HSIB

HEALTHCARE SAFETY INVESTIGATION BRANCH

22/23

HSIB maternity investigation programme year in review 2022/23

Summary of highlights, themes and future work

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 5 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)

For the last 2 years, we have adjusted our maternity investigation procedures, reports, and processes to take into account the impact of the COVID-19 pandemic on both our organisation and the healthcare system in England. In the period covered by this report, we began to move back towards more traditional working methods, including face-to-face meetings, while still accommodating remote work when it proves advantageous or is preferred.

About this report

This report provides an evaluation of the HSIB maternity investigation programme for 2022/23, including an overview of its activities during this period, key themes emerging from the investigations, and future plans. It is aimed at healthcare organisations, policymakers, and the public to provide insights into our work.

It has been an eventful year, with changes made to accommodate the post-pandemic situation and the preparations for our transition from HSIB to the Maternity and Newborn Safety Investigations Special Health Authority (MNSI), which will be hosted by the Care Quality Commission from autumn 2023.

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 **national healthcare investigation criteria** to decide whether to conduct an 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 based on our **maternity investigation criteria**.

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 programmes please visit **our website**.

Contents

Our vision

To be a global leader and educator in healthcare safety investigations

Our mission

To improve patient safety through professional safety investigations that do not apportion blame or liability

Introduction

The HSIB maternity investigation programme, which is part of the national initiative to improve safety in maternity care, has been in operation since April 2018 and was embedded in all trusts providing maternity care by April 2019. Currently our teams work with all 122 trusts providing maternity care in England.

During 2022/23, the programme received 1,070 referrals. Of these, 399 did not progress to an investigation as they did not meet HSIB criteria or the family did not agree to an investigation, for example. We completed 702 reports, taking into account the changes made to investigation criteria due to the COVID-19 pandemic.

Our Maternity Investigation Teams consist of individuals with diverse experience. They work closely with clinical advisors who are still actively practising in frontline roles, and consult with relevant experts both domestically and internationally.

Incidents are referred to us by the NHS trust where they occurred, and our investigation replaces the trust's local investigation. Completed investigation reports are shared with the family and trust, and the trust is responsible for implementing the safety recommendations made.

The maternity programme also highlights recurring themes from trust-level investigations to make safety recommendations for system-level improvements in maternity services both locally and beyond. Throughout the investigation process, the programme places a strong emphasis on involving and understanding the needs of families.

Our future

In autumn 2023 HSIB's two national programmes will separate. Our maternity investigation programme will be hosted by the Care Quality Commission (CQC) and will be called the Maternity and Newborn Safety Investigations Special Health Authority (MNSI). The new arrangement with the CQC, which was announced on 30 March 2023 via a **written ministerial statement**, will ensure the continuation of the maternity programme and maintain the independence of maternity investigations within the NHS.

The continuation of the maternity investigation programme will ensure maximum learning is achieved and will provide NHS trusts with the necessary expertise, resources and capacity to investigate maternity safety incidents in the future.

Our national investigation programme will become a Non-Departmental Public Body established under the Health and Care Act 2022 and will be called the Health Services Safety Investigations Body (HSSIB).

Highlights

Over the last year our core work in completing investigations and reports has continued. We have also continued our analysis of the data and theme discovery.

Our development programmes include continuous improvement methodology and further progress in family engagement.

- During 2022/23, the maternity investigation programme completed 702 reports. This was a similar figure to previous years. At any one time there were approximately 355 active investigations.

- The number of investigation referrals relating to brain injury indicate a sustained decrease in babies with abnormal MRI results or neurological damage.

- In the last year, the programme made more than 1,380 safety recommendations to trusts and other healthcare organisations, covering various topics.

- Families remain central to the work we undertake. We contact all families who give their consent; of these 86% agreed to participate and 14% declined further participation in the investigation.

- As part of our initial engagement and ongoing communication with families we have been supported with interpretation/translation services on 670 occasions.

- Information provided to families about our investigations has been translated into 36 languages. This helps families to make informed choices about participating in investigations and provides better support to enable their ongoing involvement.

- Our reports, and those of other organisations such as MBRRACE (Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK), have identified racial differences in maternity outcomes. HSIB has formed a race equality group to develop the data from investigations to analyse demographics and understand the impact of racial diversity on experiences, access to care, and outcomes.

- The quarterly review meetings we undertake with trusts have continued to develop with greater engagement from executive-level staff, board-level maternity safety champions, and the frontline perinatal teams.

- By working closely with trusts, the programme has helped to increase the involvement of perinatal teams in patient safety.

- The programme has deepened the understanding of the role of emerging themes and how they help to identify issues in the healthcare system as a whole that contribute to the harm experienced by pregnant women/people and their families.

- We now publish a national newsletter three to four times a year to support trusts in sharing improvements they have made in response to safety recommendations, providing learning opportunities across England and beyond.

- A Maternity Quality Matrix is being rolled out to trusts to provide insight into their HSIB maternity investigations over time.

- Feedback is received from trusts and our Maternity Quality Improvement Team continues to improve investigations and support processes.

- During investigations, 'soft intelligence' relating to the investigation is captured in a maternity observational diary, which shares concerns as well as good practices with trusts, and information about ongoing challenges.

- Members of the maternity team ongoingly present at regional and national meetings to share their work and findings from reports.

Criteria for HSIB maternity investigations

The maternity investigation programme investigates incidents that fall within a defined set of criteria.

Incidents that are eligible for investigation include all term babies born following labour (at least 37 completed weeks of gestation), who experience one of the following outcomes:

Intrapartum stillbirth: Where the baby was thought to be alive at the start of labour and was born with no signs of life.

Early neonatal death: Where the baby died within the first week of life (0 to 6 days) of any cause.

Severe brain injury: Where the baby was diagnosed with severe brain injury in the first 7 days of life. These are any babies that fall into the following categories:

- diagnosed with grade III hypoxic ischaemic encephalopathy (HIE), or
- therapeutically cooled (active cooling only), or
- had decreased central tone (or, in layman's terms, was 'floppy'), were comatose (loss of consciousness) and had seizures of any kind.

During the COVID-19 pandemic, HSIB continued to assess all referrals that met its criteria. However, for cases where a baby had a normal neurological outcome after therapeutic cooling (determined by either a normal MRI or neurological examination), and the trust and family did not raise any concerns about the care given, HSIB did not pursue an investigation. Instead, these trusts were asked to follow their internal investigation process.

Maternal deaths

We investigate incidents where a pregnant woman/person dies within 42 days of the end of their pregnancy from any cause related to or aggravated by the pregnancy or its management, and not from accidental or incidental causes. (The criteria exclude death by suicide.)

You can find more information about our **maternity investigation programme on our website**.

Reports

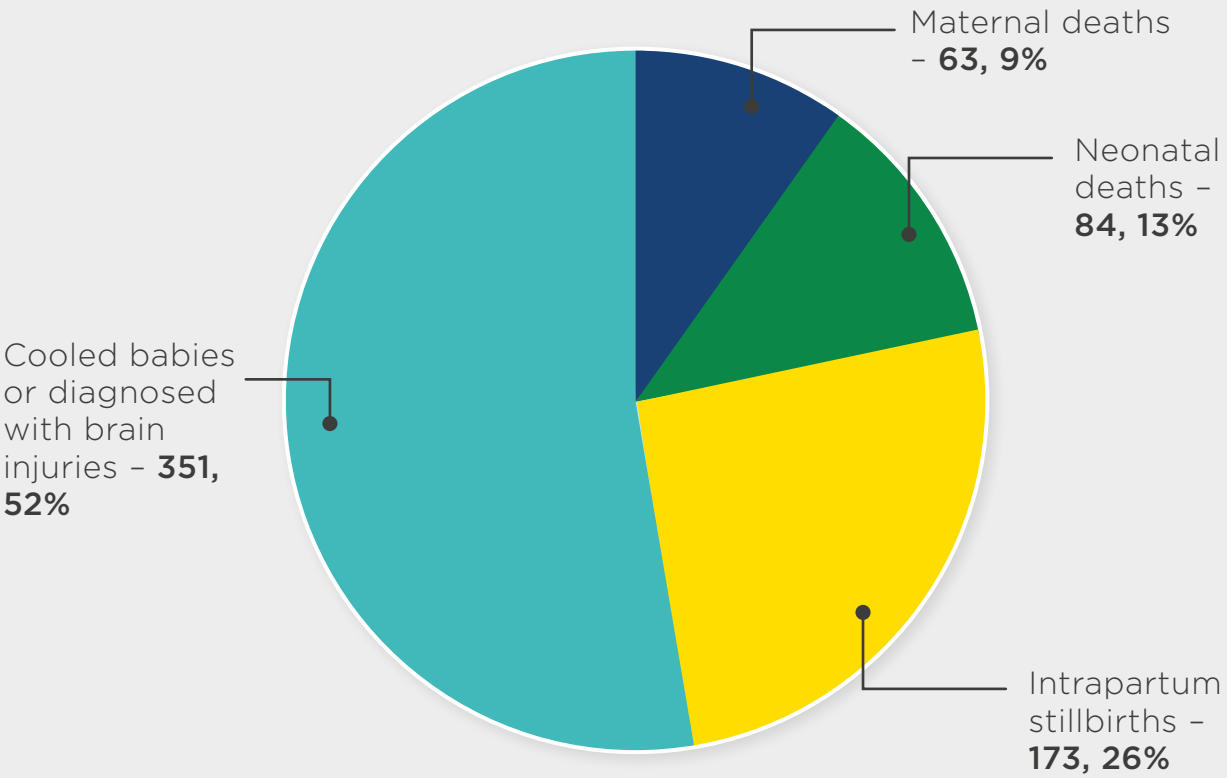
Having completed nearly 3,000 investigations since 2018, the maternity investigation programme also examines recurring themes from trust-level investigations to support system-level improvements to both the trust and also to the wider maternity services.

During 2023 the maternity investigation programme will be transitioning to MNSI, hosted by the Care Quality Commission, with the aim of maximising the learning opportunities and equipping NHS trusts with the necessary guidance and expertise to handle maternity safety incident investigations in the future. In preparation for this transition, the programme has been working to build closer relationships with stakeholders and partners to ensure the move is successful.

Operational performance in 2022/23

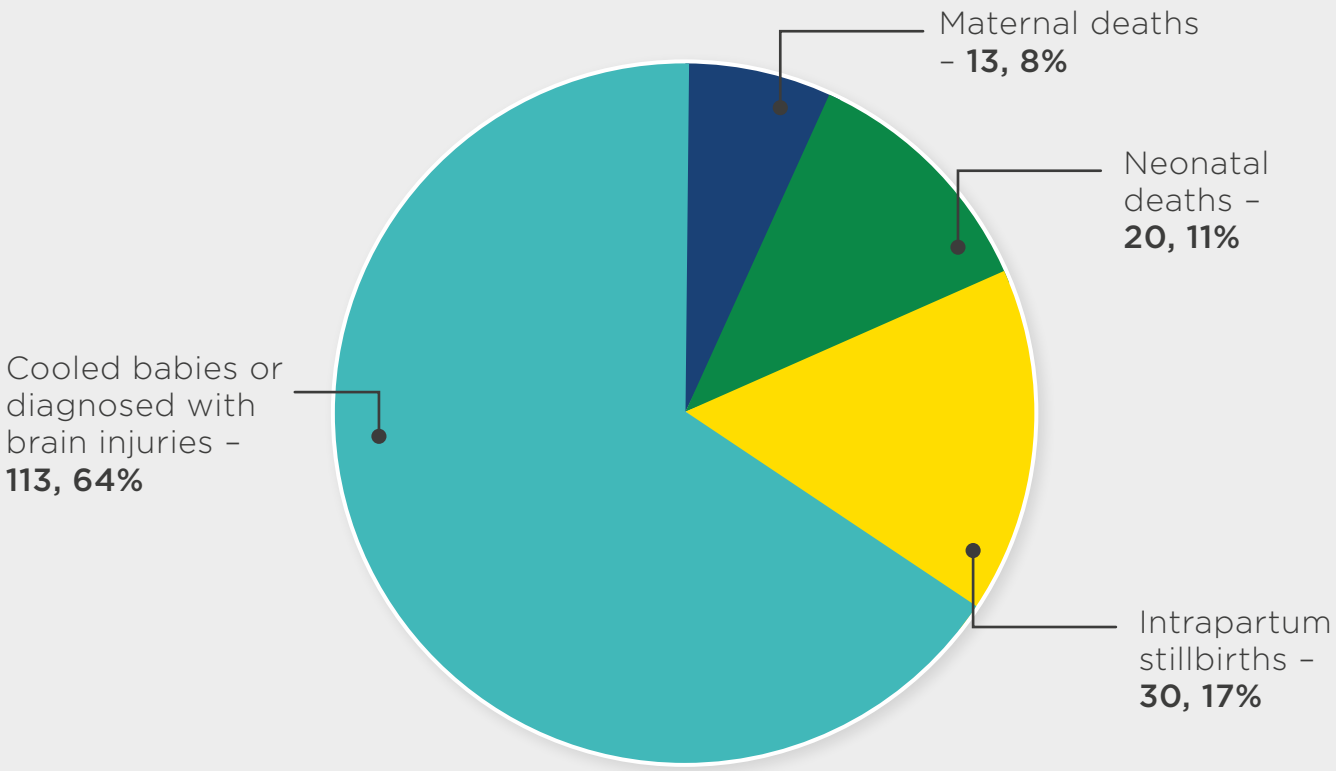
Referrals which progressed to investigation by criteria

1 April 2022 to 31 March 2023

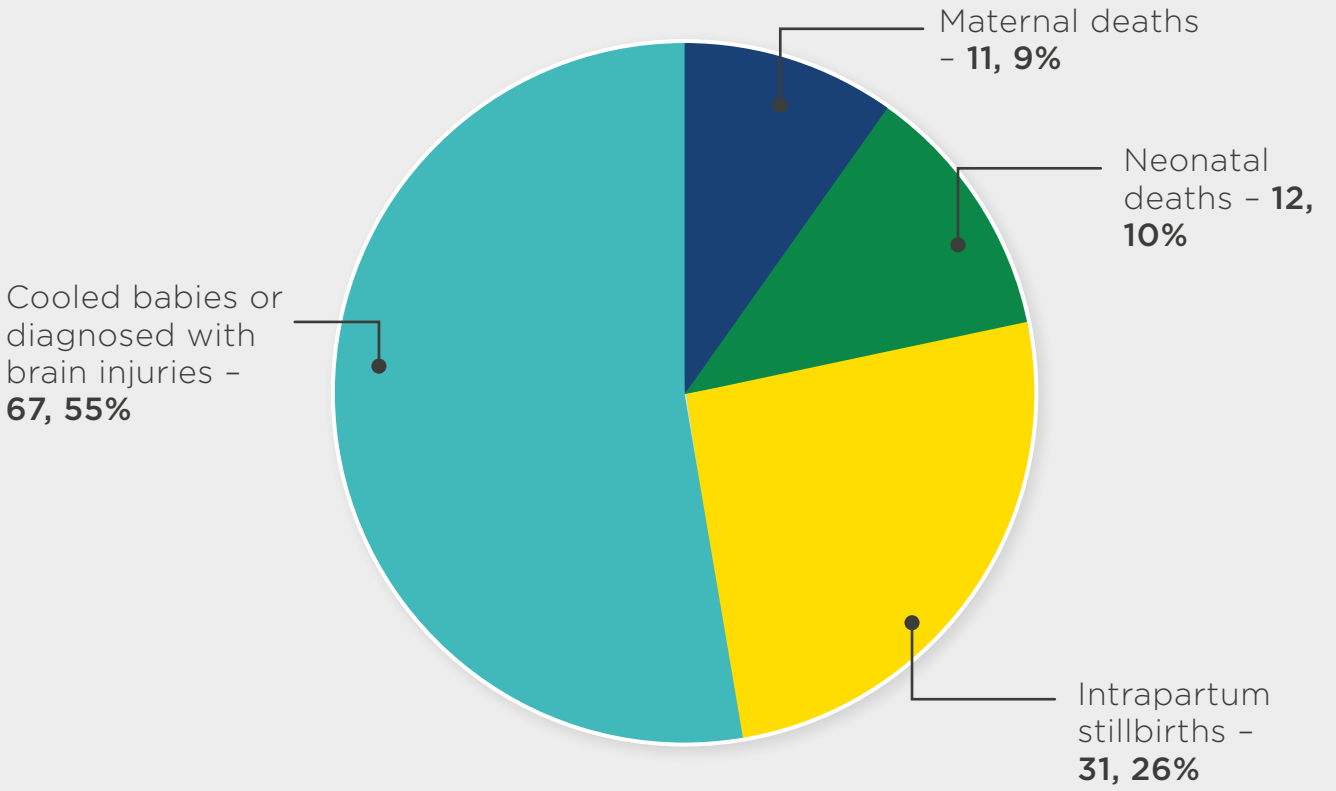


Referrals which progressed to investigation by criteria and HSIB region

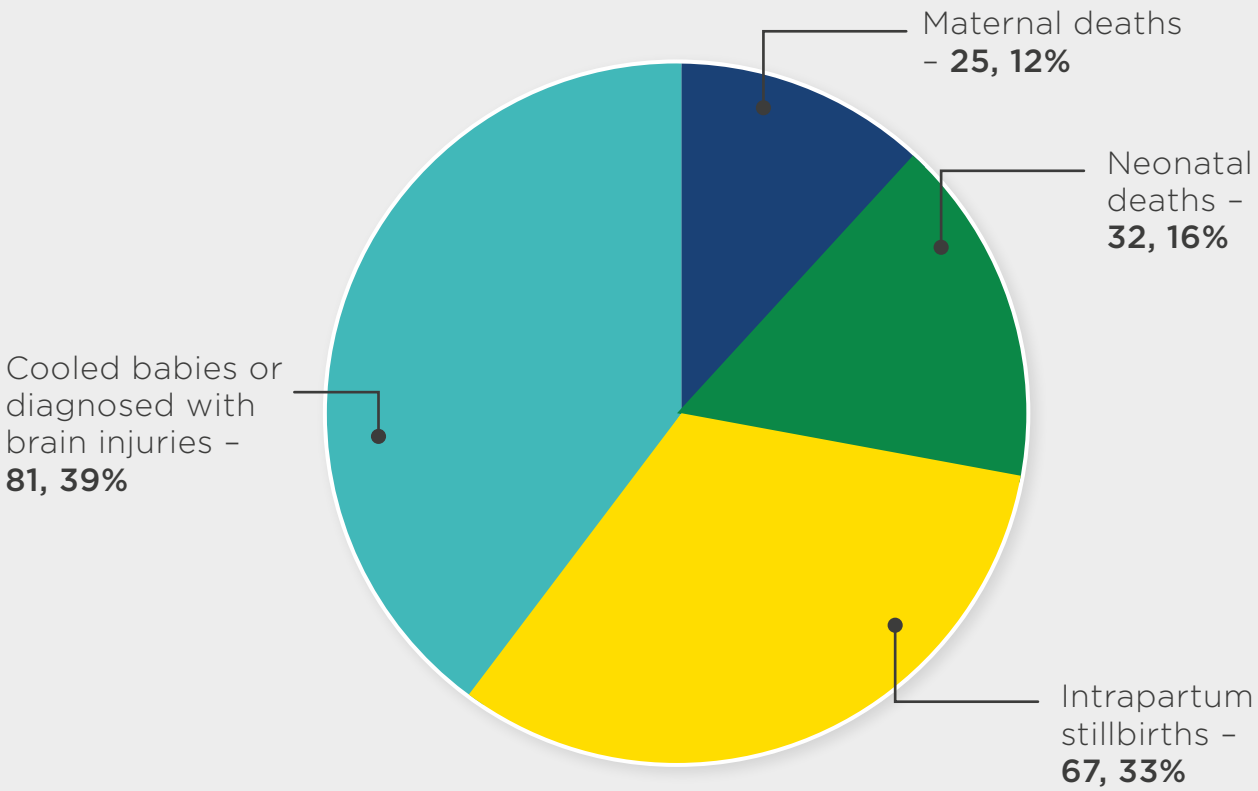
South region 1 April 2022 to 31 March 2023



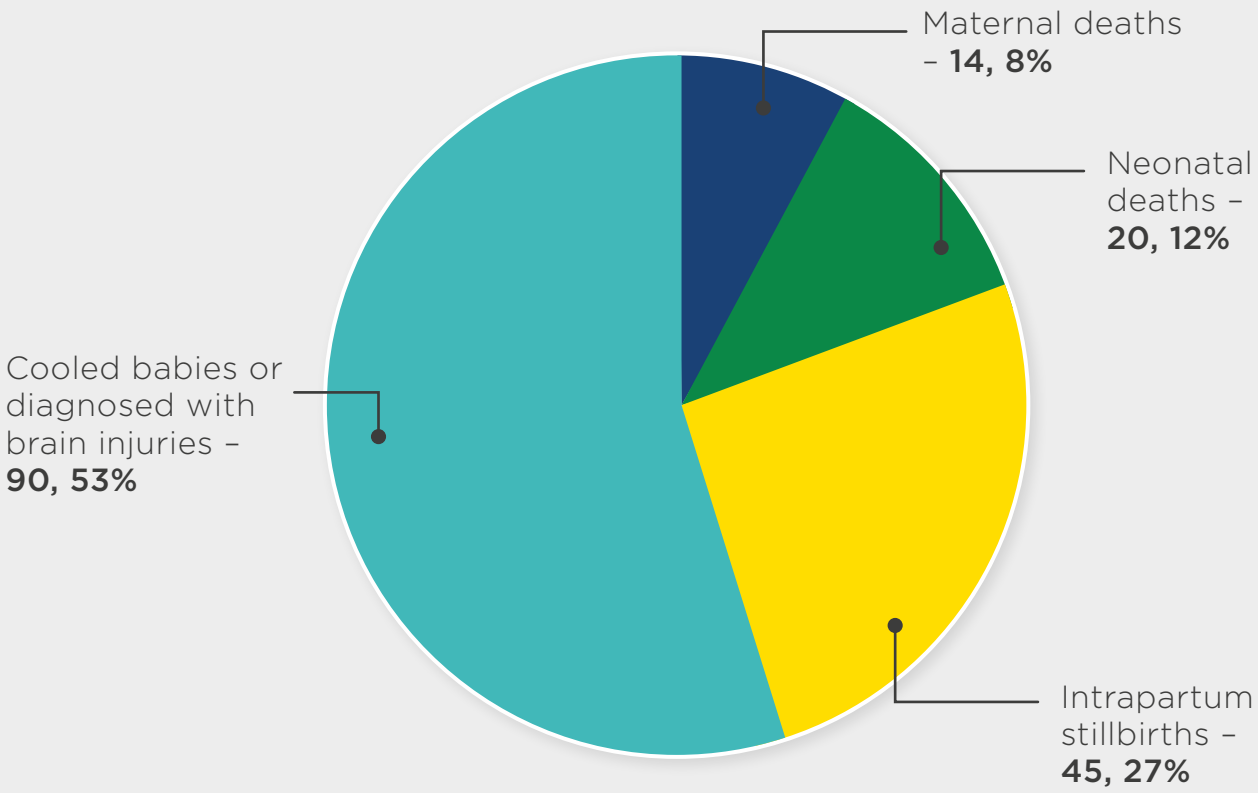
London region 1 April 2022 to 31 March 2023



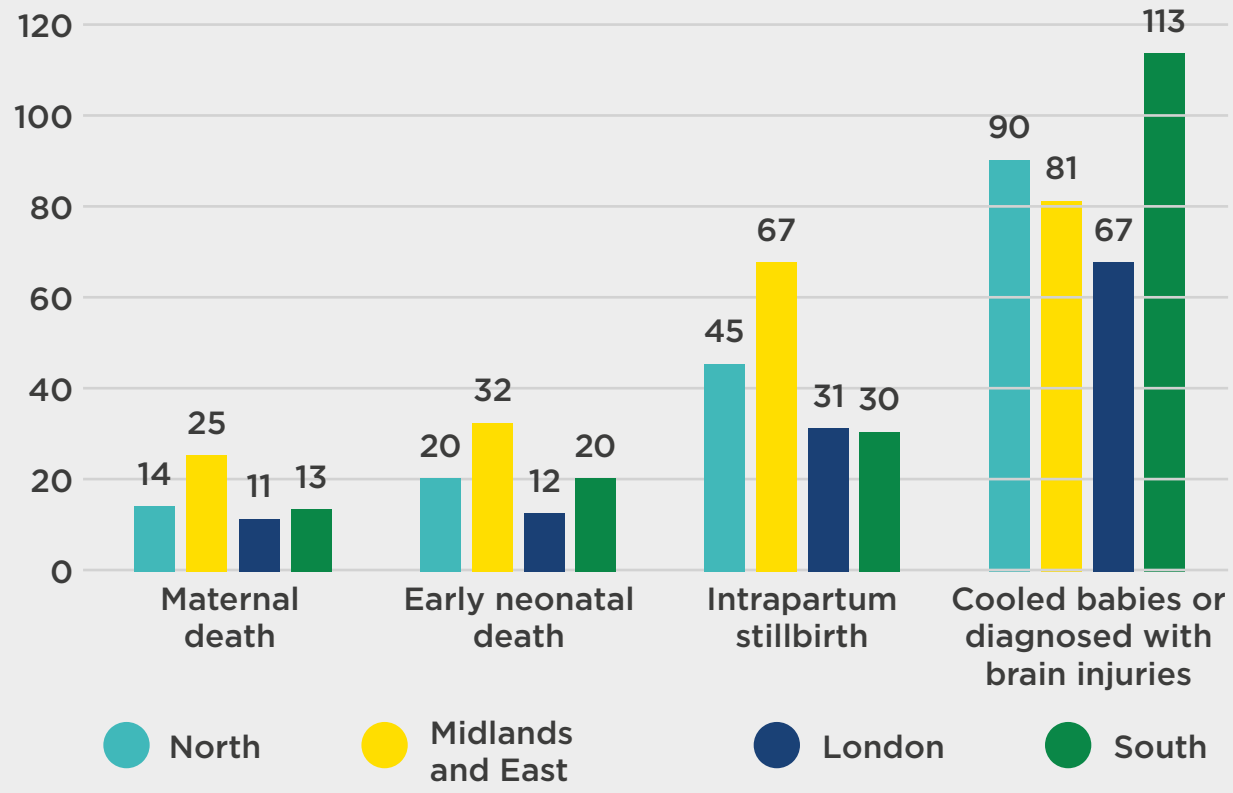
Midlands and East region 1 April 2022 to 31 March 2023



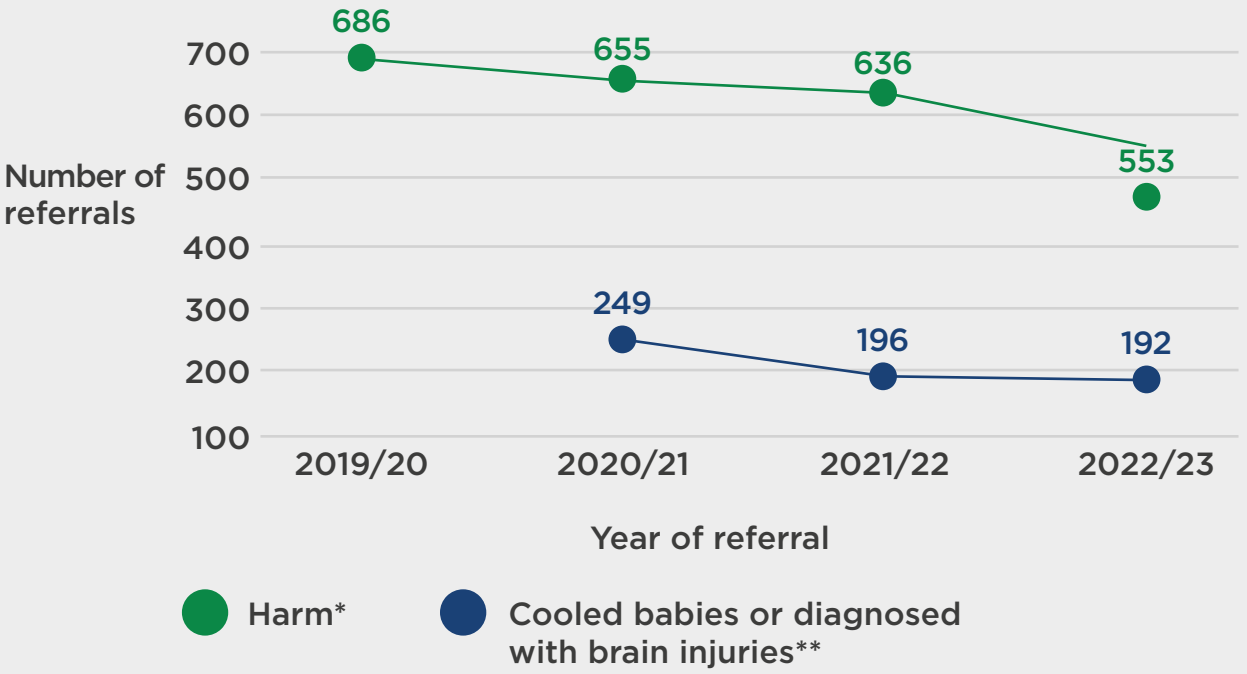
North region 1 April 2022 to 31 March 2023



2022/23 - breakdown of 671 investigations by criteria



Reduction in referrals for severe brain injury to HSIB and where harm has been identified



Reduction in referrals for severe brain injury to HSIB and where harm has been identified

Year of referral	Number of referrals that met criteria	% increase/ decrease year on year	% increase/decrease since 2019/20
2019/20	686	all trusts now reporting	
2020/21	655	5%	 19%
2021/22	636	3%	
2022/23	553	13%	

*Referrals that met standard HSIB criteria (active, completed, rejected).

** 2020/21 was the first full year of data for recording 'rationale to proceed' entries in HIMS (via triage process). 'Harm' (evidence of damage) or 'No Harm' (no evidence of damage) cannot be established without family consent to access medical records.

Outcomes and impacts: emerging themes from HSIB maternity investigations

We have identified the following themes from the safety recommendations made to trusts during 2022/23. These are similar to those found in previous years:

Top 12 safety recommendation themes in order of frequency

Clinical assessment
Guidance
Fetal monitoring
Clinical oversight
Risk assessment
Escalation
Communication
Investigations
Clinical observations
Induction of labour
Information
Triage

Over the last year we have been developing work that has helped to discover the interaction between these themes and their interdependence in their actions and effects. If one area is deficient it affects others. Carrying out a deeper dive into this work will help in designing systemic improvements to improve patient safety.

These themes occur throughout the maternity system and manifest themselves in incidents in specific areas. One example of this is escalation in Midwifery Led Units that require a combination of a number of the themes to interact to achieve a safe environment. An example is given here from our newsletter from a trust where the problems of staffing and workload led to difficulties in clinical assessment, fetal monitoring, risk assessment and escalation.

The Royal Wolverhampton NHS Trust (TRW): improvements risk assessment and escalation in midwife led care

This solution involves guidance, clinical oversight, clinical assessment, communication and escalation. There are potential additional problems relating to fetal monitoring.

Guidance for staff on escalation in the Midwife Led Unit (MLU) at TRW

An HSIB investigation learned that two clinicians were sharing the care of the mother during the latent phase of labour due to the workload on the midwifery led unit (MLU). Both were unable to spend any length of time with the mother to assess whether she was transitioning to the active first stage of labour.

So that we [TRW] could make improvements, we reviewed the different categories of clinical care being provided on the MLU to ensure the staffing requirements were suitable to cover all aspects of the care being provided. After our review we designed a flow chart to be used when MLU is busy to escalate safety concerns and ensure that senior managers are aware that, due to activity, safety may be comprised.

We launched the flow chart in September 2022 and all staff are now aware of who to contact at times when the MLU is busy, and care cannot be safely provided. We raised, via safety briefings for all MLU staff, the benefit of using concise and clear language when escalating concerns either with a patient or overall activity. We did not need to use the flow chart in the few weeks after it was launched but we have noticed (for example in a case discussion which involved a transfer from the MLU to Delivery Suite) the use of words/language to make it very clear that a woman required transfer.

Escalation Process MLU at times of high activity

The staffing model for MLU is 2 x midwives and 1 x maternity support worker – this is as agreed and recommended by Birthrate+

At times when the activity is high and potentially unsafe you must escalate

When a woman in labour cannot have the required support and monitoring it is vital the Band 7 is aware.

Inform the Band 7 Co-ordinator in first instance

↓

Contact MLU staff via social media and groups and ask if anyone can support the unit

↓

Seek support from other areas; FAU, Maternity ward, request any support from including Specialist Midwives

↓

Add additional entry on Birthrate+ acuity tool which reflects activity and any red flags

Complete a Datix

Document in maternity care records and apologise to the families on MLU

↓

Consider if Postnatal women could transfer to D10

Would any women not in established labour like to return home

Consider if any women in labour should transfer to DS

↓

Discuss with Band 7

- Community midwives being requested
- Informing matron (in hours)
- Inform manager on call (out of hours)

The Royal Wolverhampton NHS Trust

This intervention was developed to allow concerns felt by midwifery staff to be escalated and support given.

These and other concerns found during our investigations have led to the development of a thematic report we are preparing for 2023/24 called '**Factors affecting the delivery of safe care in midwifery units**'.

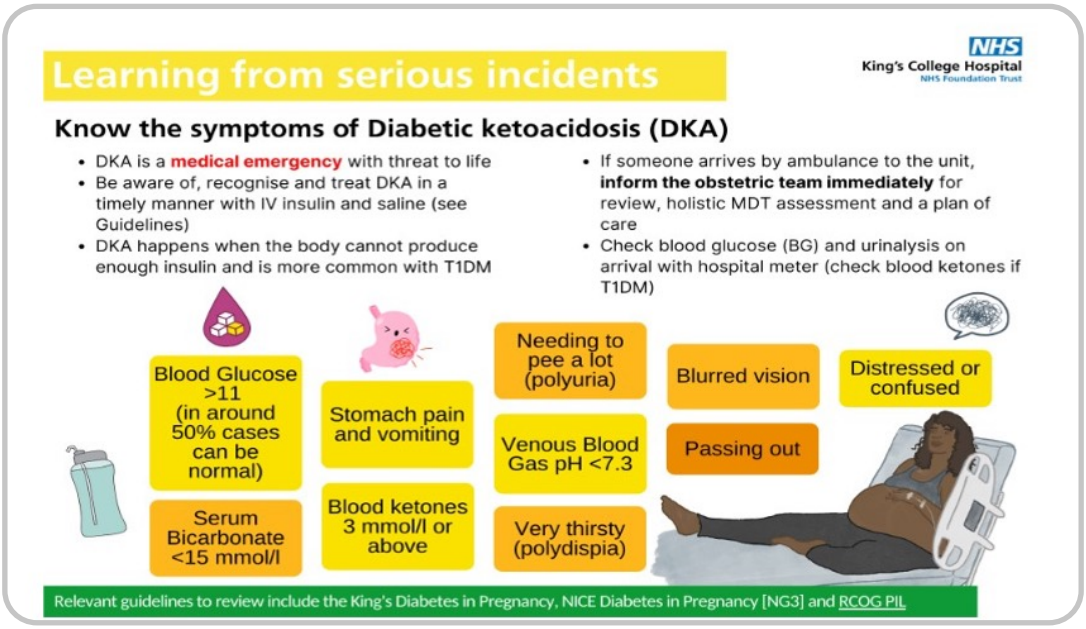
Another problem we see in our investigations is the detection of deteriorating pregnant women/people and escalation of required care. This is particularly true in areas of maternal medicine. An example in the care of diabetic pregnant women/people is given below.

This requires clinical assessment, clinical oversight, communication and escalation.

King's College Hospital NHS Foundation Trust: improvements in recognising diabetic ketoacidosis

Recognising diabetic ketoacidosis

This poster was produced to support staff in the rapid recognition of Diabetic Ketoacidosis (DKA) as an emergency that requires urgent medical attention.



For further information please contact:

Clare Clifford-Turner
c.clifford-turner@nhs.net

King's College Hospital NHS Foundation Trust

A common theme throughout our reports is the assessment of risk. This has led to a report in March 2023 called '**Assessment of risk during the maternity pathway**'.

The seven identified areas are as follows.

1 The language used to discuss and document risk assessments should encourage a dynamic and holistic assessment of the individual pregnant woman/person's risk ('dynamic' means the risk is continually assessed to allow for unknown factors and to handle uncertainty; 'holistic' refers to looking at other factors that might be relevant) that promotes the need for maternity care to be provided by multi-professional teams.

2 Telephone triage services should support 24-hour access to a systematic structured risk assessment of pregnant women/people's needs.

3 Telephone triage services should be operated by appropriately trained and competent staff who are skilled in the specific needs required for effective telephone triage.

4 Face-to-face triage in maternity units should use a structured approach to prioritise pregnant women/people in order of clinical need.

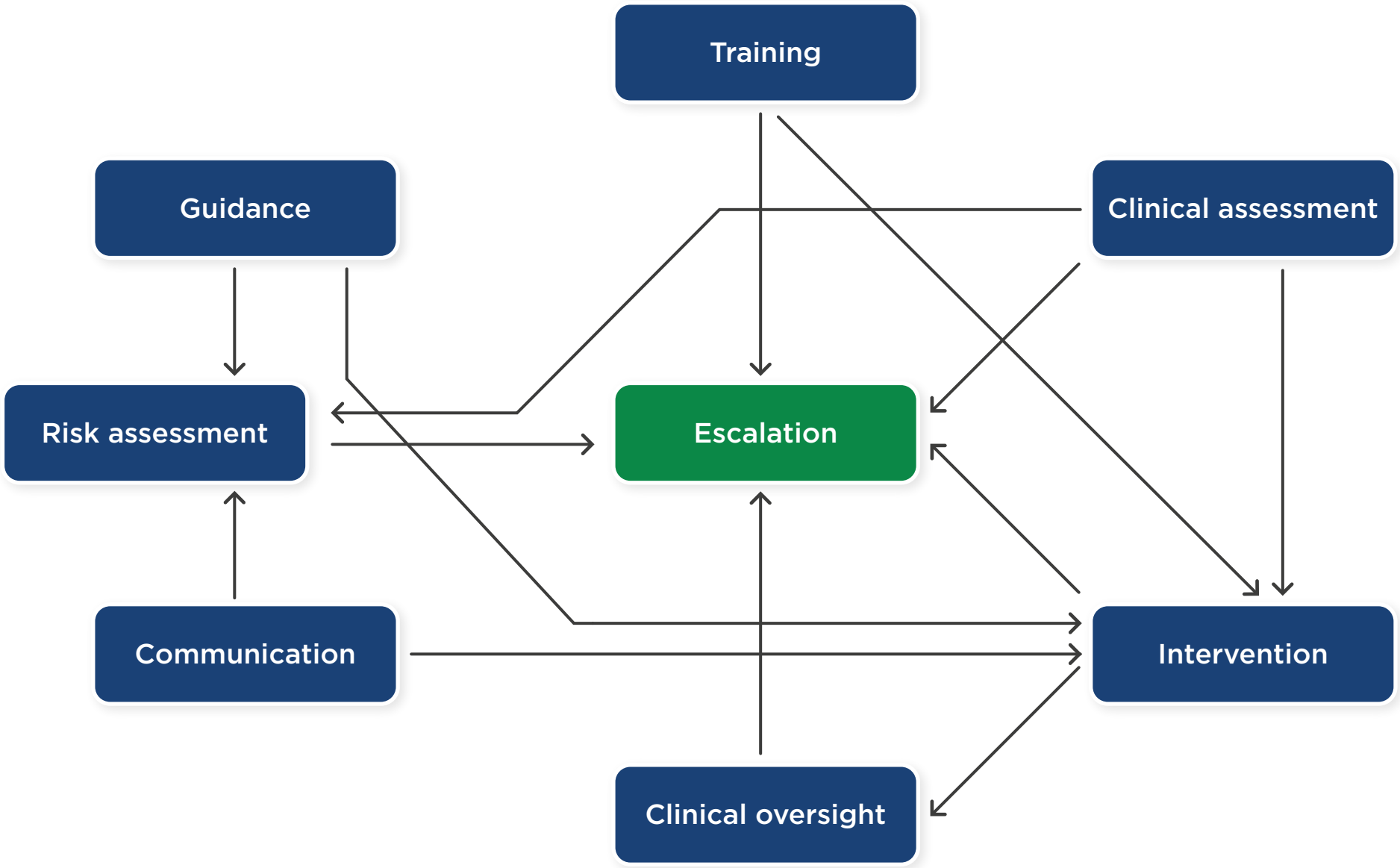
5 Staff should be enabled to proactively monitor and adjust the place of labour care and birth for pregnant women/people based on the individual's specific care needs during the course of their pregnancy and labour.

6 Each pregnant woman/person should be helped to understand their individualised risk associated with a vaginal or caesarean birth after a previous caesarean birth, based on their specific risk factors and care needs.

7 Pregnant women/people whose labour has been induced need clinical oversight and an individualised plan of care for maternal and fetal monitoring.

The overall conclusion in our report is the importance of teamworking and communication throughout. To address these challenges, it is crucial to involve senior colleagues and a multidisciplinary team to support a care plan when concerns are raised. This approach provides a platform for discussing the pregant woman/person's care from multiple perspectives, allowing all involved in their care to have their voices heard and providing opportunities for learning and improvement. The implementation of regular ward rounds by senior decision makers will help to address this.

The interdependencies between all these themes is illustrated below. No theme acts in isolation, and therefore improvement measures should be multifactorial. Improvement in communication may help across multiple areas of concern. We are working to understand the complex interactions of different themes we find in investigation reports.



The maternity team has worked in collaboration with the HSIB national team to produce the following national learning reports:

- **'The assessment of venous thromboembolism risks associated with pregnancy and the postnatal period'** – published December 2022
- **'Assessment of risk during the maternity pathway'** – published March 2023
- **'Factors affecting the delivery of safe care in midwifery units'** – to be published in 2023/24
- **'Perimortem caesarean section during the management of cardiac arrest'** – to be published during 2023/24.

Impact on trust learning and safety actions for maternity services

Over the past year, we have issued more than 1,380 safety recommendations to various healthcare trusts, covering a wide range of topics. These recommendations are made when a particular issue identified in our investigations is believed to have played a role in the outcome, and it is the responsibility of the trust to take actions that address the issue and bring about improvements.

Before our final reports are shared with families, the trusts are given an opportunity to review the drafts and make sure that any inaccuracies are corrected. This also gives them a chance to evaluate if the safety recommendations will lead to practical and effective improvements.

During our investigations, we may also uncover findings that, while not directly related to the incident in question, may have influenced the environment or response. These incidental findings are collected in our observational diary and communicated to the trust. Any adverse event 'stress-tests' the system, allowing us to assess the care environment and support services.

Management of pregnant women/people in early labour

One recurring issue that we have encountered is the management of pregnant women/people in early labour through triage services. These problems relate to training, guidance, clinical assessment, clinical oversight, escalation and staffing.

We have found that in many trusts, there is no record of previous calls made by a pregnant woman/person when she contacts the triage service, meaning that their ongoing issues/concerns are not recognised.

When presenting at triage, a pregnant woman/person in strong labour who requests pain relief may be assessed as 'not in labour' if their cervix is only 3 cm dilated, and therefore, they cannot be admitted to the labour ward as per local guidance. This results in a lack of pain relief or monitoring for both the pregnant woman/person and baby, even though there is active uterine activity. According to local guidelines, they should not be reassessed for 4 hours, and by that time, their cervix may have dilated to 4 cm or more. The pregnant woman/person may return home only to return when labour is far more advanced leading to a missed opportunity for fetal monitoring during a critical time. In babies where there is increasing compromise, this can make a difference to the outcome.

We work with the trusts to encourage them to explore alternative methods of management that ensure full monitoring for those who need it. When changes are introduced in trusts, this is then shared through our maternity newsletter.

The variations of care provided by triage services have been highlighted to national bodies, this is informing the work being taken forwards as part of NHS England's '**Three year delivery plan for maternity and neonatal services**' (March 2023).

Family and staff engagement

Meaningful engagement with, and involvement of families and patients remains at a good level with 86% of families engaged with our investigations. This engagement starts with our teams making initial contact and then, with agreement, requesting more detailed involvement throughout the time period of an investigation.

Understanding the reasons why some families do not wish to be contacted or to be involved in our investigation has developed over the last year. Understanding these reasons has helped us to look at our approach, our resources and our training to try and ensure equity of access.

The reasons for not wishing to be involved are now captured where known and are used to explore areas of engagement locally and within the programme.

Some of the reasons families have shared with us are:

- wishing to 'move on' or seeing no value in an investigation
- stating they were happy with care received or have a positive prognosis
- stating they prefer a trust/coroner's investigation
- not feeling able to discuss the events as too distressed
- not wishing for an independent organisation to access medical records
- no reason given/known, or requests not responded to.

Following last year's pilot, a new approach has been adopted to ensure accessibility and inclusivity for families. This family inclusivity toolkit (FIT) involves an initial conversation with a family to identify any particular needs they have in the areas of:

- communication
- health and wellbeing
- social and community.

The family needs assessment is recorded and enables us to adapt our approach to families and not expect them to adapt to our process. The assessment is revisited at different points in the investigation as their needs can change over time.

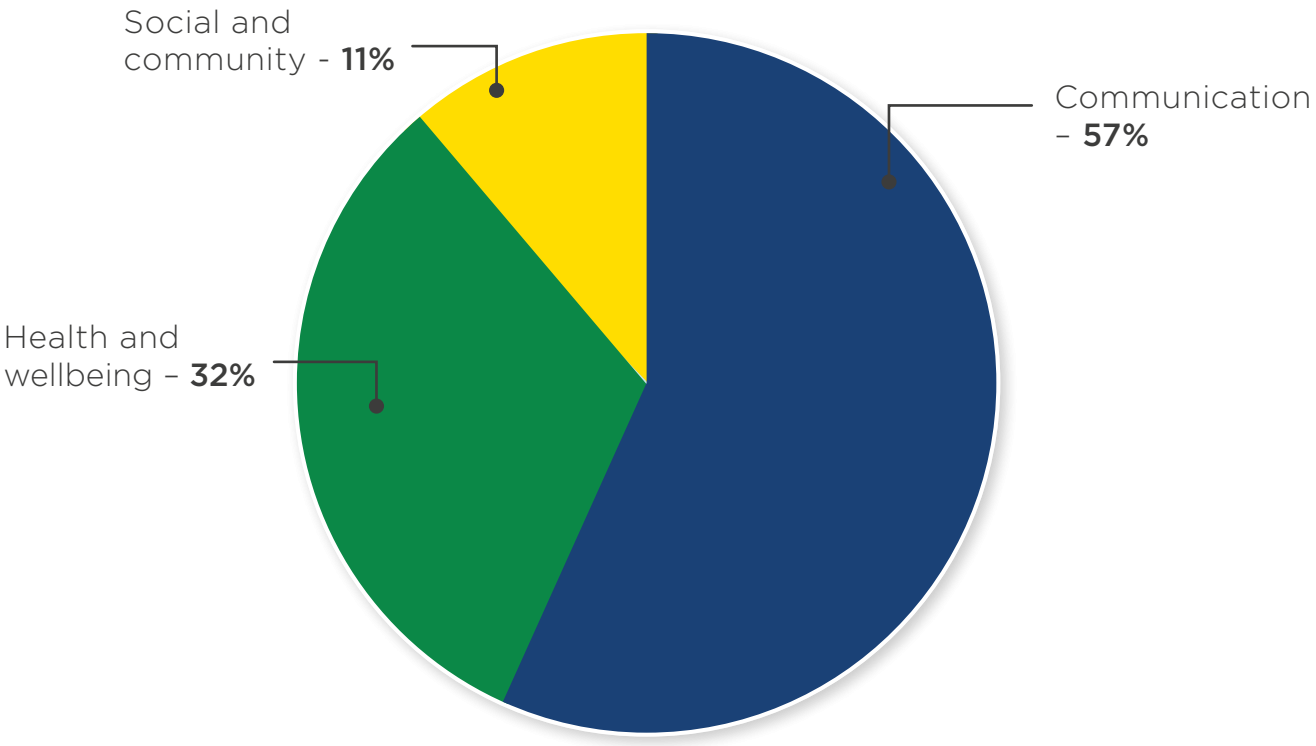
Once a need is discussed with a family and recorded, support for investigators is provided by way of information about how adaptions or adjustments could be made to the investigation process.

Data collected shows the relevance of this work with just under a third (30%) of all investigations identifying a need with the family.

57% of the needs identified involved communication considerations with the two most frequently identified being the need for interpreter/translation services and limited or no access to technology.

32% of the needs identified involved health and wellbeing considerations with the two most frequently identified as mental health concerns and the effect of trauma.

11% of the needs identified involved social and community considerations, with the two most frequently identified as concerns for the protection of a child or young person and housing matters.



During 2022 we have proactively contacted families who have been involved in maternity investigations, to ask if they would assist us in answering specific questions about their experiences of our processes in addition to the feedback process. This has assisted us in gaining greater understanding about what families expect from investigations and this information is being used to assist our ongoing development work. As we move towards our new organisation later this year we intend to develop this area of work and provide more opportunities for co-design.

We have reviewed our information and resources to better inform the tripartite meetings that are held following a maternity investigation. These meetings, where HSIB, the family, and the trust meet to discuss the next steps following our investigation are now assisted by a family resource, a trust resource, and a standard operation procedure (SOP) detailing what action the trust and our organisation take in this meeting.

HSIB

HEALTHCARE SAFETY INVESTIGATION BRANCH

What is a Tripartite meeting a[illegible]t is its purpose?

Your HSIB investigator will offer a Tripartite meeting which will take place when the final HSIB report has been completed and shared with both you and the Trust(s). This is a meeting held at the Trust with the HSIB investigators, Trust representatives, and yourselves.

The meeting provides an opportunity to revisit the findings and recommendations contained within the report, understand what the next steps intended to be taken by the Trust may be and ensure that you have an identified contact within the Trust. It is an opportunity to ensure that you understand what the Trust has already done or intends to do as a result of the findings or recommendations contained within the HSIB investigation report.

We understand that there may be further and ongoing questions that you may have and the Trust will be asked to ensure you have a named individual for your ongoing contact with them.

Following the meeting or your decision not to attend a meeting, this is likely to be your last contact with the HSIB investigator as the investigation will have ended. Should you have any questions for HSIB after this time, please direct them to **enquiries@hsib.org.uk**

WWW.HSIB.ORG.UK
@hsib_org

Patient Safety Incident Response Framework

The Patient Safety Incident Response Framework (PSIRF) was launched by NHS England in 2022. It details the new approach to responding to patient safety incidents. One of the four key aims of this framework is compassionate engagement and involvement of those affected by patient safety incidents.

In partnership with NHS England and **Learn Together** we have produced the **'Guide to engaging and involving patients, families and staff following a patient safety incident'**. The document will be evaluated over the coming year by an independent national survey and the findings will be combined with the Learn Together programme's broader evaluation, to inform the next iteration of this guidance which is expected to be published in 2024.

We have developed a 6-hour training programme to support this framework and guidance, and this has been delivered to date by six online courses and two in-person courses.

This course is aimed at those who have a lead role in engaging and involving those affected by patient safety incidents.

It discusses what makes communication effective and how inclusivity and accessibility can be achieved, along with examining the barriers to effective engagement and involvement and how to respond to these.

One module considers how continuing contact should be maintained and what challenges can be experienced in practice including the boundaries of the engagement role.

Finally, the training examines the identification and management of risk, as well as the role of other agencies and the importance of health and wellbeing.

Feedback from families during 2022/23

"We were a bit skeptical about this process, but it was actually a really helpful thing to go through and got us some very important answers on what happened."

"Thank you so much for the opportunity of the HSIB support and publication of the subsequent report. It was emotive and personalised and helped us feel even in death there would be learning from our experience."

"... was supportive, approachable and a great communicator. She was an excellent listener and made us feel acknowledged. Even though there are still some unknowns, the process helped us to come to terms with what happened. Thank you."

"This investigation made it clearer for me on what actually happened during my daughter's birth and events beforehand too. Reading it on paper allowed me to come to terms with everything. I really appreciate the time taken out for this investigation and hope it helps other future mothers."

Feedback from families during 2022/23

"The main purpose of the investigation was system change, not blame, which was important to us, and also our input as service users to help implement change was equally as important, so the interaction with the team was the most helpful."

"Feeling as though someone was listening to our experience and doing something constructive with the information ... when I asked the investigator for help, she always got back to me immediately and put me in touch with hospital contacts that I couldn't otherwise get hold of. It made me feel like I had a voice that I wouldn't have had without her help."

"It was interesting to hear the findings of the report and I take comfort that by our case being investigated it could prevent someone else going through a similar situation with their baby."

Feedback from families during 2022/23

"I was given information regarding the aim, scope, process and possible outcomes of the investigation. Realistic outcomes were outlined. All was done with significant empathy and personal consideration of my circumstances."

"Thank you from [us] for agreeing to this investigation. I believe it's important that we are allowed to look at concerns like these without placing blame on certain individuals, while at the same time admitting that system change is needed."

How equality and diversity is influencing our work

We established a race equality group in 2021 with the following objectives:

1 To review, analyse, and utilise internal demographic data related to the ethnicity of individuals involved in our investigations in order to gain insights and address health disparities.

2 To promote education within our own organisation about the effects of race on people's lives.

3 To examine how the race of someone referred for one of our investigations might have affected their experience and/or healthcare outcome.

4 To identify any racial biases in language, equipment, or procedures that HSIB is investigating or needs to consider in healthcare.

Within maternity, this work is being developed in collaboration with external partners such as the Royal College of Obstetricians and Gynaecologists and patient advocacy groups.

We recognise the significance of its involvement with families in exploring, reporting on, and learning from the impact of race in regards to our investigations. Our goal is to enhance our understanding of health inequalities by optimising the data we have and taking into consideration the unique needs of individuals. This work will further inform staff training and development in this area.

During the year we held an 'Equality, Diversity and Inclusion (EDI) Vision Day' in the context of our future organisation. During the day, the values of respect, journey, compassion, trust, culture, accessibility, commitment, equity, and others were highlighted. Through roundtable workshops, discussions centered around aligning efforts towards embedding the EDI agenda within the organisation and especially early on in the investigation process. This will be a key area of focus moving forward.

How the HSIB maternity investigation programme is influencing national learning

Perinatal meetings

The seven NHS England regions conduct regular surveillance meetings to facilitate the prompt recognition and escalation of any concerns. The meetings draw upon inputs from regional representatives, regulators, and other national organisations to inform learning and decision making.

We have been increasingly integrated into these systems and a representative from each region participates in the relevant regional meetings to share and inform thematic learning. These meetings offer a chance to establish connections with stakeholders, exchange learning, and support ongoing monitoring of the quality and safety of maternity services.

Close working with regional chief midwifes and regional lead obstetricians

Our representatives in each of the seven NHS England regions maintain supportive relationships with their respective regional chief midwives. This helps facilitate the swift escalation of any concerns and demonstrates a co-operative approach towards ensuring the safety of maternity services. The regional chief midwives are invited to attend the quarterly review meetings of individual trusts to provide additional insight into the investigations and any recurring issues that may arise.

At a national level we have developed a productive working relationship with the Chief Midwifery Officer and Regional Chief Midwives.

Maternity Quality Matrix

The Maternity Quality Matrix is a tool that provides trusts with a comprehensive overview of their HSIB maternity investigations on a quarterly basis. It gathers data from our maternity investigation process and presents it in a single document.

The Health and Social Care Select Committee's inquiry into the safety of maternity services recommended that we share our learning from maternity reports in a more organised and accessible manner. This includes sharing top-level summaries of individual cases and their key learnings.

The Matrix will help trusts meet the 'immediate and essential actions' recommended in the Ockenden review of maternity services at the Shrewsbury and Telford Hospital NHS Trust, monitor clinical change, and communicate with local networks. It will also be used for the quarterly review meetings, which will be more tailored to each trust, allowing for timely discussion and rapid learning from the incidents investigated.

Maternity observational diary

Our maternity observational diary is a recent addition to the investigation process that allows investigators to keep track of important information and observations during the course of an investigation. This includes examples of good practice, challenges encountered during the investigation and observations which may be of interest from a thematic perspective.

Incidents 'stress test' an organisation and this 'soft data' allows an assessment of the environmental factors influencing the care provision and the support services in place for when emergencies occur.

The information captured in the diary is used to inform discussions at the quarterly review meetings with trusts and to support the escalation of immediate concerns. It will also contribute to the Maternity Quality Matrix and aid in the continuous improvement of our investigation process.

Escalating significant safety concerns arising from investigations

As our investigation programme became more established and mature, we realised there needed to be a standardised escalation process when the investigation team have concerns about clinical care or the response of the trust to safety concerns. To overcome these problems a process of escalation was developed to allow a stepwise balanced response to the concerns raised.

The purpose of this process is to support our maternity investigation teams in escalating serious and significant safety concerns that lie outside individual investigation scope or require action before the completion of an investigation. It further supports staff and managers in deciding when these concerns should be shared with external regulatory bodies or other authorities. These decisions must take into account our duty to promote safety and to carry out investigations that do not apportion blame or liability.

All our team have a duty to raise safety concerns as soon as is practicably possible, and those registered as health professionals have additional duties relating to their professional codes of conduct.

The escalation process is aimed at ensuring that all our team are aware of the process to raise concerns that require escalation.

Over the past year, we have issued 32 letters indicating an urgent concern or emerging theme.

Newsletter

After an initial pilot the maternity investigation programme now has a national newsletter, using a 'we said, you did' format. The purpose of the newsletter is to share learning between trusts by providing a way for staff to share what they have done to make changes and improvements. It is published three to four times a year, with contributions from all four HSIB regions in England, and it has received positive feedback from trusts and external stakeholders.

The submissions come from various healthcare providers involved in maternity care, including ambulance services.

An example from our newsletter features North West Ambulance Service NHS Trust (NWAS).

NWAS: supporting HSIB process, internal governance and addressing safety recommendations

What we learnt...

Ambulance services provide emergency care and many services employ midwives for training and support purposes. As a result, our HSIB reportable incidents often include the ambulance service.

Recent investigations including the ambulance service highlighted the importance of strengthening internal processes to support staff, families and the HSIB team when involved by the HSIB investigation. Additionally, an opportunity to raise awareness of the work undertaken by the HSIB amongst prehospital clinicians, and a focus on how we undertake quality improvement (QI) work on the back of safety recommendations, was identified.

Areas for improvement related to clear processes for supporting the HSIB team, ensuring that learning was approached collaboratively across the local maternity systems and that internal process included supporting staff who are asked to partake in an interview.

What we wanted to improve...

1 To ensure we had a clear internal mapping process

2 To support the HSIB with investigation requests in a timely manner

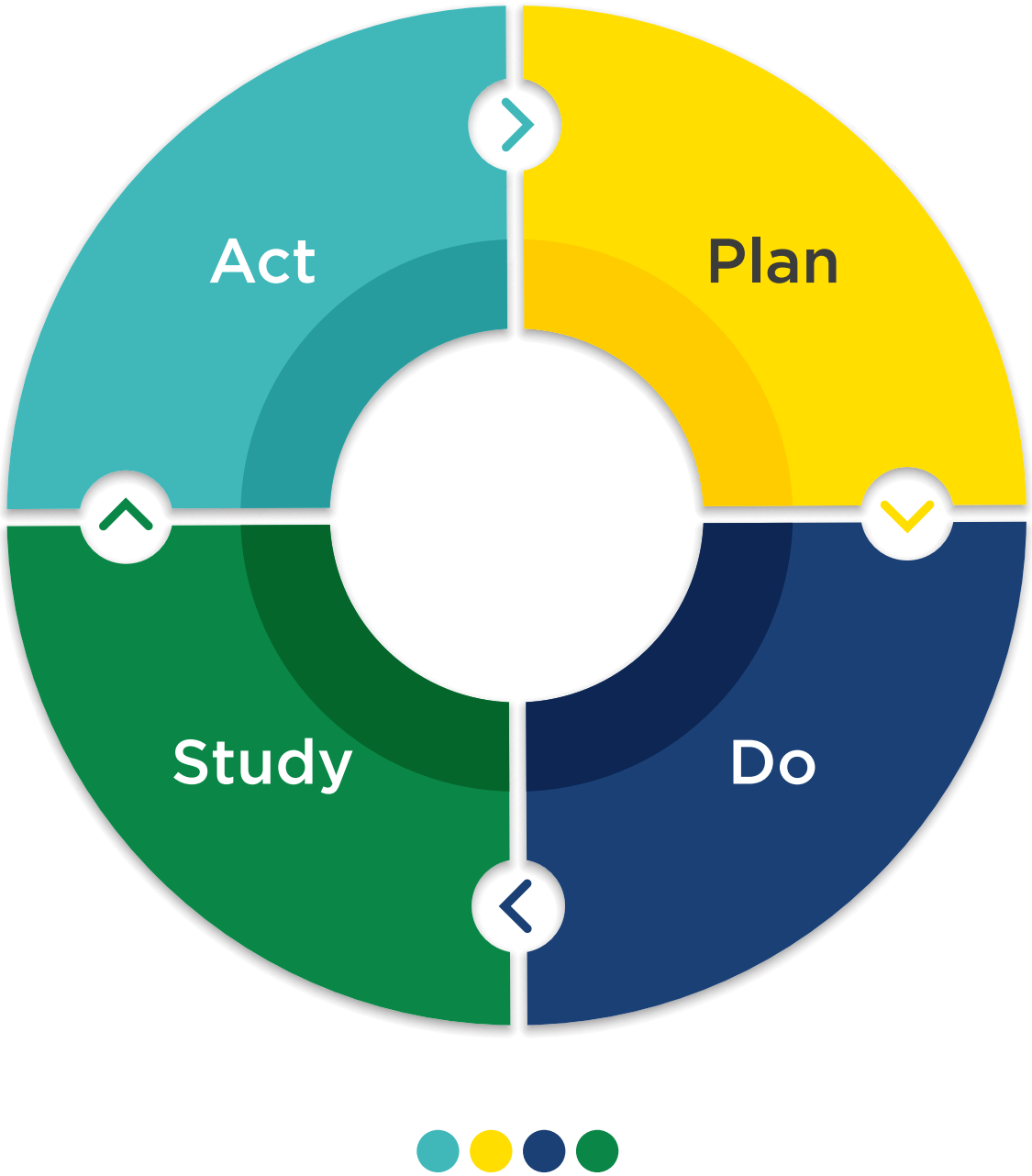
3 To identify potential the HSIB reportable incidents via our internal reporting system

4 To ensure that all findings and safety recommendations from the HSIB reports were reviewed and charted, ensuring safety themes could be identified and any organisational specific safety recommendations shared internally and externally to positively influence change

What we did...

To improve the situation, we developed an HSIB working group, ensuring representation from each of the teams within the ambulance service. The working group included the medical directorate, the patient safety team, consultant paramedics, staff who had experienced the HSIB process and the governance team. This allowed the group to clearly map out each step of the process to, ensuring a seamless and governance led approach. The PDSA (Plan, Do ,Study, Act) cycle approach was adopted to test the accuracy and effectiveness of the process once a HSIB request / incident was identified. The mapping document and identified themes were shared with the regional maternity teams, highlighting shared learning and actions. A regular update process has been agreed in which NWAS shares actions and learning into the regional maternity team for cascade across all the local maternity systems.

PDSA Example



What happens now...

The HSIB process is now live within the NWAS system. Each area and lead within the organisation are aware of the role they play when working with a HSIB investigation. This includes providing support and resources to staff who may be asked for interview, ensuring the draft investigation report is reviewed for factual accuracy and retuned in a timely manner and that findings and recommendations are proactively fed back into the trusts and regional maternity teams for action and shared learning. Each completed HSIB investigation is charted into a shared drive in which the case is detailed, findings are discussed with the patient safety team, safety recommendations are addressed, and learning is captured.

Example:

A recent HSIB safety recommendation stated:

The Ambulance Service [is] to ensure that clinicians are supported to gain competence and confidence in the management of uncommon obstetric emergencies.

Guided by our revised HSIB internal process, this recommendation was discussed at regional level, with funding provided via the local maternity systems (LMS) to support collaborative learning within NWAS. A midwife has been seconded to the ambulance trust for six months to help scale up and deliver the Pre-Hospital PROMPT training to support the management of obstetric emergencies in the prehospital setting. Additionally, a formal evaluation will be undertaken of the training to explore impact.

In conclusion, the ambulance service plays a vital role in supporting women and babies in the prehospital setting. Covering a large demographic area, the service holds a unique position to influence system change, by identifying areas for focus, leading on QI initiatives that support the NW networks and working in partnership with the regional HSIB teams.

Other examples included changes in the handling of telephone calls to ambulance trusts, Pre-Alert and Pre-hospital maternity care.

Sometimes the developments related to the findings in our reports that may not be causative to the outcome but highlight an important area of patient care. An example of that is post-partum haemorrhage published in our January 2023 newsletter.

Improving the management and outcomes of post-partum haemorrhage (PPH)

HSIB investigation highlighted that the Trust should focus on ensuring that;

- the massive obstetric haemorrhage process is based on principles that support staff to deliver the required care in a timely manner, with the process reflected in staff training
- escalation for an obstetric review occurs to ensure a holistic assessment is undertaken with a documented plan of care

Our goal was to improve outcomes for service users, and to take a multidisciplinary team (MDT) approach to audit, education, and risk reviews.

An obstetric consultant commenced a quality improvement (QI) project for 'PPH prevention management'. Updates of the ongoing project are shared with staff.

The actions we have taken include:

1. Undertaking a staff survey to assess the general understanding of the code red process and content of blood product 'packs'
2. Education for maternity staff on the back to basics, and the fundamentals of care for labour management in the 1st stage, 2nd stage and 3rd stage of labour
3. Circulating key messages to maternity staff about back to basics
4. A video demonstration of the code red process
5. Starting the process of implementing quarterly multidisciplinary simulation/drills training which incorporates learning from the findings of the staff survey around PPH process
6. Undertaking audit e.g., an audit of compliance of escalation of blood-stained liquor to obstetricians
7. Making changes to guidelines

Gloucestershire Hospitals NHS Foundation Trust

Trust PPH guideline changes:

Recommendation for blood-stained liquor to prompt obstetric review and consideration of PPH bundle, if not already, as well as a BMI of <18 to be added to the criteria for PPH bundle.

Staff should use ultrasound to guide the insertion of a uterine tamponade balloon.

As a result of the survey, the PPH policy has also been updated to include a requirement to request 'pack A' once a code red has been called.

We also designed a printed 'code red' board to include the patient weight and the estimated circulating blood volume in the management of a PPH, to avoid concentrating on the volume alone.

A monthly MDT PPH risk meeting was started. All midwives and senior midwifery team, obstetricians, anaesthetists, blood transfusion staff and the patient safety team are invited to attend. Any learning identified is communicated to the multidisciplinary teams.

Data collection has shown significant improvement in PPH rates as a result of the PPH QI project.

In the first 6 months of 2022, the trust PPH rate >1500mls was below 4%.

This remains an ongoing project, with a continuing MDT approach to the fundamentals of PPH prevention and management.

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Gloucestershire Hospitals NHS Foundation Trust

These examples can be discussed during quarterly review meetings between HSIB and the trusts, and trusts are encouraged to submit their own examples for publication in the newsletter.

The newsletter shares examples of learning and tools that may be useful to other trusts. These examples include updates to guidelines for escalation in midwife-led maternity units, care pathways for older pregnant women/people, recognition and management of diabetic ketoacidosis, and management of post-partum haemorrhage.

Examples of tools shared by trusts include newly designed cardiotocograph stickers, posters, and checklists.

The newsletter is constantly evolving as trusts look to learn from each other's experiences in implementing changes. Additionally, the newsletter is responsive to the requests of trusts, such as providing examples of action plans from other trusts.

Sharing learning through posters and presentations

Over the last year we have continued to present our work at both invited presentations as well as the submission of abstracts. Examples are:

Understanding the doula's role in maternity safety investigations

Presented at the British Intrapartum Care Society Conference, 29-30 September 2022.

We submitted a poster showing observations from our investigations that doulas were increasingly being employed by pregnant women/people for support in labour.

We commented that we should understand why families were choosing to employ doulas; and that staff working within a maternity unit needed to understand the role of a doula in supporting pregnant women/people. We commented that we were working with our partners to consider how we may assist in the introduction of national guidance for health professionals, doulas and pregnant women/people.

Peripartum hyponatraemia: findings from the HSIB cohort

Presented at the British Intrapartum Care Society Conference, 29-30 September 2022.

We submitted work that showed that pregnant women/people in labour who have an excess fluid intake, much of which was not monitored by staff looking after them, were associated with low sodium levels (hyponatraemia) in both women/people and babies. This in turn may have caused seizures in both women/people and babies. We recommended that fluid balance in labour (the amount of fluid consumed, and urine passed) should be monitored in labour; and blood levels of sodium taken and acted upon if there was excessive fluid input. This work won the prize for the best poster at the conference. The judges commented that it won because of its important take-home message, its simplicity and excellent graphics.

Learning from independent safety investigations of vaginal breech birth in England

Presented at the British Maternal and Fetal Medicine Society Annual Conference, 17-18 November 2022.

We found that holistic and ongoing review was needed of pregnant women/people in the second stage of labour with a baby presenting by breech. We commented that skilled clinicians should be able to intervene when birth is delayed, as this delay in intervening contributed to poor outcomes seen during our investigations.

We also concluded that a diagnosis of breech presentation in advanced labour, does not support fully informed consent for women about mode of birth; and that other factors for the baby such as infection or placental dysfunction influenced a baby's ability to cope with the demands of labour, sometimes further compounding delays in progress in labour.

MBRRACE-UK report

The HSIB maternity team co-authored a chapter in the **'Saving lives, improving mothers' care'** report published in November 2022 by MBRRACE-UK looking at prevention and treatment of maternal hypertensive pregnancy disorders.

The HSIB reviews used were those where maternal hypertensive pregnancy disorders were considered an associated cause. All available reviews of the care of babies who died were assessed (4 babies who were stillborn and 8 who died

in the neonatal period), together with all reviews of the care of babies with severe brain injury from Black, Asian, mixed and other ethnic minority groups (13 babies), and a sample, stratified by English region, of reviews of the care of babies with severe brain injury from White ethnic groups (15 babies). The reviews of the care of 40 babies were assessed in total.

For three quarters of the women, different care might have made a difference to their outcome. It is clear that continued attention to enabling women/people with risk factors to receive aspirin is needed, and to ensure that abnormal blood pressure measurements are not normalised. The reviews emphasised the need to avoid prolonged induction processes and the need for renewed focus on fluid management.

Baby Lifeline National Maternity Safety Conference, 22 September 2022

Louise Page, Deputy Clinical Director, presented in the session on 'Safer Systems: Sharing Insights and Learning from National Maternity Initiatives'.

The presentation was part of a panel from other agencies emphasising the need to look at overall safety systems to find solutions rather than individual events. Our maternity theme development and work in ethnic diversity are examples of this.

Joint Clinical Directors and Heads of Midwifery Meeting (Scotland), 23 January 2023

Professor James Walker, Clinical Director, presented on 'Culture and Safety within Maternity Care'.

The presentation demonstrated the integral role culture has in the systemic workings of healthcare provision, the importance of leadership, and the concept that to be safe then healthcare must be well led.

Better Births, 20 March 2023

Sonia Barnfield, Clinical Advisor, presented findings from our report **'Assessment of risk during the maternity pathway'**.

National Meeting of Chief Midwives, 21 March 2023

Sandy Lewis, Associate Director of Maternity Investigations, presented our work to support safer maternity care: collective action.

Developing our team and investigation processes

Our maternity investigation team is comprised of individuals from a variety of clinical and non-clinical backgrounds. Our organisation values diversity and encourages individuals with diverse skills and experience to join our team, in order to accurately reflect the diverse communities and trusts that we investigate.

Maternity Quality Improvement Team

We have an active Maternity Quality Improvement Team (MQIT), which was set up to support improvement projects across the maternity investigation programme.

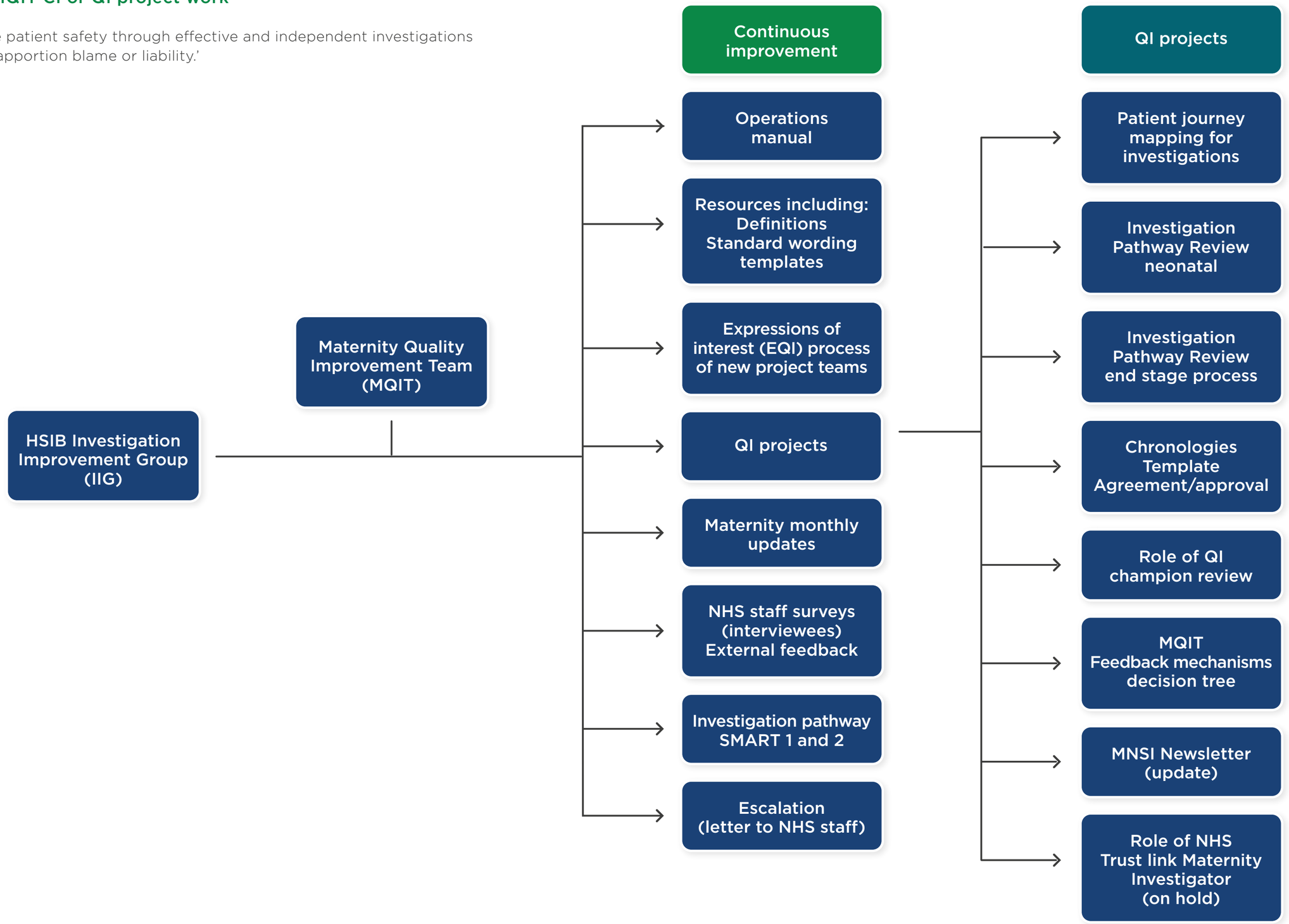
The MQIT brings our teams and individuals together to work on quality improvement (QI) projects which will enhance our approach to maternity investigations and support feedback to NHS trusts and maternity services. This year the MQIT has supported some projects linked to our organisational transition.

QI champions have been established in each of the maternity teams and have completed six QI projects. These projects have now moved to a continuous improvement pathway. This means that a plan is in place to continue to evaluate change which supports us in our continual learning journey.

Looking ahead, the MQIT is continuing to work on eight key QI projects that started in 2022/23 and is aiming to move these towards completion in 2023.

Current MQIT CI or QI project work

'to improve patient safety through effective and independent investigations that don't apportion blame or liability.'



Definitions

This year we have developed a standard document of definitions which we use in our investigations. These are constantly updated and reviewed by the relevant experts to make sure that they are up to date and accurate.

In the Ockendon report (2022) it was suggested that trusts should use the HSIB definitions when doing their own reports. We have placed our **definitions document on our website** for all to use.

HSIB Investigation Management System (HIMS)

We have helped to design a custom-made investigation management system called HIMS to assist the team's handling of investigations as part of the maternity investigation programme. The system, which operates in the cloud, allows for the creation, storage, and management of investigations from start to finish. It facilitates teamwork, improves data analysis, and streamlines operations.

The HIMS system includes an NHS trust interface that links to a web portal, making it easier to manage cases and refer them. We are continuously working with stakeholders within trusts to enhance the system and make it more user-friendly.

The impact of the COVID-19 pandemic

Over the past year, we have further analysed the results of our reports and the impact of the COVID-19 pandemic. The key discovery from our investigations is the influence of COVID-19 on the delivery of regular care and access to maternity services.

The situation was exacerbated by the increased impact of staff absence due to illness. By shedding light on these issues, we aim to educate maternity services on the significance of having contingency plans in place to ensure the continuation of maternity services during any future public health crises.

University Hospitals of Derby and Burton NHS Foundation Trust (UHDB) thematic safety review

This review was undertaken by our investigators and was commissioned by NHS Derby and Derbyshire Integrated Care Board (ICB) in agreement with the University Hospitals of Derby and Burton NHS Foundation Trust to evaluate a specified number of maternal death and maternal collapse incidents that occurred from January 2021 to May 2022.

The review found that at the point the seven women experienced their collapse or cardiac arrest, there were no identified common themes that directly impacted on all outcomes. We made five safety recommendations relating to massive obstetric haemorrhage and communication with the families. The review found that it was not possible to know if a different approach to safety investigations and implementation of learning, or a different safety culture within the maternity unit could have influenced a different pathway of care prior to the critical events.

This investigation approach serves as a pilot for future practices within our new organisation and demonstrates an adaptable approach to work with trusts on a cluster of cases to support thematic learning.

Planned developments for 2023/24

The focus during 2023/24 will be on establishing MNSI, hosted by the CQC, and to build on the knowledge and experience gained over the past 4 years.

Family engagement remains a top priority and efforts will be made to make it more accessible and reflective of our diverse population. We have plans to explore new areas of investigation using our expertise and will be considering opportunities for collaboration and joint learning to support a more rapid approach to investigations and enhance learning.

We are in discussions with our main stakeholders about joint ventures to investigate the data we have collected and look at the possibility of appointing clinical fellows to help in this work.

Conclusion

Our maternity investigation programme has made significant strides in enhancing patient safety and reducing harm in maternity care over the past year. This annual review has provided a moment to reflect on the work accomplished by the programme and to share the learning and themes emerging from the investigations across England's trusts.

Our team consists of skilled and experienced staff, and is dedicated to representing both the perspectives of families and staff involved in distressing situations. The feedback and information gathered from maternity investigations are used to continuously improve our investigation processes and the experience of families engaging with us. We are grateful for the courage, honesty, and dedication of families who have shared their often tragic experiences with us.

We also extend our gratitude to the trusts and their staff, many of whom have faced unprecedented challenges during the COVID-19 pandemic, for their commitment to providing exceptional care and their drive to improve when needed.

However, there is still room for improvement in ensuring that pregnant women/people and babies receive the best quality of care. Our maternity investigation programme will continue to prioritise patient outcomes and work collaboratively with all stakeholders to make maternity care safer for everyone.

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HSIB
HEALTHCARE SAFETY INVESTIGATION BRANCH

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 from 09:00 hours to 17:00 hours. We aim to respond to enquiries within five working days.

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