our investigators come from both clinical and non-clinical investigatory backgrounds. This was the 11th group of maternity investigators to join the organisation, bringing the total maternity investigator workforce to 130 investigators across the 14 regional teams; this is equivalent to one investigator per trust.

All maternity investigators receive a comprehensive 3-week induction and training programme. The training focuses on developing the skills required to work effectively as an HSIB healthcare safety investigator in NHS maternity services, drawing from the knowledge and experience of practitioners and academic staff. This includes the application of safety science and analysis tools to identify the systems and processes that impact on safe maternity care.

Subjects delivered during the training programme include:

- learning from investigations
- human factors
- the System Engineering Initiative for Patient Safety (SEIPS) (a model used in safety investigations)
- culture
- working with families
- working with staff
- organisational and safeguarding
- interviewing
- analysing evidence
- understanding health providers' responsibilities after an incident has happened.

Clinical advisors

We recruited 12 additional clinical advisors to the maternity programme in October 2020, specialising in obstetrics, neonatology, obstetric anaesthetics, and intensive care.

The new clinical advisors completed a two-day induction programme prior to joining their clinical and midwifery advisory colleagues. The clinical advisor team supports the work of the programme by providing multidisciplinary clinical input to inform the analysis undertaken by maternity investigators throughout investigations.

The clinical advisors work for HSIB one or two days a week. Most maintain active clinical practice in their speciality, working in hospitals across the NHS in England, in addition to their work for HSIB.

6 Outcomes and impacts: emerging themes from HSIB maternity investigations

HSIB has a unique insight into local maternity services which informs our work at local, regional and national level to support joined-up learning. Our investigations provide us with granular detail of the safety, risks and culture within individual maternity units, and the recurrent safety themes at trust level and across the country.

We have made over 1,500 safety recommendations to trusts addressing a wide array of issues.

The most frequently recurring themes, which will be explored in more detail, include:

- effective escalation of safety concerns about mothers and babies
- clinical oversight
- clinical assessment and monitoring.

In addition, our investigations have highlighted:

- how the use of clinical guidelines influence the care provided
- the impact of pathways of care crossing healthcare boundaries on the care provided to mothers and babies.

Effective escalation of safety concerns about mothers and babies

Our investigations have identified recurring recommendations relating to effective escalation. A lack of effective escalation can impact on the outcome for mothers and babies, for example:

- when concerns about mothers and babies are not effectively communicated to more senior or more specialist clinicians
- where the response to escalation does not influence a change in a mother's or baby's clinical condition.

The themes identified in the recommendations included timeliness of escalation, the environment in which the care was being given, anticipation of events and communication within and outside of the clinical team.

Our investigations explore the reasons behind these issues and particularly the human factors related to team working and communication.

HSIB has observed that effective escalation can be supported by:

- **Mechanisms that enable early recognition and correct identification of a concern**

Early warning physiological scoring tools that are adapted for use with pregnant women should be used in any environment a mother attends, such as the emergency department. These tools are often only applied within maternity services. This means that thresholds for escalation may not be identified. Early warning physiological scoring tools should be supported with clear escalation pathways that enable maternity expertise to be supported by those with critical care skills.

HSIB receives feedback on improvements trusts are undertaking. For example, one trust has implemented a requirement for mothers to be reviewed by a consultant obstetrician and anaesthetist, and physically examined, if their observations are outside the expected ranges or if their early warning scores for sepsis are above an agreed score.

- **Effective and timely communication between individuals and teams**

Sharing of accurate information with the right people at the right time is essential for effective escalation. This needs to ensure the key pieces of information about a mother's or baby's condition are communicated, to enable the clinician receiving the information to make an informed decision about next steps.

Once a mother or baby has been assessed, detailed documentation and clear management plans need to be completed to support the clinicians caring for the mother or baby to provide ongoing care. These plans need to include when further escalation should be undertaken and to whom.

HSIB investigations have highlighted the importance of continuity of care and oversight of mothers' or babies' care, particularly when multiple clinical specialities are involved.

Examples of actions trusts have implemented include:

- A trust with multiple hospital sites that introduced a series of meetings between key staff at all its sites (known as 'safety huddles'). The introduction of cross-site safety huddles improved communication and raised awareness of workload and complexity of clinical issues, particularly out of hours.

- The implementation of an operational co-ordinators role to oversee workforce and activity. This role builds resilience into services by enabling oversight of the current situation, and forward planning for future shifts. This supports recognition of potential safety concerns and supports escalation across the perinatal service.

- **A trust culture that supports individuals and teams to raise concerns when the initial actions and decisions in response to a mother's or baby's deteriorating clinical condition are ineffective**

Clinical oversight is essential to ensure escalation is actioned and effective. The culture of a trust and clinical environment should support staff at all levels to challenge decisions. This means that staff should be empowered to escalate concerns when decisions relating to care have not been effective. In scenarios where there is difference of clinical opinion, a second opinion should be sought to ensure the mother or baby remain central to ongoing decisions and a dynamic approach is taken to care planning.

HSIB has observed the development of a communication tool in a trust for use in complex situations. The tool allows all members of the multidisciplinary team to challenge a situation where they feel that the safety of a mother or baby could be compromised. Another trust has been creating an environment that supports 'psychological safety' as part of multidisciplinary training, ensuring that all members of the team feel safe and empowered to speak up and share ideas, questions and concerns.

Clinical oversight

The care a mother and baby receive involves many members of staff who may be involved at particular stages during the pregnancy, labour, birth, and in the immediate postnatal care. Above we have highlighted where clinical oversight can impact on escalation; this section provides more detail on clinical oversight throughout a mother's pregnancy pathway.

Throughout a mother's pregnancy, effective multi-professional working requires open channels of communication and effective documentation of care plans. Co-ordinating care prevents 'silo working' and ensures staff and mothers have a clear understanding of care plans. This is particularly important when mothers have complex care needs, or care is delivered across multiple healthcare providers. HSIB has observed situations where a mother or family has had to take responsibility for updating clinical teams.

For a mother with complex care needs, the importance of allocating responsibility for her care to a named consultant is often underestimated. There is a need to ensure a robust delegated approach is in place to provide consultant-led care when a named individual is not available. Without this approach care can be fragmented, ineffective and impact on the overall outcome for the mother or baby.

HSIB has observed that clinical oversight can be supported by:

- **Effective documentation and communication with mothers and clinical teams providing care**

Healthcare records should include detailed documentation and communication which are accessible to the mother and clinical teams providing care. Detailed clinical records should be accessible and provide information that identifies changes at any point within a mother's care pathway. This is particularly important when a mother receives care outside of the trust where she has booked for her maternity care.

In emergency situations clinicians need to be able to access clinical information to support the care they provide. This cannot rely on the mother or family being in a position to accurately provide the information. Changes to a mother's care plan can occur at any point in her pregnancy; it is important that these changes are effectively communicated to ensure they can be supported by the environment in which the care is being provided and the clinical team.

HSIB has highlighted the importance of accurate, timely and repeated risk assessment to enable clinical oversight and management of ongoing care. The interim report of the Ockenden review of maternity services at the Shrewsbury and Telford Hospital NHS Trust, published in 2020, identified risk assessment throughout pregnancy as an essential action with the recommendation that formal risk assessment should be undertaken at every antenatal contact. HSIB investigations have observed the importance of this extending throughout the intrapartum and postnatal care of a mother and baby.

HSIB has examples of trusts that have reinforced intrapartum risk assessments in birth centre settings to include senior midwifery oversight. These risk assessments, undertaken by the midwifery team, include hourly reviews of partograms. This supports a 'fresh eyes' review of a mother's progress in labour and her uterine contractions, and leads to a regular holistic review of a mother's and baby's wellbeing.

- **Robust communication of changes to care plans**

To fulfil the essential requirement of safe care and meet the expectation of a mother during pregnancy requires effective and detailed communication. This is particularly important when the pathway of care is changed.

Mothers who may initially be assessed as being low risk of complications can move between a low-risk and high-risk pathway during their pregnancy. Mothers considered suitable for a low-risk antenatal care pathway may develop conditions that require them to move to an obstetric-consultant led pathway, either temporarily or for the duration of their maternity care. This may subsequently influence birth planning choices, and requires skilled conversations to ensure safety, expectations and experiences are all supported following robust risk assessment.

HSIB is aware of a trust that has introduced detailed, face-to-face holistic reviews that are undertaken when changes in a mother's condition are identified. Another example includes the categorisation of all operative births to enhance clinical oversight and ensure timely delivery of babies.

- **Robust systems that support a named consultant to have overall responsibility for a mother's care**

The lack of a named consultant can result in decisions being made around one particular aspect of a mother's or baby's care without consideration of the impact on another aspect. Clinical oversight in complex clinical situations is important to maintain situation awareness.

Mothers may have pre-existing conditions that require support from clinical specialities outside of maternity during pregnancy. This requires planning and co-ordination to ensure care and information does not conflict or become confusing for the mother. It is also important when the health and wellbeing of a mother or baby changes rapidly that there is oversight and co-ordination of urgent decisions. A named consultant should be responsible for the oversight of care for mothers with complex care requirements. The on-call consultant should be informed in emergency situations.

HSIB knows of an example where a trust that has implemented robust care planning and clinical oversight for mothers whose preferred place or method of plan to birth falls outside of national guidance.

Other examples include the implementation of joint reviews with different clinical specialities during a mother's antenatal and intrapartum care; and the involvement of multidisciplinary team 'huddles' to co-ordinate emergency care of the mother and ensure a named point of contact is provided to the family.

Clinical assessment and monitoring

The clinical assessment of mothers and babies incorporates many factors which influence ongoing monitoring and can affect subsequent actions taken as part of their care. The initial monitoring of a mother's observations, measurement of the baby's growth, the interpretation of cardiotocograph (CTG) monitoring, or assessment of progress in labour are just a few examples.

Each clinical assessment is an opportunity to re-evaluate a mother's care pathway and consider whether it needs to change. Such a change could be a referral for an obstetric review in the antenatal period, request for a review of a progress in labour or a move from one birthing environment to another. Decisions that are not fully informed can adversely influence both the outcome and experience for families and staff involved.

- **Examples of situations where HSIB has observed the influence of clinical assessment**

The importance of symphysis-fundal height measurements along with accurate plotting on growth charts to enable escalation for growth scans and review. Symphysis-fundal height measurement is used to assess a baby's growth during pregnancy. When plotted on a chart, the measurements provide a visual indication of growth and can identify changes that need additional action.

It is important that there is recognition when a baby is not growing as expected and that this is escalated for appropriate action. Babies whose growth is below the 10th centile require additional ultrasound scans and senior clinical review. If a baby's growth exceeds the 90th centile this can also have implications when planning the birth.

Information about a baby's growth and size informs the clinical teams to anticipate a need for additional support at birth, such as neonatal resuscitation, or for larger babies the increased risk of the baby becoming stuck (shoulder dystocia).

HSIB made safety recommendations following several undetected small for gestational age (SGA) babies at one trust. As a result, the trust reviewed the accessibility of customised growth charts alongside the information and support provided to clinicians relating to detection of SGA babies. This trust has reported a marked improvement in its SGA detection rates as a result.

- **Triage services being available 24-hours a day with dedicated and appropriately skilled clinicians**

Triage services are often the recommended point of contact given to families if they have concerns in relation to the pregnancy, or if a mother has gone into labour. It is important that trusts have a dedicated triage service that is available 24-hours a day and staffed by skilled clinicians.

The clinicians need to have access to the mother's records to ensure they provide informed, individualised advice. Each contact needs to be recorded accurately, with a process to support identification of multiple contacts so these can be escalated.

HSIB has identified variation across England in the triage service model and associated resource; this has resulted in several safety recommendations to trusts to review the services they provide.

HSIB made a safety recommendation to a trust identifying that the triage unit was not always accessible. The trust has now reviewed its service and introduced a new triage system, ensuring that it is open 24/7 with dedicated skilled staff.

- **Recognition of labour**

At the start of labour, a mother's or family member's first contact with maternity care is often by telephone. This initial telephone assessment at the start of labour informs decisions about the timing of admission for intrapartum care and may influence the care pathway. HSIB has observed that the timing of a mother's transition from latent to active labour may be difficult to recognise and affects when one-to-one intrapartum care starts. A structured approach to telephone triage has been recommended, and documentation and handover of care has also been found to affect this period of care.

When a mother goes into labour, clinicians undertake an assessment to establish how the labour is progressing and to inform them of the wellbeing of mother and baby. The initial assessment is often carried out over the telephone to advise the mother whether she should attend the maternity unit or can safely remain at home.

Clinicians need to ensure the advice they provide supports mothers to receive assessment and monitoring throughout their labour. This needs to be individualised for each mother and informed by risk assessments undertaken during antenatal care.

HSIB has highlighted through safety recommendations the importance of accurate recognition when a mother transitions from latent phase to established labour. This supports the decisions made in relation to the environment in which mothers are cared for. Our investigations have identified mothers' and babies' need to be in an appropriate environment to ensure they are monitored and receive one-to-one care when in established labour.

HSIB has recognised that on occasion trusts have been unable to transfer mothers to a labour ward due to availability of beds or because the baby was going to be born imminently. HSIB has observed a number of examples where trusts have developed the ability to move clinicians and equipment to a mother's location to support safe care and birth of the baby.

- **Accurate application, recording and interpretation of monitoring for a mother and baby during labour**

Intrapartum care requires clinicians to undertake ongoing assessments of a mother's and baby's wellbeing to ensure labour is progressing as planned. One key element is the assessment of fetal wellbeing throughout a mother's labour. For mothers confirmed as being at low risk of complications, intermittent auscultation (IA) is suitable. IA allows mothers with non-complex pregnancies to be monitored using a Pinard stethoscope or handheld Doppler. Clinicians need to be trained to undertake IA effectively and to follow guidance, ensuring deviations from expected ranges are identified. Any changes require action, escalation, and commencement of continuous cardiotocograph (CTG) monitoring to assess a baby's wellbeing.

The monitoring of a mother and baby during labour (CTG monitoring) is used for more complex pregnancies, labour, maternal choice, and for other factors. Interpretation is complex and requires training, support, multi-professional input and tools to support clinical interpretation.

Following HSIB safety recommendations a trust has successfully won a bid for funding, enabling it to appoint a fetal monitoring midwife and set up a CTG working group. The Ockenden report, identified an essential action that required the appointment of a lead midwife and obstetrician to champion best practice in fetal monitoring.

Use of guidance

The use of national policy and guidance to support staff to provide care to mothers and babies is variable. There is a significant volume of national guidance available, and at times it can be unclear or conflicting.

Our investigations have highlighted these issues and made safety recommendations accordingly. Our investigations often identify that local guidance does not reflect the national perspective, or local interpretation is different or unclear. Where a trust has multiple sites, the guidance may be different at each site, which can be confusing for staff. In addition, where a trust has implemented guidance without a co-ordinated approach, staff can find it challenging to follow.

HSIB recognises that the effective and appropriate use of national policy and guidance to support staff to provide care to mothers and babies is variable. HSIB has contacted the National Institute for Health and Care Excellence (NICE) regarding updates to its induction of labour guidance, and has responded to maternity-related NICE guidance consultations to share feedback and learning from our investigations.

Pathways of care crossing healthcare boundaries

To support improvement in local maternity units, our investigations have tackled challenges that are presented by care pathways that cross multiple healthcare boundaries. This can be internally within trusts across clinical settings such as intensive care, haematology, radiology and oncology services, and operating theatres. It also includes local system partners such as GPs, ambulance trusts, and external services for social care, pregnancy termination, substance misuse, learning disabilities, mental health and police forces.

HSIB investigations regularly involve care provided by road and air ambulance services, highlighting the importance and complexities of pre-hospital care. HSIB has supported a systematic approach to investigations and opportunities for learning to be shared within this specialism of care. HSIB has recognised opportunities to develop this further and will be developing a quarterly review meeting approach similar to those that take place in trusts, and is undertaking a webinar with ambulance services in June 2021.

Historically trusts have only been able to investigate aspects of care they have provided. This has meant that multiple providers investigate the aspects relevant to their service. These investigations are often not joined together or shared, resulting in families not being able to fully understand what happened during their whole journey or having to contact individual providers to have their questions answered.

Families have told us that this can result in them reliving their experience multiple times, often without fully understanding what has happened. HSIB investigations are able to look at the whole care pathway and independently understand the

care provided at each stage by the relevant provider. This has enabled us to identify the opportunities in a mother's or baby's care where something different could have been done.

For families, we explore all aspects of care, answer any questions they have and provide them with a detailed explanation of events. For staff, being involved in an investigation can enable them to recognise that they were unlikely to have been able to change the outcome in the situation they were presented with.

An example is described below:

A recent investigation highlighted safety risks associated with ineffective communication within and between trusts, for the identification and care of mothers with complex care needs. A mother with multiple risk factors was referred by one trust for further assessment by a specialist unit at a different trust. The assessment involved screening for two concerns: suspected placenta accreta spectrum (PAS – a condition where the placenta is firmly stuck to the uterus and can cause severe bleeding complications during birth) and potential complications with the baby. The assessment required separate appointments; the mother only attended for the checks relating to her baby.

There was a misperception in and between the trusts that screening had also been undertaken for PAS with no problems identified, so the mother was referred back to the original trust for ongoing care. Following the birth of the baby, the mother experienced extensive bleeding caused by PAS which could not be stopped and resulted in her death.

HSIB's recommendations supported improved communication arrangements between the trusts, and the clarity of information provided to mothers about complex risks such as PAS.

7 Impact on trust learning and safety actions for maternity services

Trusts embraced the introduction of HSIB's maternity investigation programme with differing levels of confidence. Most trusts are keen to work with us, although some required greater effort to build relationships that are open, engaged and encourage learning.

After two years of full operation, we are confident that we have constructive, effective working relationships with all trusts and their staff. Visible engagement by senior leaders is a strong signal that a trust is willing to recognise the safety issues we have identified and respond to our safety recommendations. Trusts have supported HSIB to understand what 'works well' for both organisations and have actively shaped our approach to investigations.

The regular information we produce for trusts about our maternity investigations has helped to improve the flow of patient safety communication across the perinatal teams (midwifes, obstetricians, obstetric anaesthesia, neonatologist and neonatal nurses).

For example:

- There is increasing representation at our quarterly review meetings from across the perinatal team and from the executive board. This is encouraging wider discussion around learning identified within our investigations.

The benefits of the HSIB maternity programme extend beyond learning and implementation of change for safer NHS maternity care.

Improvements to the safety culture within trusts are being supported by HSIB's family engagement model. Our learning focus in safety investigations enables staff to speak freely about their experiences. This enables the unique insight our approach provides into the relationship between engaged leadership and a positive safety culture at trust level.

We encourage trusts to meet with HSIB and the family on completion of an investigation. These tripartite (three way) meetings can be complex to arrange to ensure they provide a supportive environment to talk through the learning from the investigation and ongoing communication the trust may wish to undertake. For example, we have worked closely with a trust that in the past had limited communication with families during investigations. During our time working with the trust, we have seen a significant changes as it has adopted a proactive and collaborative approach for each family at the beginning and throughout

the investigation. This has meant at the tripartite meeting on completion of the investigation we are confident that we can step back and leave the ongoing communication and care of the family with the trust.

HSIB is influencing change at local and system levels

A newsletter sharing changes that trusts have made in response to HSIB maternity investigations has been piloted in the London region, and we expect to roll this out to all regions in 2021/22. Below are some examples of local changes made in response to learning from HSIB maternity investigations.

HSIB rapidly escalated concerns from an investigation about the pre-printed algorithm used by a trust's maternity triage team to assist the home birth of a baby. The algorithm was not in line with national guidance and the discrepancies may have contributed to a delay in the baby's birth. As a result of HSIB's letter of concern to the trust, the breech birth algorithm was immediately withdrawn and replaced with one that aligned with national guidance. This action has ensured that mothers in a similar situation are given advice to reduce the risk of recurrence and of harm.

A trust immediately relocated a resuscitaire from the maternity unit to the emergency department (and ordered a new resuscitaire to replace it), following an HSIB investigation which found that the lack of a readily available resuscitaire in the emergency department had delayed vital care for a baby born with no signs of life in an ambulance on the way to the hospital. This response ensures that in future, the required equipment will be available to enable safe and timely provision of emergency neonatal care.

A trust had received repeated recommendations from six HSIB investigations relating to fetal monitoring, paying particular attention to intermittent auscultation and continuous fetal monitoring from the perspective of interpretation and escalation. The trust used the findings to establish a new fetal surveillance midwife post. The importance of this role is highlighted in both the 'Saving Babies Lives' care bundle' (guidance published by NHS England to reduce the number of stillbirths) and the interim Ockenden report.

8 Family and staff engagement

HSIB defines 'family engagement' as the prompt, effective liaison between a family and an investigation to ensure the family is integral to the investigation and is treated professionally, respectfully, and according to their individual needs. For this purpose, 'family' is defined widely, to include patients, mothers, partners, parents, siblings, children, guardians, and others who have a direct and close relationship with the individual concerned. This ensures HSIB's family engagement approach can be tailored and nuanced for each investigation.

Meaningful engagement with families during an investigation delivers better learning, higher-quality reports and an improved experience of the investigation for all involved. Family engagement is embedded throughout our entire investigation process, providing an environment where a family's insights can inform the investigation, their questions can be answered within the boundaries of an investigation, and they can be signposted to further support if required.

Feedback continues to show that our family engagement approach offers improved learning and a better experience for both families and trusts when compared with the scope of engagement that most trusts can offer through their local investigations. Families have described how HSIB investigations have helped them to fully understand the circumstances of their care; to trust that the knowledge generated has been fair, transparent, and independent; and to feel reassured that they have been an important part of the investigation. Non-English-speaking families have benefited from HSIB's inclusive approach which ensures that family materials and investigation reports are provided in the most appropriate language or format for each family.

Family information has now been developed and is available in over 20 languages to ensure greater inclusivity.

In addition, we will produce reports in other formats, such as audible, to support a family's needs.

Some illustrative quotes about HSIB's positive impact with families include:

'The investigation itself was thorough and we feel that it gave our baby girl a voice.'

'I was always updated by the investigator as to what was happening and at what part of the process we were at, which I really appreciated.'

'The report enabled me to try and process the most difficult time I have had to deal with in my life ever.'

'We were treated with care and consideration at this most difficult time in our lives. All communications were very open and honest and our views were fully considered.'

'We found it very helpful that the investigators came to our home in the early days after it had happened when the shock was still very raw and we did not feel up to leaving the house. That we could contact the investigator at any point and know that we would get a prompt response and be listened to. The report was detailed and helped us to build a fuller picture about what happened throughout the labour process which helped towards the initial incorrect feelings of self-blame that we experienced. Having an impartial investigation was helpful because we knew that is wasn't going to be biased.'

Other work we have undertaken to promote family engagement includes contributing to investigation training provided by charities; serious incident investigation training at Northumbria Healthcare NHS Foundation Trust; and participating in the DISCERN (Strengthening the disclosure of harm in maternity care in the NHS) study.

We are also collaborating with the Bradford Institute for Health Research and the University of Leeds on a National Institute for Health Research-funded research project to co-design processes and resources for supporting patients and families participating in serious incident investigations, which is due for completion in 2022.

HSIB Maternity Investigation Process

A Summarised 10 Step Guide for Families

STEP 01

- The hospital refers your case to HSIB as required to by Department of Health & Social Care
- The hospital informs you about HSIB and asks for your agreement to pass your contact details to us
- The hospital gives you our HSIB introduction card

STEP 02

- An investigator contacts you and explains more about our investigation process
- We ask for permission to access your data (your medical notes) and to process your personal data as part of the investigation (medical notes/interview).
- You discuss with the investigator how and to what extent you would like to be involved and contacted

STEP 03

- An initial meeting with investigators is planned with your agreement
- The investigation process is explained further, and you ask any questions you have
- We provide you with a family information leaflet
- We can give you information about additional support you may require
- You can change your mind at any time but this does not mean our investigation has to stop

STEP 04

- We arrange to interview you and other key family members about your experience
- We discuss with you the terms of reference of the investigation
- We revisit any support you may require
- (Steps 3 and 4 can happen at the same time if this is what you wish)

STEP 05

- Your investigators will interview key members of staff
- The investigators will seek expert clinical advice surrounding your experience
- Your investigators will keep you updated of the progress of the investigation

STEP 06

- Investigators will analyse findings
- Further clinical advice will be sought to review the progress of the investigation
- Your investigators will keep you updated to their progress

STEP 07

- A draft report will be prepared detailing what happened, any findings and recommendations
- The report will go through a comprehensive quality assurance process

STEP 08

- Draft report will be shared with the hospital
- The draft report will be shared with you and details explained
- Any details that you believe are inaccurate are discussed

STEP 09

- You are given your copy of the final report
- The final report is also given to the hospital
- We will discuss with you the opportunity of a three way meeting with the Trust to discuss with them any next steps. This will be led by the Trust.

STEP 10

- We ask you and your family for feedback on our investigation process
- The HSIB investigation concludes

Staff engagement

HSIB conducts staff interviews during the investigation process. Staff have told us they are now more familiar with HSIB's processes, and they feel more confident about the learning-oriented approach and purpose of HSIB investigations. It has been important for HSIB to remain aware of the pressures on staff of being involved in multiple external investigations, as well as the operational pressures associated with the COVID-19 pandemic. We continue to refine our staff communication materials and our interview processes, as we have with our family engagement work, to accommodate the constraints imposed by the pandemic in response.

Feedback we have received from staff during 2020/21 includes:

‘It was an open, non-pressured, pleasant, professional yet friendly safe space to share what I really thought, with no judgement attached.’

‘I felt the HSIB investigation would be useful for the trust, the parents and myself as an individual in terms of learning for the future. Having since read the prepared report I feel this would be very helpful to parents in understanding events more clearly’.

‘The investigators were kind and understanding, especially as they were aware I had had another HSIB interview only the week before. I felt that the questions that were asked were sensible and just to gain a deeper understanding.’

‘Having completed two interviews in such short succession, I had previously been very anxious about them. However, both were led by very kind and understanding investigators and I felt valued and that the information I had provided would help them with their investigations.’

I feel very confident & comfortable to participate in HSIB investigations in the future if needed.’

9 How the HSIB maternity investigation programme is influencing national learning

Publication of thematic reports

The 2018 maternity Directions require HSIB to produce thematic reports that draw together the overarching themes and aggregate points of learning from our investigations and, where appropriate, make recommendations for the purposes of securing continuous improvement in the quality of services. During 2020/21, we published the following thematic reviews:

- **Severe brain injury, early neonatal death and intrapartum stillbirth associated with group B streptococcus infection'** (HSIB national learning report, July 2020)
- **'Neonatal collapse alongside skin-to-skin contact'** (HSIB national learning report, August 2020)
- **'Severe brain injury, early neonatal death and intrapartum stillbirth associated with larger babies and shoulder dystocia'** (HSIB national learning report, February 2021)
- **'Maternal death: learning from maternal death investigations during the first wave of the COVID-19 pandemic'** (HSIB national learning report, February 2021).

The HSIB investigation teams work collaboratively on investigations that are undertaken under the 2016 Directions (secondary legislation that sets out HSIB's functions and responsibilities) and have a broader scope of investigation.

These include:

- **'Detection of retained vaginal swabs and tampons following childbirth'** (HSIB national investigation, December 2019)
- **'The diagnosis of ectopic pregnancy'** (HSIB national investigation, March 2020)
- **'Giving families a voice: HSIB's approach to patient and family engagement during investigations'** (HSIB national learning report, September 2020)
- **'Delays to intrapartum intervention once fetal compromise is suspected'** (HSIB national investigation, November 2020)
- **'Support for staff following patient safety incidents'** (HSIB national learning report, January 2021).

Engagement with national maternity improvement programmes

The landscape of maternity safety in the NHS is complex, with many organisations at all levels working to deliver on government commitments and support the safer delivery of maternity services. HSIB is one part of the national system to improve the safety of maternity services. An advantage of our function is the perspective our role provides us. We have a unique insight into local maternity services, working across multiple organisations and pathways of care at local, regional and national level.

This gives HSIB's maternity investigators nuanced and detailed knowledge of the safety risks and culture of the trusts they work with, which aids HSIB's contribution to national activity in a joined-up way.

HSIB has an ongoing working relationship with NHS Resolution and in response to the COVID-19 pandemic both organisations considered how they could reduce the burden of reporting for trusts. Since 1 April 2020 HSIB has been the main reporting portal for HSIB and the NHS Resolution Early Notification scheme. This has meant trusts continue to refer all cases to HSIB and in cases where harm to the baby has been confirmed, these are shared with NHS Resolution.

This has been strengthened further with joint leadership on safety action 10 of the NHS Resolution maternity incentive scheme and collaborative working at regional and national safety meetings. Both organisations provide unique insights and opportunities for learning in the work they are undertaking with trusts.

Nationally, we are involved in the following activities led by other NHS bodies:

Engagement across NHS England and NHS Improvement Maternity and Neonatal Safety Improvement Programme (MatNeoSIP), including the development of a national maternity early warning score (MEWS) for England.

HSIB's observations and insights about maternity care are feeding into national projects such as the RCOG Each Baby Counts + Learn and Support programme's improvement work in relation to escalation.

The NHS Early Warning Safety Surveillance and Response group was created at the start of the COVID-19 pandemic to share intelligence regarding safety risks related either to COVID-19 itself or risks related to care pathway changes made in response to the pandemic. HSIB has been actively involved in this work and has made contributions based on observations from safety investigations during this time.

HSIB has also become increasingly involved in the national Maternity Transformation Programme which implements the five-year vision for maternity services set out in the National Maternity Review's 2016 report, 'Better Births'.

We are working collaboratively with the programme's representative group of stakeholders to support national learning and prevent duplication and burden to trusts.

This work includes involvement in what was previously known as Workstream 2: Promoting Good Practice Through Safer Care. This programme has been reviewed during 2020 and the remit of the Maternity Transformation Programme Board and associated workstreams restructured. HSIB has become an integral part of the new Insights group. This oversees the existing work being undertaken in the following areas:

- Core Competency – work is progressing, with the involvement of relevant stakeholders, to agree a training curriculum and core competency framework for the multidisciplinary staff involved in maternity care.

- Recommendation group – the group's remit is to review the 400 current national recommendations from a variety of organisations against agreed criteria to produce a manageable set of realistic, effective actions that will improve safety.

HSIB is also engaged with local maternity systems, maternity clinical networks and neonatal operational delivery networks. Through this ongoing work we are also building productive relationships with the NHS England and NHS Improvement regional chief midwives. Our maternity programme investigations produce outcomes that have an impact at national level.

For example:

A local investigation into the death of a mother found that the mother had not received a postnatal management plan for 6 weeks' postnatal thromboprophylaxis, as this did not display on the pregnancy summary screen of the electronic records. The mother subsequently had a pulmonary embolism and died, which may have been preventable if her high risk of venous thromboembolism (VTE) had been more clearly identifiable from the electronic record. Based on the trust sharing HSIB's report, Clevermed, a company that provides maternity patient records has made a national change to BadgerNet for all trusts which was implemented in September 2020. This will ensure that that if a VTE postnatal plan is made anywhere in the system, at any stage of pregnancy, it will be visible on the summary screen of the electronic maternity records system.

Response to the Ockenden report – emerging findings and recommendations from the independent review of maternity services at the Shrewsbury and Telford Hospital NHS Trust

HSIB welcomed the Ockenden report's seven immediate and essential actions to improve care and safety in maternity services. Through our investigations we have developed a detailed understanding of where trusts have already undertaken considerable work to implement these actions, alongside trusts which require further support to achieve them. We wrote to trusts on 18 December 2020 to reinforce how we can support them to assist their response to the Ockendon report. We have highlighted where our work has already encouraged change in response to the recommendations in the report.

10 Planned developments for 2021/22

For the coming year, there are several priority areas for the maternity investigation programme.

National themed reports

HSIB's maternity programme will continue to produce national themed reports to support the learning and improvement work undertaken by the local maternity systems and other national and regional improvement initiatives.
Forthcoming publications include:

- **'Suitability of equipment and technology used for continuous fetal heart rate monitoring'** (HSIB national investigation, 2021/22)

- **'Intrapartum Stillbirth: Learning from maternity safety investigations that occurred during the COVID-19 pandemic 1 April to 30 June 2020'** (HSIB national learning report, 2021/22)

- **'The assessment of venous thromboembolism risks associated with pregnancy'** (HSIB national investigation, 2021/22).

HSIB's data about maternity investigations

HSIB maternity investigations have generated large volumes of quantitative and qualitative data. We are currently exploring how we can make this data more accessible to individuals and organisations. We are also working with academic partners to identify themes or trends for further analysis. This information is captured predominantly within our findings and recommendations. We are also aware that we gather 'soft intelligence and incidental findings' during investigations – this type of information is more challenging to robustly evidence. There is considerable potential for the use of advanced data processing techniques, such as natural language processing and artificial intelligence, to identify areas for investigation by HSIB and insights into areas of focus for national healthcare bodies.

Health and Social Care Committee inquiry into safety of maternity services

We were invited to give evidence to the UK Parliament's Health and Social Care Committee inquiry into the safety of maternity services in England.

HSIB highlighted the successful roll out of the maternity programme to the Committee; currently 96% of all reports are completed with the 6 month target.

The high levels of positive feedback that has been received from the public and the trusts alike have demonstrated the value that an independent maternity safety investigation programme in the NHS has achieved. There are cases which fall outside our current criteria which trusts and families have asked us to investigate.

HSIB is keen to maximise the maternity programme's positive impact on NHS patient safety more broadly, and further work will clarify how professional safety investigation could be effectively introduced for other clinical services in healthcare in the future. We would also like to explore learning from events where trusts have adapted and adjusted, and it has been possible to intervene to prevent harm – known as a safety II approach. We are working with various institutions to embed our findings into the training of doctors, midwives and related health professionals by informing training programme curriculums.

HSIB welcomes and supports the role of the maternity safety champions

We consider there to be greater scope for the contribution of trusts' board level maternity safety champions, to have executive oversight of the local action plans from HSIB findings and recommendations. HSIB is seeing increased attendance of maternity safety champions from within the clinical teams, and at executive and non-executive level, at quarterly review meetings. As part of the HSIB escalation process, board-level maternity champions will be informed when a safety recommendation is not accepted by a trust. In addition, HSIB has highlighted opportunities to develop this role further as part of the 2021 maternity incentive scheme. The NHS England and NHS Improvement perinatal quality surveillance model has indicated that one of its key principles is to support the development of the responsibilities of the board-level maternity safety champion and strengthen trust board oversight.

System-level changes needed to support improved maternity safety

Currently (excluding the changes made to NHS Resolution reporting during the COVID-19 pandemic) trusts are required to report certain maternity incidents to several bodies – HSIB, NHS Resolution and MBRRACE – in addition to reporting patient safety incidents to the National Reporting and Learning System (NRLS) and serious incidents to the Strategic Executive Information System. The development of a single reporting portal would minimise administration time for trusts and prevent the need to enter the same data onto multiple different portals. Trusts have told us that this is a change they would welcome.
Through the development of the new national NHS learn from patient safety events (LEPSE) service (previously called the the patient safety incident management system (PSIMS)), NHS England and NHS Improvement is already working towards a system that meets the need for future serious incident reporting, in addition to being the successor to NRLS. HSIB understands that the

PSIMS project, in conjunction with the Maternity Transformation Programme, has undertaken a discovery phase to explore the options for incident reporting and has established some principle plans to take it forward. Further development of PSIMS work will be scheduled later in 2021/22, once initial launch and other urgent developments are complete.

11 Conclusion

During 2020/21 healthcare has experienced unprecedented challenges worldwide due to the COVID-19 pandemic. This has required the provision of healthcare to be reviewed and adapted to support a different delivery approach. HSIB has seen the impact this has had on the systems in which care is provided and on families whose care has been directly affected.

The HSIB maternity investigation programme has continued to develop its approach in relation to investigations and sharing learning to improve the safety of mothers and babies during their maternity care. The reduction in our investigation timeframes enables us to share the majority of reports with trusts in draft form at 4 months. This also supports early escalation of immediate concerns; as soon as we identify these during an investigation we share them with the trust to support prompt action.

The involvement of families in our investigations remains pivotal and we thank them for sharing their stories with us and enabling us to work with them to understand what has happened and answer their questions.

The engagement of trusts and their staff has provided significant insight into their experience of working within maternity services. This work provides high quality care for the majority of mothers and their families.

Through our investigations the candour of staff has demonstrated the commitment to learn and improve care for mothers and babies. This has enabled us to explore the factors that influence and challenge how this care is provided. These achievements have been delivered during a period of time when trusts and the staff working within them have responded and adapted to the immense pressures of a pandemic.

HSIB has developed the work we undertake with trusts to optimise opportunities for sharing learning and engaging with all clinicians providing perinatal care. Our ambition is to continue to further develop this approach, building on the engagement of the board-level maternity safety champion in addition to the executive teams.

HSIB continues to provide input and support to the work of the Maternity Transformation Programme Board, and to support trusts at local and regional level in response to the Ockenden report.

In 2021/22 the HSIB maternity programme is in a position to provide national learning at a level of detail that has not been previously accessible in one place. This is an opportunity to continue to influence the changes required to improve maternity care for all mothers, babies and their families.

12 Glossary

Antenatal

Period of pregnancy up until the onset of labour.

Antenatal Partograms

The partogram is a graph in which all the relevant observations of a mother and the unborn baby prior to labour are written.

Cardiotocograph (CTG)

Cardiotocography (CTG) is an electronic means of recording the unborn baby's heart rate pattern, to assess their wellbeing. This is used both during the antenatal period, and during labour. During labour, a mother's contractions are also monitored by this machine which produces a printed or electronic record referred to as the CTG. It is usually performed externally, using two devices (transducers) placed on a mother's abdomen.

Categorisation of operative births

Categorisation of all births to agree expected time frame and clinical assistance required to support the safe birth of a baby.

Cooling therapy

Therapeutic hypothermia (Active cooling) is a procedure where a baby is cooled to between 33C and 34C, with the aim of preventing further brain injury following a hypoxic (lack of oxygen) injury.

Early warning physiological screening tools

A scoring system in which a score is allocated to physiological measurements to indicate early deterioration in a patient's condition. This is aligned to agreed triggers to support clinicians to increase monitoring or escalate for additional clinical assessment.

Established Labour

Established labour is the period of time during which the woman's cervix dilates from about 4cm to 10cm (fully dilated) and they experience regular and painful contractions.

Freedom to speak up guardian

An individual appointed to give independent support and advice to staff who want to raise concerns.

Haematology

A medical science that deals with the blood and blood-forming organs.

Handheld Doppler

Doppler ultrasound is a test performed during an ultrasound examination that measures blood flow in a baby and/or the placenta. It is used in a variety of situations to check on the health of a baby.

Human factors

Are organisational, individual, environmental and job characteristics that influence behaviour in ways that can impact safety.

Intermittent auscultation

Intermittent auscultation (IA), or 'listening in', is the recommended method of a listening to a baby's heart rate in labour, in pregnancies where there are no anticipated complications. This is performed by using either a hand-held (Pinard) stethoscope or hand-held Doppler machine. During labour midwifes listen a baby's heartbeat for at least a minute, immediately after a contraction. This is repeated at least every 15 minutes in the first stage of labour, and at least every 5 minutes in the second stage of labour. A mother's pulse should be measured, recorded hourly and compared to a baby's heart rate, to check both heart beats are being monitored. Further information available from: **NICE - care in labour (includes IA)**.

Intrapartum

Period of time between onset of labour and birth of the baby.

Latent to active labour

The latent phase of labour can last several days before active labour starts. Some women can feel backache or lower period type pain cramps. The pains can be irregular with no particular pattern to them, and it is quite common for the pains to last for a few hours and then stop altogether.

Maternity safety champions

Maternity safety champions develop strong partnerships, can promote the professional cultures needed to deliver better care, and play a central role in ensuring that mothers and babies continue to receive the safest care possible by adopting best practice.

Neonatal resuscitaire

A piece of equipment which combines a warming therapy platform along with the additional equipment required for managing neonatal clinical emergencies and resuscitation.

Neonatology

A subspecialty of paediatrics that consists of the medical care of newborn infants especially the ill or premature.

NHSR: Maternity incentive scheme - Safety Action 10

https://resolution.nhs.uk/wp-content/uploads/2021/03/Maternity-IncentiveScheme-year-3-March-2021-FINAL.pdf

Obstetric anaesthetics

A subspecialty of anaesthetics that specialising in the care of women during birth.

Obstetrician

A medical subspecialty that concentrates on the medical care of women during pregnancy, labour and the post partem period.

Oncology

A branch of medicine concerned with the prevention, diagnosis, treatment, and study of cancer.

Perinatal care

The care of the pregnant women and her baby throughout pregnancy, labour, birth and the newborn up to 28 days of life.

Perinatal teams

The clinical team involved in caring for a women and baby this includes midwifes, obstetricians, obstetric anaesthetists, neonatologists and neonatal nurses.

Perinatal quality surveillance model

A quality surveillance that seeks to provide a consistent and methodological oversight of perinatal services.

Pinard stethoscope

A small trumpet shaped device placed on a mother's abdomen. The midwife places their ear on the other end to listen directly to a baby's heartbeat.

Placenta accreta

Placenta accreta is a rare and serious condition when the placenta is stuck to the muscle of the womb and/or to nearby structures such as the bladder. This is more common if a mother has previously had a caesarean. It may cause heavy bleeding at the time of birth.

Postnatal thromboprophylaxis

Administration during the postnatal period of preventive measure or medication that reduces the likelihood of the formation of blood clots.

Pulmonary Venous thromboembolism

A condition in which one of the pulmonary arteries in the lungs gets blocked by a blood clot.

Radiology

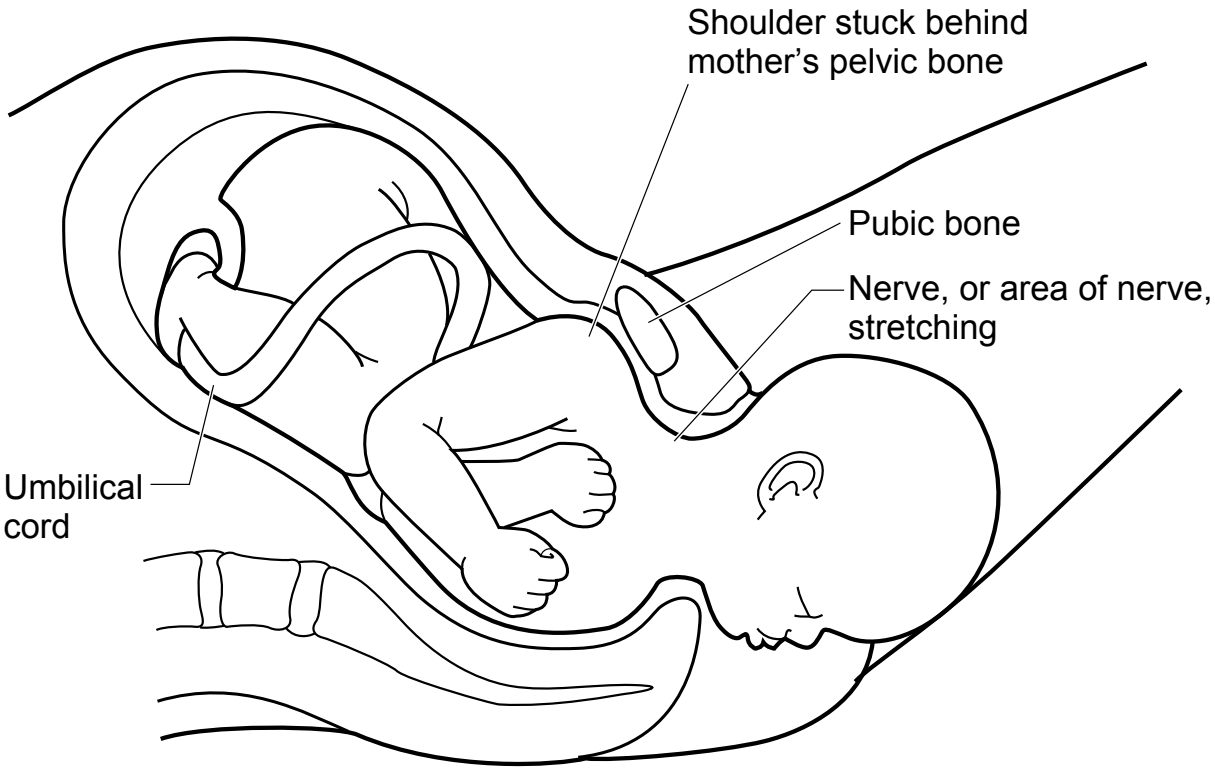
The scientific study of the medical use of radiation, especially X-rays.

Safety science

The methods by which the knowledge of safety is acquired and applied to create systems to prevent safety incidents.

Shoulder dystocia

Shoulder dystocia is when a baby's head has been born and one of the shoulders becomes stuck behind a mother's pubic bone, delaying the birth of the baby's body (see figure). If this happens extra help is usually needed to release the baby's shoulder. Image courtesy of **RCOG PIL**.



Venous thromboembolism (VTE)

A thrombosis is a blood clot in a blood vessel (a vein or an artery). Venous thrombosis occurs in a vein. Veins are the blood vessels that take blood back to the heart and lungs whereas arteries take the blood away. A deep vein thrombosis (DVT) is a blood clot that forms in a deep vein of the leg, calf or pelvis. Venous thrombosis can be serious because the blood clot may break off and travel in the bloodstream until it gets lodged in another part of the body, such as the lung. This is called a pulmonary embolism (PE) and can be life threatening.

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Further information

More information about HSIB – including its team, investigations and history – is available at **www.hsib.org.uk**

If you would like to request an investigation then please read our **guidance** before contacting us.

@hsib_org is our Twitter handle. We use this feed to raise awareness of our work and to direct followers to our publications, news and events.

Contact us

If you would like a response to a query or concern please contact us via email using **enquiries@hsib.org.uk**

We monitor this inbox during normal office hours - Monday to Friday (not bank holidays) from 09:00 hours to 17:00 hours. We aim to respond to enquiries within five working days.

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