HSIB

HEALTHCARE SAFETY
INVESTIGATION BRANCH

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HEALTHCARE SAFETY INVESTIGATION BRANCH

Annual Review 2018/19

CHIEF INVESTIGATOR

Welcome to the Healthcare Safety Investigation Branch (HSIB) 2018/19 annual review. Our organisation became operational in 2017, and we were originally tasked with conducting independent national safety investigations in healthcare with the overall aim of improving patient safety through shared learning and promoting better local NHS investigations.

As we have been operating for only 24 months, our team has needed to learn, develop and adapt quickly to deliver. Our experience so far has been that establishing a new independent organisation to explore patient safety concerns across the NHS brings unique challenges.

While there is much the NHS can gain from approaches in other safety-critical industries, healthcare organisations are widely recognised as among the most complex of working environments. This means from each of our investigations we are learning, how to develop safety investigations that are a model of best practice for healthcare.

Adding further to the need for rapid learning and development, from 1 April 2018 we also became responsible for conducting all investigations of patient safety incidents in NHS maternity services that meet certain criteria. This work is different to our national investigations programme, as it requires HSIB to complete the local investigation within a trust, and our report is provided directly to the families and the trust rather than being published.

We continue to develop the programme and by 1 April 2019 had built a national workforce of skilled maternity investigators who are now working in all trusts in England with maternity services. Our approach has emphasised the need to work closely with mothers and families, and with healthcare staff and organisations during these investigations. Our safety recommendations are predominantly directed to the trust, but we will also publish themed reports that will support safety recommendations to national organisations for system-level improvements in maternity services.

The support and engagement of patients and families, providers, NHS staff and other healthcare bodies we've worked with has been critical for our early achievements, in our national and maternity investigation programmes, and in the success of our family engagement model, all of which are discussed in this report.

It is important to recognise that the NHS-wide culture shift from fear and blame when things go wrong, to transparency for learning and improvement, is a journey in which we can play a part within the wider safety system.

Independent safety investigations are only one part of a wider approach to patient safety that encompasses the whole healthcare system, where all organisations and individuals recognise that they have responsibility for supporting improvement.

While we make recommendations for change in our investigations, we don't hold (and do not seek) the enforcement powers that are needed to require other organisations to make changes. For this reason, it is critical that there is an independent mechanism to co-ordinate and oversee responses from organisations that are subject to HSIB recommendations.

In August 2018, the draft Bill for establishing the Health Service Safety Investigations Body (HSSIB) was scrutinised by a Joint Committee of MPs and peers who were supportive of establishing the new body.

We consider this a vital step to ensuring our ability to operate fully in the way that was originally intended, with powers and protections equal to our counterpart organisations in the transport sector.

There has been great progress in our second year and this is testament to the hard work and commitment of our staff and supporters.

Keith Conradi
Chief Investigator

ADVISORY PANEL

ADVISORY PANEL

We are pleased to provide our first overview as an Advisory Panel of the performance of HSIB during 2018/19. Over the past year the relationship between HSIB's Executive and the Advisory Panel has developed well, with good levels of constructive challenge and comment both at our regularly quarterly meetings and in between.

Our engagement has also evolved since the Panel's inception. Initially our discussions focused on strategic decisions that had already been taken by HSIB, rather than us engaging collaboratively with proposed future developments.

The emphasis has shifted in recent months, though our influence and approach has been limited given the ambiguous governance role of the Advisory Panel.

There are areas where we've had a recognisable impact on HSIB's direction and operations. We provided advice and support to the Chief Investigator as the draft Bill was scrutinised by the Joint Houses of Parliament Committee and an extraordinary meeting of the Advisory Panel generated a detailed written submission.

We've provided detailed views and feedback on several HSIB national investigation reports from within our own professional networks, mainly through our quarterly meetings, with some further limited engagement outside that forum.

This feedback has been welcomed, although has highlighted the need for a more systematic approach to using and responding to feedback – especially from interested citizens.

We are pleased to see more attention will be given to this important domain over the year ahead, along with more central involvement of patients and families, and other experts by experience. The planned development of the *'Citizens' Partnership'* this coming year is a welcome initiative. We are also keen to see HSIB expand its frameworks for analysis and foci of remedy during investigations, with greater attending on socio-cultural aspects of healthcare safety. We are currently working with the HSIB Executive to consider how this might be best achieved.

We applaud the significant achievement to rapidly develop and implement the NHS maternity investigations programme which created a huge organisational challenge.

The first recommendation of the Report of the Expert Advisory Group: Healthcare Safety Investigation Branch, chaired by Dr Mike Durkin, from May 2016 was that:

> ***HSIB must be, and perceived to be, independent in structure and operation, and be established in primary legislation with stable institutional arrangements to guarantee this***

The risks we identify include:

- timely delivery of the national investigation programme
- an appropriate level of scrutiny, assurance and accountability necessary for an operationally independent body
- the public and health sectors' confidence in HSIB's good intent, rigour and independence from NHS Improvement and the Department of Health and Social Care (DHSC), and therefore
- the long-term credibility and success of HSIB.

Despite these concerns, Panel members believe in the concept of the HSIB and we continue to be significantly invested in the success of HSIB as a national investigator for the NHS in England.

HSIB was the first organisation of its kind in the world and the learning curve has been a steep one both for the staff and for us as an Advisory Panel.

We are proud of HSIB's achievements to date and remain supportive, optimistic and committed to its ongoing success, as well as realistic about the challenges that must be overcome.

ADVISORY PANEL MEMBERS

Professor Murray Anderson-Wallace

Steve Clinch

Dr Mike Durkin

Farrah Pradhan

Dr Joe Rafferty

Suzanne Shale

Richard Von Abendorff

Jennie Stanley

www.hsib.org.uk/about-us/our-advisory-board

We do not apportion blame or liability, we carry out investigations to learn and improve safety

HSIB

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ABOUT HSIB

WHO WE ARE

The Healthcare Safety Investigation Branch (HSIB) is an organisation dedicated to improving patient safety. We conduct independent investigations into patient safety concerns in NHS-funded care across England. Formed in April 2017, we are funded by the Department of Health and Social Care (DHSC) and hosted by NHS Improvement[1], but we operate independently.

WHAT WE DO

Most harm in healthcare results from problems within the systems and processes that determine how care is delivered. By undertaking effective and independent safety investigations, we identify the contributory factors that have led to harm or the potential for harm to patients. Through recommendations to specific organisations we aim to improve healthcare systems and processes, in order to reduce risk and improve patient safety. We also share our findings across the wider health and social care system.

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

OUR INVESTIGATIONS

We conduct two types of safety investigation.

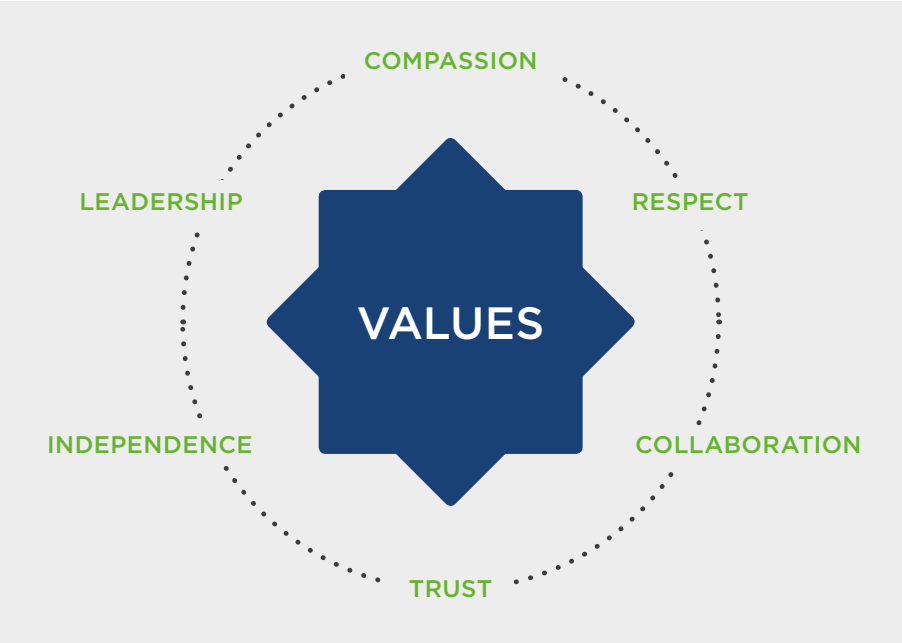
National investigations: Concerns about patient safety in any area of NHS-funded healthcare can be referred to us by any person, group or organisation. We review these concerns against our investigation criteria to decide whether to conduct a national investigation. National investigation reports are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

Maternity investigations: We investigate incidents in NHS maternity services that meet criteria set out by two national maternity healthcare programmes, Each Baby Counts and MBRRACE-UK. 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. We will publish an annual review of themes and key points of learning that we identify across all our investigations.

[1] From 1 April 2019, NHS England and NHS Improvement have come together to act as a single organisation.

OUR VALUES

Our values were developed together in an all staff away day in 2018 and they align to the NHS Constitution.



Independence

- We are independent and work with integrity, acting without obligation or direction from external organisations.
- Our investigations are carried out in a professional manner with integrity, confidentiality and compassion.

Collaboration

- We treat each other with respect and collaborate openly to make a greater impact.
- We work in a way that supports our values and takes advantage of different perspectives.
- We seek to understand and reflect the views of everyone we engage with.

Trust

- We are truthful and are informed by evidence and experience.
- We have courage to say and do the right thing.
- We are people focused and will create a trusting professional relationship with everyone we meet.

Respect

- We seek out alternative perspectives and put our shared interests ahead of any individual or team.
- We embrace, and seek to increase, the diversity of our organisation.
- We are respectful of the importance of honest feedback to the people involved and the wider community on investigations.

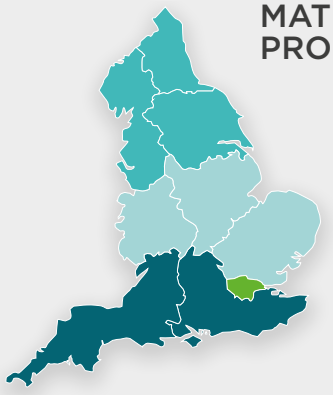
Compassion

- We treat everyone as we would expect to be treated ourselves.
- We are accountable for failure as well as success and will not allocate blame.
- We will show kindness and humility in our actions and behaviours.

Leadership

- We have a workplace *'just'* culture that values people and relationships, ensuring all HSIB staff have the ability to speak openly and honestly but retain accountability.
- We are accountable for our conduct and our decisions.

OUR HIGHLIGHTS 2018/19



MATERNITY PROGRAMME

WORKING WITH ALL

130

Trusts

FAMILY ENGAGEMENT

'best emerging solution for patient safety' **finalist**

2019 HSJ PATIENT SAFETY AWARDS

FAMILY INFORMATION LEAFLETS

Available in

ALL

languages

174

Staff recruited - investigators and support staff

100

Safety Awareness Notifications submitted for National investigations

127

Investigators have been trained

440

Maternity referrals received

12

National investigations launched

RESPONSIBILITIES, ACCOUNTABILITY AND INDEPENDENCE

We are accountable to the Secretary of State for Health and Social Care and our performance is scrutinised by the DHSC.

Through this annual review we report every year to the Secretary of State for Health and Social Care on our performance in meeting our core functions and we produce a business plan for each coming year. These documents are available on our website.

Our functions and responsibilities were established in two sets of secondary legislation[2] from the Secretary of State for Health and Social Care:

- The National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) Directions 2016. These are the Directions under which the organisation was established and they set out our responsibility for national investigations.

- The National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) (Additional Investigatory Functions in respect of Maternity Cases) Directions 2018. These Directions set out our responsibility for maternity investigations.

As well as setting out our functions, the Directions state that we must carry them out in a way that is independent from the organisations that host and fund us.

In December 2018, the government responded to recommendations by a parliamentary select committee on a draft Health Service Safety Investigations Body (HSSIB) Bill, which would establish a new, fully independent body to investigate healthcare safety incidents in the NHS in England.

The Bill, which is expected to be introduced in Parliament soon, will make us independent in legal terms, set out the provisions for protected disclosure (commonly known as *'safe space'*. As an independent statutory body, we will be governed by an independent executive and non-executive board.

[2] Secondary legislation is law created by ministers (or other bodies) under powers given to them by an Act of Parliament.

OUR STRATEGIC GOALS AND OBJECTIVES

The formation of HSIB represented a landmark moment for the NHS in England. Our mission is simple: to help improve safety in our healthcare system by developing recommendations and sharing lessons from our investigations. This is underpinned by a philosophy focused on safety and improvement that avoids blame or liability.

We operate in a complex environment, where accountability and responsibilities are changing. This year we have continued to establish ourselves as an effective and independent organisation, while coping with a significant increase in the volume of investigations to be undertaken each year.

The following sections of this annual review describe our activities and achievements during 2018/19 against our strategic goals and objectives.

We have six strategic goals, which reflect our responsibilities as set out in law and in our agreements with the Department of Health and Social Care and NHS Improvement. For each strategic goal we have outlined a set of objectives – the actions we are taking to achieve our goals.

This work is carried out by the following teams:

- National Investigation Team
- Maternity Investigation Team
- Intelligence Unit
- Corporate Services.

INDEPENDENT HEALTHCARE SAFETY INVESTIGATIONS

INDEPENDENT HEALTHCARE SAFETY INVESTIGATIONS

STRATEGIC GOAL 1

Undertake independent safety investigations with objectivity, underpinned by competence, credibility and integrity.

TO ACHIEVE THIS WE WILL:

1 operate as an exemplar within safety investigation
2 carry out up to 30 national investigations
3 carry out circa 1,000 maternity investigations
4 not to apportion blame or liability within our investigation reports
5 influence improvements in quality, safety and patient experience through professional investigations that identify systemic learning
6 involve patients and families in investigations, as far as practicable and appropriate
7 develop and define investigation methodologies that are exemplar.

ABOUT OUR INVESTIGATIONS

We conduct two types of investigation – national investigations and maternity investigations. They are different in terms of how referrals are made, the local status of the investigation, and how we report on our findings. However, for both types of investigation:

- we do not apportion blame or liability – we carry out investigations to learn and improve patient safety
- we aim to involve patients and families throughout the investigation process
- we gather information about themes that arise across different investigations to identify areas of risk; these may inform future investigations.

National and maternity investigations at a glance show the difference on our approach for each.

AT A GLANCE - NATIONAL AND MATERNITY INVESTIGATIONS

	NATIONAL INVESTIGATIONS	MATERNITY INVESTIGATIONS
Start date	Programme began in April 2017.	Programme began in April 2018.
Number of investigators	Full complement of 12 investigators recruited by end of December 2017.	Full complement of 120 investigators recruited by end of March 2019.
Number of investigations	We were set the task of carrying out up to 30 investigations per year.	We were set the task to complete around 1000 investigations per year that meet the criteria.
Training for investigators	Investigators attend an intensive three week training programme as soon as they join and they attend regular professional development workshops throughout the year.	Maternity Investigators attend an intensive two week training programme as soon as they join and they attend regular professional development workshops throughout the year.
Referrals	Any person, group or organisation can refer a patient safety concern to HSIB through our **website**. We also identify issues for investigation through research.	Individual NHS trusts refer incidents to us that meet the criteria.
Criteria for investigations	We evaluate patient safety issues against our own criteria and decide whether to go ahead with an investigation.	We investigate maternity healthcare safety incidents that meet the criteria set out Each Baby Counts or MBRRACE-UK.
Investigation status	Our investigation does not replace the local trust's investigation into the patient safety incident (also known as the 'reference event').	Our investigation replaces the trust's investigation into the maternity incident for those investigations that meet the criteria.
Reporting	We publish all our national investigation reports on our website.	Maternity investigation reports are shared with the family and trust. They are not published.
Recommendations	We make safety recommendations to relevant named organisations. The organisations must respond to the recommendations within 90 days and we publish the responses on our website. We may also make safety observations (where we consider our findings warrant attention but there is not enough information on which to make a recommendation) and identify safety actions that have been taken during an investigation to immediately improve patient safety.	We make safety recommendations for learning to the trust, which is responsible for putting them into action. We gather information about themes arising from our investigations to share learning across the health sector.

NATIONAL INVESTIGATIONS

HSIB identifies healthcare safety risks by evaluating the notifications we receive from professionals, patients, families and the general public, and by looking at information from organisations (for example, prevention of future death reports from coroners). We also identify risks through:

- *'horizon scanning'* – looking at potential safety risks by analysing serious incidents[3]

- thematic reviews, which involve starting with a theme (for example, high-risk drug administration) and working through information and literature

For both of these approaches, we use existing NHS information databases, research literature and data sources.

NATIONAL INVESTIGATION CRITERIA

We assess referrals and other sources of information against agreed criteria to determine the safety value of an investigation. The criteria are based on international patient safety research and approaches to system-level investigations in other industries.

Initial notifications are assessed against the criteria to determine if an investigation should be instigated; they are re-assessed at regular intervals throughout the investigation process to ensure that the criteria are still being met.

These criteria are based on:

OUTCOME IMPACT

Assessing the scale and severity of the actual or potential impact that an issue represents helps to identify the most serious. This includes potential harm so that *'near miss'* and *'low harm'* individual events can be included, which is common practice in other industries (as they are recognised as a rich source of learning) but has been less common in healthcare. We consider the physical and emotional effects on patients and families as well as the impact on services, such as public confidence in the healthcare system and whether the safety issues have reduced the ability to deliver safe and reliable care.

SYSTEMIC RISK

We review the system-wide risk associated with safety issues, including the extent to which an issue is common, widespread or persistent across the healthcare system. Some events that have occurred within very different healthcare settings have shared underlying safety issues – our approach ensures these are taken into consideration.

LEARNING POTENTIAL

We carefully consider whether an HSIB investigation and its recommendations are likely to lead to meaningful safety improvements. We are unlikely to initiate a national investigation if we cannot anticipate recommendations that could be implemented. An example of where this might happen includes issues that have already been extensively investigated and robust recommendations for improvement already exist.

On the other hand, we have initiated national investigations on a number of safety issues where there has already been a lot of attention (like some recurring Never Events[4]) but where existing interventions are clearly not robust enough or correctly directed to prevent an issue from recurring.

HSIB CRITERIA FOR A NATIONAL INVESTIGATION

OUTCOME IMPACT

People: physical, psychological, loss of trust
Service: quality and reliability, capacity and capability
Public: confidence, political attention, media profile

SYSTEMIC RISK

Systemic safety deficiency: range of care settings; geographic/specialist spread; scale through system structures; complexity of interactions
Dormancy period: time taken to identify risk; route of discovery
Persistence and expansion: Permanence; potential for escalation and spread

LEARNING POTENTIAL

Potential for increased knowledge: new knowledge; gap in current knowledge
Potential for systemic improvement: opportunity to positively influence system, practices, safety culture
Practicality of action: feasibility of conducting effective investigation; practicality of issuing influential recommendations
Value of intervention: adequacy and scope of safety actions by others; potential to develop local investigative capacity; potential to develop HSIB capacity and capability

NATIONAL INVESTIGATION TEAM

The National Investigations Team comprises 12 national investigators led by three principal national investigators, working across teams based in our two offices in Farnborough and Derby.

We maintain a bank of subject matter advisers in clinical and non-clinical fields, and experts by lived experience, to support our investigations.

The following chart shows the national investigations pipeline.

NATIONAL INVESTIGATIONS

KEY

- Investigation published 2018/19
- Investigation commenced
- Investigation completed and not published

INVESTIGATION NUMBER	REPORT TITLE	REPORT PUBLISHING
I2017/010	Implantation of wrong prostheses during joint replacement surgery	●
I2017/008	Transition from child and adolescent mental health services to adult mental health services	●
I2017/004	Administering a wrong site nerve block	●
I2017/012	Insertion of an incorrect intraocular lens	●
I2017/006	Provision of mental health care to patients presenting at the emergency department	●
I2017/013	Design and safe use of portable oxygen systems	●
I2018/014	Neo-natal death (report shared with family, Trust & coroner)	●
I2017/002a	Transfer of critically ill adults	●
I2018/017	Piped supply of medical air and oxygen	●
I2017/009	Inadvertent administration of an oral liquid medicine into a vein	●
I2017/007	Recognising and responding to critically unwell patients	●
I2018/012	Undetected button and coin cell battery ingestion in children	●
I2018/015	Failures in communication or follow-up of unexpected significant radiological findings	●
I2018/011	Management of acute onset testicular pain	●
I2018/018	Delayed recognition of acute aortic dissection	●
I2018/020	Electronic prescribing and medicines administration systems and safe discharge	●
I2017/002b	Risks of medicine prescribing in hospital to frail older people	●
I2018/019	Management of chronic health conditions in prisons	●
I2018/021	The diagnosis of ectopic pregnancy	●
I2018/022	Potential under-recognised risk of harm from the use of propranolol	●
I2018/023	Management of VTE risk in patients following thrombolysis for an acute stroke	●
I2018/024	Recognition of acutely ill infant	●

PUBLISHED NATIONAL REPORTS AND SAFETY RECOMMENDATIONS 2018/19

IMPLANTATION OF WRONG PROSTHESES DURING JOINT REPLACEMENT SURGERY (JUNE 2018)

2018/001 - **NHS Improvement** amends the national Prosthesis Verification Standard to incorporate the specific aspects of verification practice developed to mitigate error identified in this investigation.

2018/002 - The **British Standards Institute** amends existing standards for prosthesis labels to include details of design that make them easier to read in operating theatres. The American Society for Testing and Materials' '*Standard Guide for Presentation of End User Information for Musculoskeletal Implants'* is a useful reference.

2018/003 - The **National Joint Registry** changes the response when data is entered into the registry suggesting the wrong prosthesis has been implanted due to incompatible manufacturers, so that it is consistent with the response when data indicates the wrong size or side has been implanted.

2018/004 - The **Department of Health and Social Care** expands the remit of the working group consisting of Derby Teaching Hospitals NHS Foundation Trust's Scan4Safety Programme, the National Joint Registry, and the Medicines and Healthcare products Regulatory Agency to include alerts to identify wrong prostheses prior to implantation.

2018/005 - The **Department of Health and Social Care** commissions the development and implementation of an interim basic scanning system to identify wrong prostheses prior to implantation.

TRANSITION FROM CHILD AND ADOLESCENT MENTAL HEALTH SERVICES TO ADULT MENTAL HEALTH SERVICES (JULY 2018)

2018/006 - That **NHS England**, within the *'Long-Term Plan'*, works with partners to identify and meet the needs of young adults who have mental health problems that require support but do not meet the current criteria for access to adult mental health services.

2018/007 - That **NHS England** requires Clinical Commissioning Groups to demonstrate that the budget identified for current children and young people's services – those delivering care up until the age of 18 – is spent only on this group.

2018/008 - That **NHS England** and **NHS Improvement** ensure that transition guidance, pathways or performance measures require structured conversations to take place with the young person transitioning to assess their readiness, develop their understanding of their condition and empower them to ask questions. NHS England and NHS Improvement must then ensure that the effectiveness of this is robustly evaluated.

2018/009 - That NHS England, within the *'Long-Term Plan'*, requires services to move from aged-based transition criteria towards more flexible criteria based on an individual's needs.

2018/010 - That **NHS England** and **NHS Improvement** work with commissioners and providers of mental health services to ensure that the care of a young person before, during and after transition is shared in line with best practice, including joint agency working.

2018/011 - That the **Care Quality Commission** extends the remit of its inspections to ensure that the whole care pathway, from child and adolescent mental health services to adult mental health services, is examined.

ADMINISTERING A WRONG-SITE NERVE BLOCK (SEPTEMBER 2018)

2018/012 - The **Royal College of Anaesthetists** establishes a specialist working group to evaluate the current practices used to reduce wrong-site block incidents. This group should consider how safety initiatives to reduce wrong-site blocks can be standardised in anaesthesia training and practice.

It is recommended that the specialist working group consider the impact of the patient's state of consciousness, changes in a patient's position and the prevalence of wrong-site block incidents compared to the number of blocks administered.

2018/013 - The **Royal College of Anaesthetists** ensures any further work identified by the specialist working group to reduce wrong-site block incidents is subject to human factors-based testing and evaluation.

INSERTION OF AN INCORRECT INTRAOCULAR LENS (NOVEMBER 2018)

2018/014 - The **Medicines and Healthcare products Regulatory Agency** (MHRA) should strongly recommend the manufacturers of ophthalmology electronic patient record systems (including systems for making and storing ocular biometry measurements), where they fall under the remit of the Medical Device Regulations, undertake an assessment against the MHRA Human Factors and Usability Engineering guidance and this should form part of the documents assessed by a Notified Body as part of any declaration or assessment of conformity with the requirements of the Medical Device Regulations.

2018/015 - The **Department of Health and Social Care** commissions a set of standards for the NHS that utilises appropriate technologies to provide digital alerts when incorrect intraocular lens are selected.

2018/016 - The **Royal College of Ophthalmologists** establishes an expert working group to evaluate the variance of practice for cataract surgery, and subsequently establishes standardised and workable processes to minimise the risk that a patient will receive an incorrect intraocular lens.

PROVISION OF MENTAL HEALTH CARE TO PATIENTS PRESENTING AT THE EMERGENCY DEPARTMENT (NOVEMBER 2018)

2018/017 - **NHS England** ensures there is a sustainable funding model to support 24/7 urgent and emergency mental health liaison services in acute general hospitals with emergency departments.

2018/018 - The **National Institute for Health and Care Excellence** reviews and amends guidance for the management of self-harm in the emergency department.

2018/019 - The **Royal College of Emergency Medicine**, in conjunction with the Royal College of Psychiatrists, develops and disseminates national guidance for emergency department practitioners to standardise the initial assessment of a person presenting following a mental health emergency.

2018/020 - The **Care Quality Commission** reviews and updates its inspections criteria for emergency departments to ensure equal weight is given to the quality of care provided to people with urgent mental health problems as they do to people with urgent physical health problems. This would be consistent with its commitment to parity of esteem for mental health.

DESIGN AND SAFE USE OF PORTABLE OXYGEN SYSTEMS (NOVEMBER 2018)

2018/021 - It is recommended that the **Medicines and Healthcare products Regulatory Agency** evaluates how its Human Factors guidance document is used in practice by manufacturers and by Notified Bodies. Based on the review, the MHRA should make any changes necessary to the document or use other mechanisms to improve the implementation of Human Factors in the pre-market approval process.

2018/022 - It is recommended that the **Medicines and Healthcare products Regulatory Agency** requires oxygen manufacturers to submit evidence of human factors summative testing of the complete product as part of the market authorisation process for medicinal licence.

2018/023 - It is recommended that the **Medicines and Healthcare products Regulatory Agency** reviews its documentation to determine whether more specific guidance is required on how to incorporate human factors into post-market adverse event investigations.

2018/024 - It is recommended that, when reviewing manufacturers' Field Safety Notifications, the **Medicines and Healthcare products Regulatory Agency** discourages the use of weak barriers as defined in ISO 14971 (Risk Management for Medical Devices) particularly as long-term solutions.

TRANSFER OF THE CRITICALLY ILL ADULT (JANUARY 2019)

2019/025 - The **Department of Health and Social Care** should co-ordinate the development of national guidance, with the arm's length bodies, for the transfer of critically ill adults, both in planned and emergency situations.

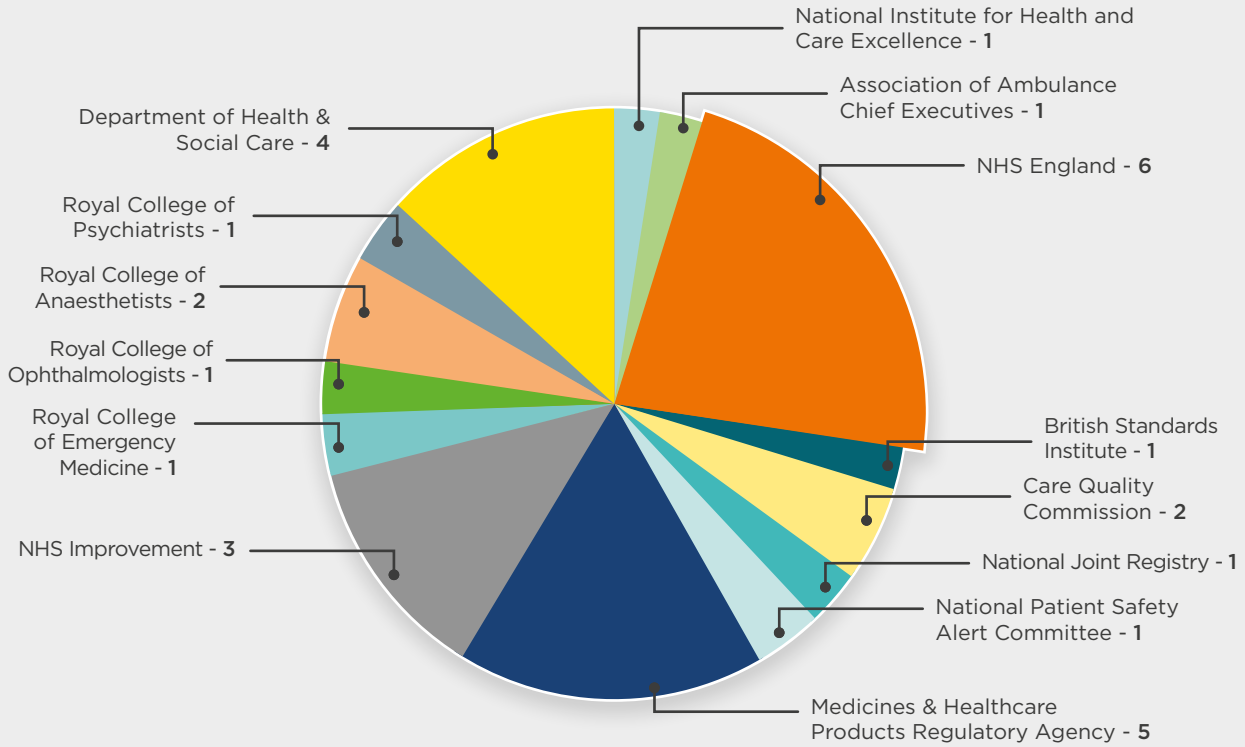
2019/026 - The **Association of Ambulance Chief Executives** should work with partners to define best practice standards for the criteria, format, delivery and receipt of ambulance service pre-alerts.

PIPED SUPPLY OF MEDICAL AIR AND OXYGEN (FEBRUARY 2019)

2019/027 - The **National Patient Safety Alert Committee** should set standards for all issuers of patient safety alerts that require an assessment for unintended consequences, the effectiveness of barriers in the alert, and the advice the alert issuers give providers on implementation and ongoing monitoring.

WHO WE HAVE MADE SAFETY RECOMMENDATIONS TO THROUGHOUT 2018/19

NATIONAL INVESTIGATIONS SAFETY RECOMMENDATIONS



RESPONSES TO OUR SAFETY RECOMMENDATIONS THROUGHOUT 2018/19

HSIB does not have the power to require organisations to respond, or to ensure that our accepted recommendations are implemented. For this reason, we have been encouraged by the response that we have received from across the health sector. 100% of our recommendations have received a response within our requested 90-day timescale, and several of those recommendations have already been implemented.

Prompt evidence-based actions by national organisations are an important recognition of the validity of our work, and demonstrate the potential for rapid change to improve patient safety.

MAKING CHANGE HAPPEN THROUGH NATIONAL-LEVEL RECOMMENDATIONS

Examples of recommendations/safety actions implemented in 2018/19

Safety recommendation: Transition from Child and Adolescent Mental Health Services (CAMHS) to Adult Mental Health Services (July 2018)
Our safety recommendations regarding ring-fenced local commissioning budgets for CAMHS services and expanding CAMHS services to 25 years of age were both accepted as part of NHS England's commitments in the NHS Long Term Plan.

Safety action: Investigation into the provision of mental health care to patients presenting at the emergency department (November 2018)
In response to our findings, the National Institute for Health and Care Excellence updated clinical guideline CG16 to recommend that the Australian Mental Health Triage Scale not be used to predict future suicide or repetition of self-harm.

Safety recommendation: Insertion of an incorrect intraocular lens (November 2018) and Design and safe use of portable oxygen systems (February 2019)
The Medicines and Healthcare products Regulatory Agency (MHRA) issued a combined response to recommendations in these reports, and in light of the implications of responses to recommendations we made in our report, *Implantation of wrong prostheses during joint replacement surgery*. MHRA said:

> *... we agree these are good recommendations and are areas we have also identified where further systemic safety improvement effort should be directed. We intend to implement them as fully as we can, within the constraints of our regulatory abilities...We think the recommendations you have made are logical conclusions from the specific investigations you have undertaken. However, we think these are examples of wider problems, and so we intend to implement improvements to the whole category of problem we identify, rather than concentrate on the specific examples you give.*

This is an excellent example of the impact we are having – identifying sound evidence-based safety recommendations that provide the impetus for national organisations to recognise opportunities for safety-oriented changes that go beyond the scope of our investigation, representing truly system-level change. The full response from the MHRA with actions taken is available on our website.

REFINING OUR APPROACH

As HSIB matures as an organisation we continue to refine our national investigation process.

During 2018/19 we have:

- developed the National Investigation Team's knowledge of how complex healthcare services interact, to focus on safety problems within their specific clinical and operational context
- developed our processes to support the scoping of approximately two new investigations a month
- invested in developing the National Investigation Team's knowledge to ensure they remain at the cutting edge of investigation methodologies and analysis techniques.

LOOKING AHEAD: NATIONAL INVESTIGATIONS

Assessing other investigation techniques

The National Investigation Team is working with the Intelligence Unit to undertake provisional assessments on several other investigation techniques, looking at their applicability and usability within the healthcare setting.

Due to the diversity of safety issues investigated by HSIB national team, our aim is to continue to build and enhance our investigation tool set, sharing learning when appropriate.

Evaluating our methodologies

During 2019/20 we will commission an initial research and evaluation project to support the detailed analysis of evolving HSIB national investigation methodologies and their effectiveness.

HOW DOES A SINGLE INCIDENT BECOME A WINDOW TO THE HEALTHCARE SYSTEM?

Case study: Insertion of an incorrect intraocular lens

Initial referral

The initial referral for this investigation came from a practising ophthalmologist, who was aware of the continuing problem of incorrect intraocular lens insertion but was not sure what else could be done at a local level. It was hoped that a national organisation might be able to offer a new perspective on the issue.

Understanding the problem

The Intelligence Unit explored available sources of information to understand the context and extent of the problem. This included targeted searches on healthcare incident databases, as well as understanding how common the procedure was by accessing national datasets. Information was also sought from clinical and national literature to understand the context of the issue and previous approaches to reducing errors.

The information was then used to assess the issue against the HSIB investigation criteria, to understand the outcome impact, systemic risk and learning potential. Through national incident databases, a specific incident at an NHS trust was identified as being representative of the issue, and this was proposed as a suitable reference event from which to launch the national investigation.

Scrutiny process

The information was collated and presented at the regular scrutiny panel, where a multidisciplinary team reviewed the intelligence gathered, the criteria review and the Intelligence Unit recommendation to proceed to a scoping investigation. It was agreed that the risk was widespread and could benefit from an HSIB investigation.

The scoping investigation
An investigation team began the scoping investigation by contacting the Trust involved in the reference event, the patient and their family. Through these contacts the team was able to conduct a thorough investigation of the local reference event, to understand key risk points and opportunities for learning or explore issues at a wider level. Once the investigation team analysed the findings, the information was presented to a multidisciplinary panel, where terms of reference for the wider investigation were discussed and agreed. An interim bulletin was published, and the investigation moved to the next phase; full investigation.

The full investigation
This phase involved understanding how the findings and analysis from our local-level investigation could allow insight into how the issue could be addressed across the healthcare system. The Australian Transport Safety Bureau (ATSB) analysis model was used to explore higher-level contributions to error.

The ATSB model helped link factors in the specific event to factors at the highest levels of the system and enabled the team to demonstrate that many risk factors that local trusts mitigate against daily are often based in issues beyond their control, such as the design of operating theatres, software and lens packaging.

Report and recommendations
The final report, published November 2018, represented the culmination of intelligence gathering, investigative work, analysis and stakeholder engagement that was key to developing meaningful recommendations to reduce the risk of incorrect intraocular lens insertion.

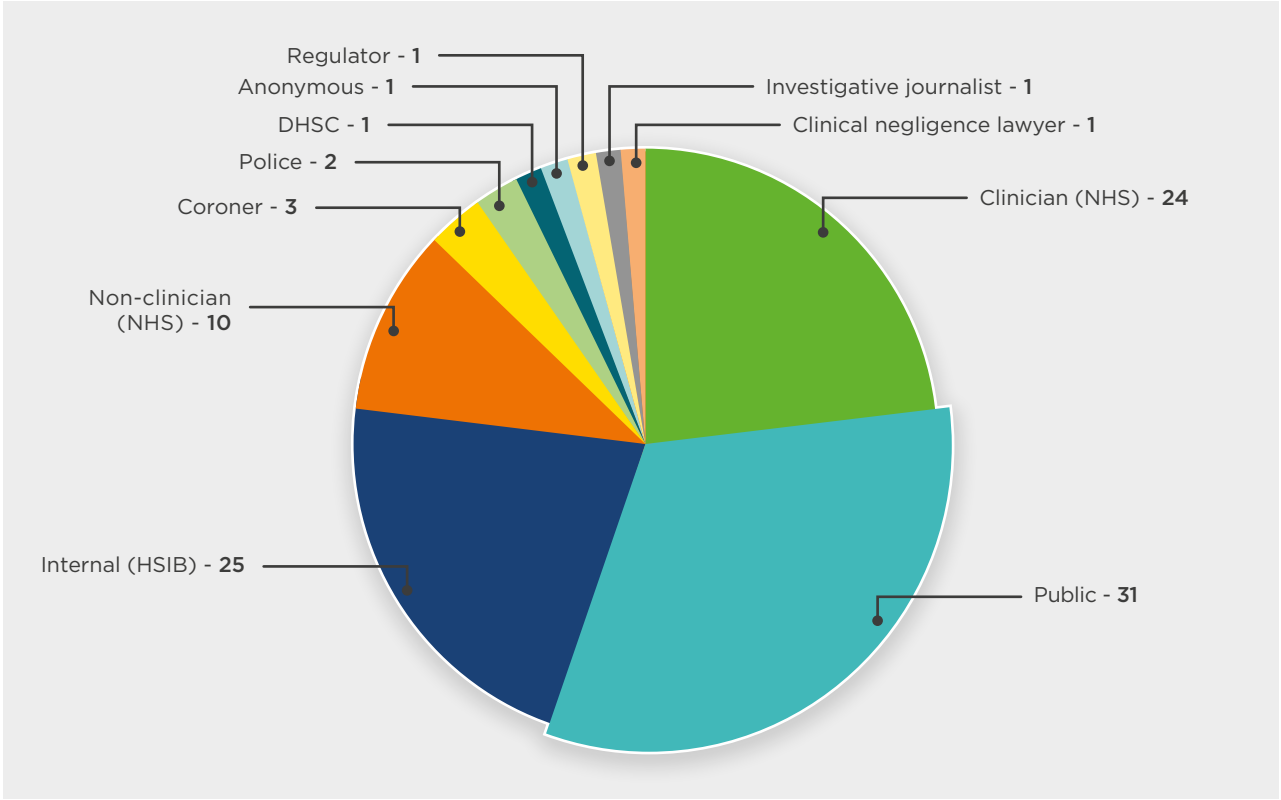
Our impact: raising awareness of button battery danger
During 2018, HSIB launched an investigation into undetected ingestion of button batteries. This followed the referral of a case of a three-year-old girl who had died after swallowing a button battery, but whose symptoms were not recognised because nobody was aware that she had swallowed it. Following our interim bulletin on the case, published on 11 October 2018, we noted that an important safety message could be developed to raise awareness of the dangers of button batteries among relevant audiences (parents, industry, clinical staff) before Christmas.

A news release and media resource pack, supported by paediatrician Dr Rachel Rowlands and the Child Accident Prevention Trust, helped us achieve wide reach. The media activity prompted public responses from industry bodies responsible for button battery manufacturing, child safety groups, clinicians and services from across the health sector. Members of the public shared the message across their own channels, and the issue was covered in mainstream news and consumer media.

The British and Irish Portable Battery Association (BIPBA) published a response to our warning on its website. As an influential body, BIPBA's support was key, not only to publicise the safety message but also to help with the further development of the safety recommendations for the final HSIB investigation report, which was published in June 2019.

THE INTELLIGENCE UNIT

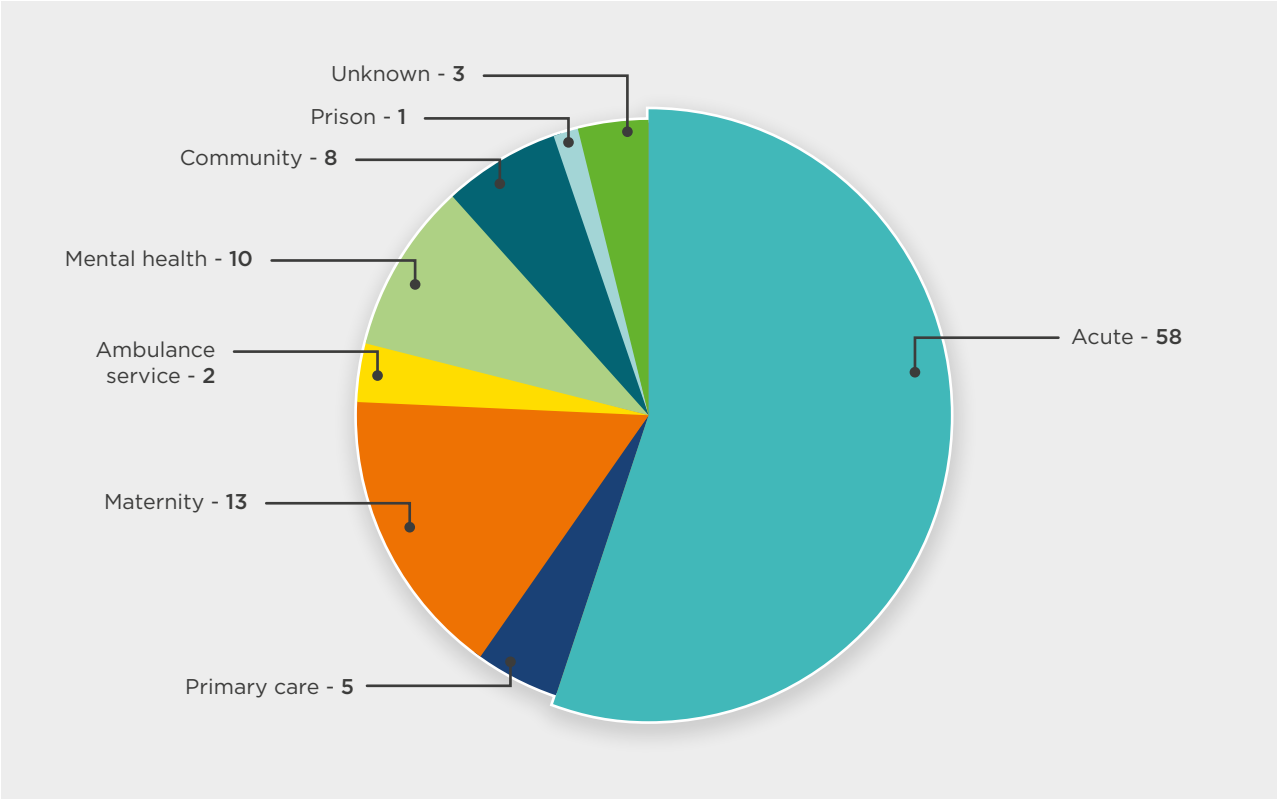
NATIONAL INVESTIGATIONS BY NOTIFIER 2018/19



The Intelligence Unit (IU) identifies safety risks and reference cases for investigation that offer strong opportunities for system-wide learning and safety improvement. The team come from a variety of backgrounds, including clinical, operational and academic. The IU's remit includes:

- Intelligence analysis to understand the healthcare landscape and systemic safety risks
- Identifying potential risks for HSIB investigation, often acting as the initial contact for organisations, patients and families and staff and establishing relationships
- Processing all new notifications to HSIB, including engaging with patients, families, academics, clinical experts and healthcare professionals
- Providing ongoing analysis, review and challenge throughout investigations as members of the investigation team
- Identifying and connecting with subject matter advisors and broadening HSIB's clinical and academic network
- Evaluating the impact of HSIB reports, including responses to safety recommendations
- Working with Maternity Investigators to provide contextual and academic information to support analysis throughout investigations.

NATIONAL INVESTIGATIONS BY CARE SETTING 2018/19



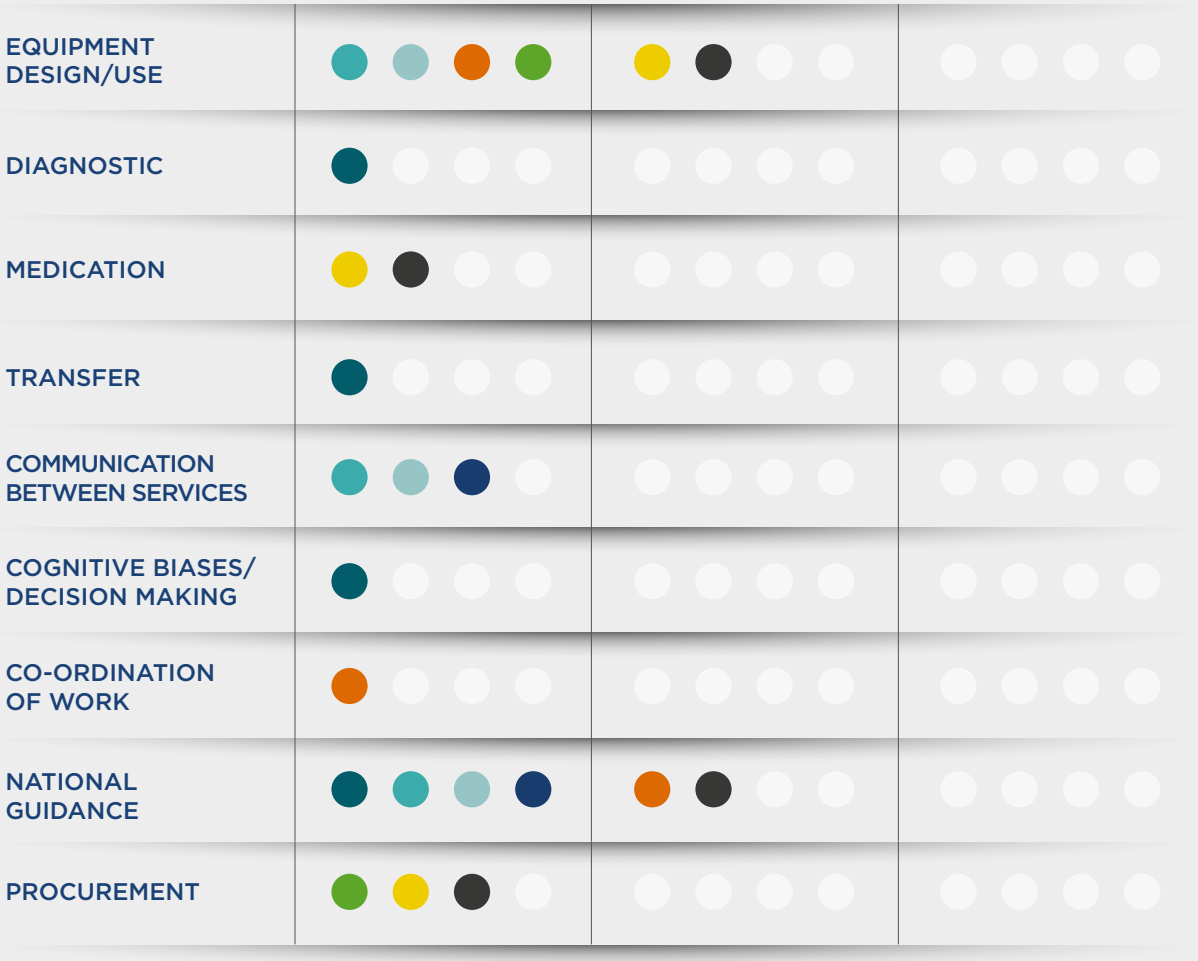
INTELLIGENCE UNIT ACTIVITY

As HSIB's profile has grown, the volume of information submitted to us has also grown. We received 47 formal safety awareness notifications in 2017/18 and 100 in 2018/19. Approximately one third of notifications originate from patients, families or the general public and a quarter from clinicians and a quarter from our reviews of incident and research data.

Most of the notifications are from Acute care, 13% in Maternity and 10% from Mental Health although at investigation stage it become apparent that many of these often involve multiple sectors.

Above shows HSIB investigations by both care setting and themes identified can be seen on the following page. The data shows that HSIB's activity has been wide-ranging across the NHS, with investigations that have impacted multiple care settings. The thematic data delivers valuable insight into what has already been found across investigations, including factors such as communication and national guidance that have been highlighted across several investigations. These themes help to identify potential stakeholders and recommendations in ongoing cases, as well as contributing to the IU's aim of understanding risk factors across the healthcare system, so that future HSIB investigations can address these broader issues.

THEMES FROM NATIONAL INVESTIGATIONS PUBLISHED 2018/19



The IU team members actively participate in professional development with the National Institute for Healthcare Research's Clinical Leadership, Applied Health Research Programme and NHS Digital Academy collaboratively run by Harvard University, Imperial College London and Edinburgh University.

The IU team contribute to learning within the wider healthcare community, presenting on academic safety courses, at conferences and professional seminars. The audiences are varied, including clinical specialists, healthcare professionals and expert from industry and human factors and ergonomics. The IU have been developing a clinical network and hosting an inaugural clinical network seminar to inform the healthcare community about professional safety investigation.

PATIENT AND FAMILY ENGAGEMENT

INVOLVING PATIENTS AND FAMILIES

Our investigation approach puts patients and families at the heart of our work. Many previous NHS reports and inquiries, such as the Morecambe Bay investigation and the independent review of deaths of people with a learning disability or mental health problems in contact with Southern Health NHS Foundation Trust, have identified that patients and families often feel excluded from safety investigations into incidents that have profoundly affected them. This research has shown that failure to work effectively with patients and families compounds physical and emotional harm, reduces trust in investigation findings and compromises openness. It can also mean that crucial information for the investigation is missed.

NHS investigations involve only **30+%** of patients and families throughout a safety investigation. We are involving **90+%** of patients and families throughout our investigations. This is possible because we have dedicated investigators allocated to each independent investigation and they are supported by a clear engagement protocol that is supported and led by a dedicated Head of Patient and Family Engagement.

Through our model we ensure that patients and families are fully informed about, and given the choice to be closely involved with, our investigations. In August 2018, we appointed a Head of Family Engagement to fully develop the processes, training and ongoing guidance to support our investigators to meet these objectives.

Our patient and family engagement model is based largely on the police approach to gathering evidence from families during serious crime investigations. This serves a dual purpose:

- it helps with a more professional and evidence-based approach to gathering additional evidence for the investigation
- it is a proven effective method of ensuring that patients and families are respected, included and engaged at every stage of the investigation.

ACHIEVEMENTS TO DATE

In our first six months of using the model, 93% of families agreed to participate in our maternity investigations, and 87% of patients/families in our national investigations. We would ideally like to achieve 100% participation from patients and families, however we recognise there are reasons why they may sometimes choose not to be involved. Our higher priority is therefore to ensure informed choice by patients and families about their participation.

As part of our family engagement model, we have considered barriers to communication such as foreign languages or other areas where support is needed. Timely and specialist language services need to be in place to ensure families can fully participate in the investigations and understand final reports. This is particularly the case for maternity investigations. Such provision also ensures investigators can operate in as sensitive and compassionate manner as possible. In order not to rely on the limited resources of trusts, we have engaged language services, both translation and interpretation, so that initial engagements around consent and information on what is involved in an investigation can be as smooth and supportive as possible for families in what are often difficult circumstances. In addition, timely provision of services can be made available for British Sign Language, Braille, and other accessible formats. So far we have translated our family information sheet into 10 languages and we have interpreters and resources made available to families on request.

We have started a formal evaluation process with patients and families whose investigations are complete, from which early feedback has been very positive.

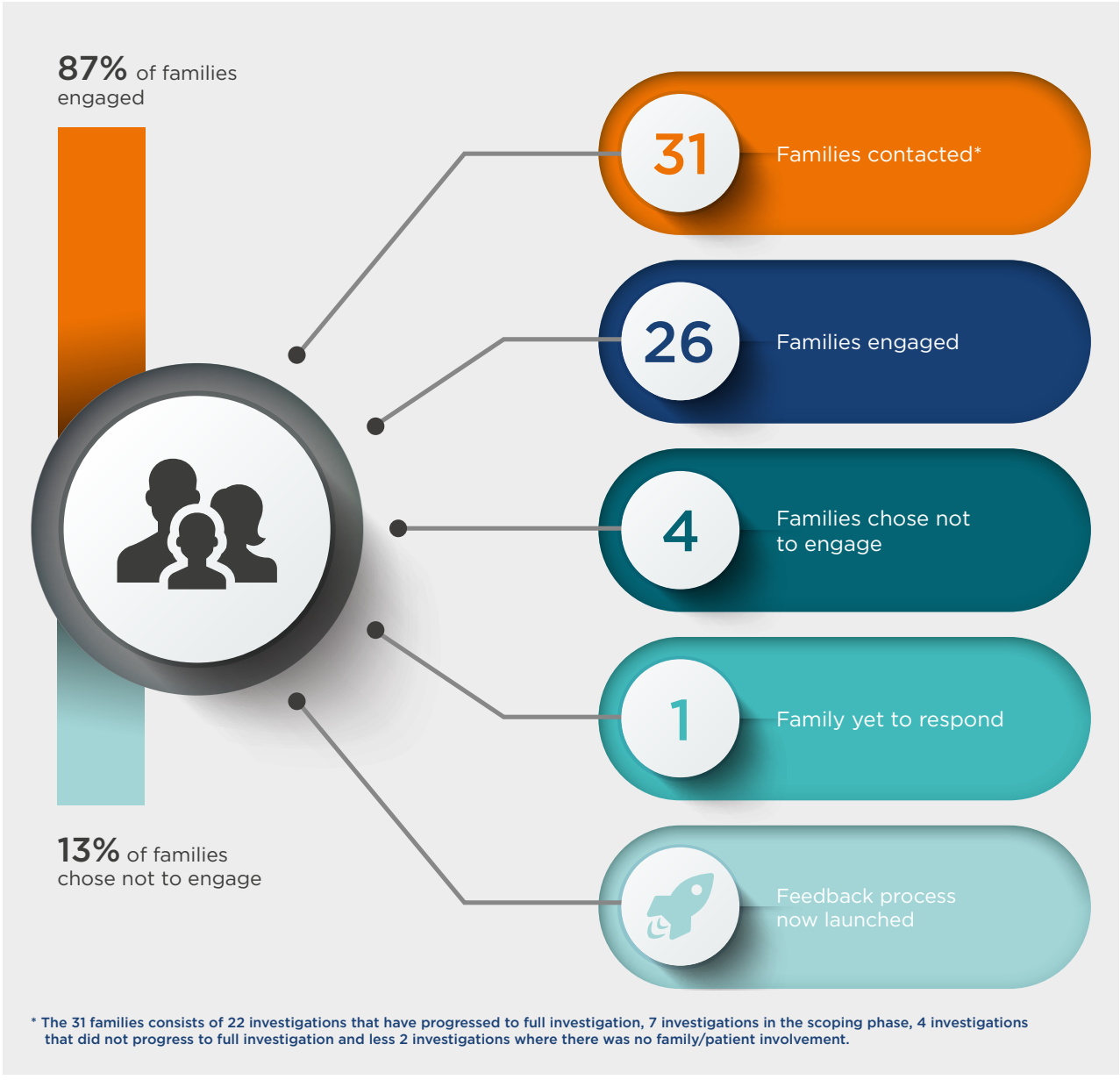
FAMILIES COMMENTS ABOUT OUR FAMILY ENGAGEMENT

I found the process so supportive in the way it was approached.

It is great feeling you have got a voice which is entirely down to your approach.

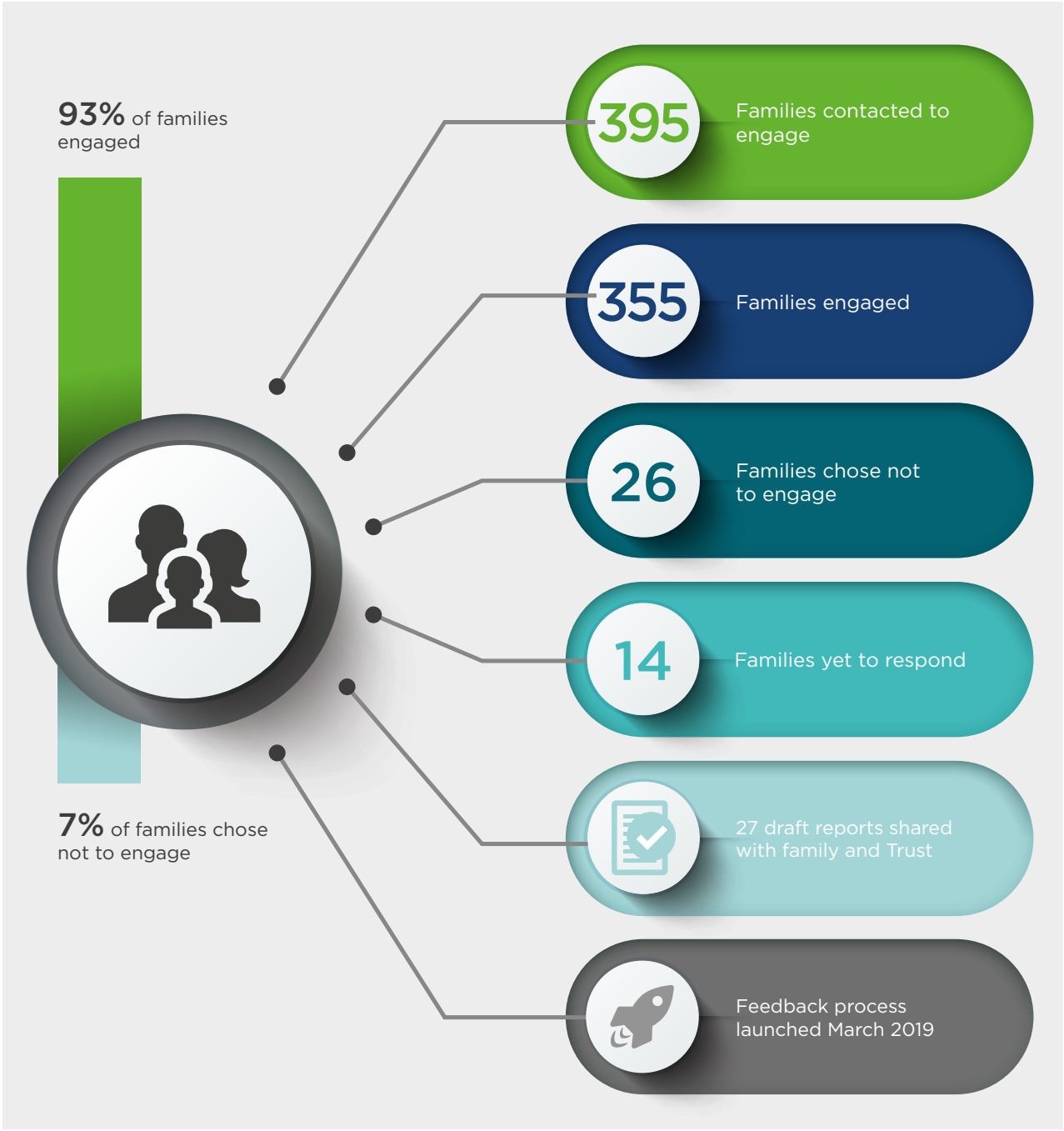
The family would like to convey their thanks for the care & consideration taken by the HSIB in relation to this on-going investigation...
...In what has been a difficult year, it is reassuring to know that the matter is being taken seriously...

INVOLVING PATIENTS AND FAMILIES IN OUR NATIONAL INVESTIGATIONS



* The 31 families consists of 22 investigations that have progressed to full investigation, 7 investigations in the scoping phase, 4 investigations that did not progress to full investigation and less 2 investigations where there was no family/patient involvement.

INVOLVING PATIENTS AND FAMILIES IN OUR MATERNITY INVESTIGATIONS




FAMILY
ENGAGEMENT


HSIB

TRAINING OUR INVESTIGATORS IN PATIENT AND FAMILY ENGAGEMENT

Our investigators receive ongoing support, training and professional development in a wide range of topics, including:

- how to work sensitively and effectively with patients and families
- diversity awareness
- enhanced bereavement training
- involving patients/families at draft and final report stages to ensure their views and experiences have been correctly represented
- facilitating patient/family engagement with other sources of support after the HSIB investigation has finished
- gaining family and NHS staff feedback on our processes to inform training and continuous improvement.

This year we have also worked closely on the training programme with a range of patient representatives, professional bodies and other organisations, in particular SANDS, the national charity for stillbirth and neonatal death, the Royal College of Obstetricians and Gynaecologists, and the Royal College of Midwives.

LOOKING AHEAD: PATIENT AND FAMILY ENGAGEMENT

Sharing our approach

We will build on our success by sharing our approach with those who wish to improve their take-up of family engagement.

Improving integration with trusts

We will improve our integrated approach with trusts to ensure smooth and timely handovers of cases, to maximise the window of opportunity to enable family participation.

Gathering feedback

We will be gathering formal feedback from every patient/family that we engage with during an investigation. This will help us to comprehensively review and improve our approach, enable us to identify risks, themes or trends from all available feedback, both internal and external, and ensure we maintain a high level of family engagement. We will include the information we gather from the feedback in our next annual review.

MATERNITY INVESTIGATIONS

We began our maternity investigation programme in April 2018.

OUR MATERNITY INVESTIGATION CRITERIA

We undertake maternity investigations that meet the *'Each Baby Counts'* criteria for infant deaths/injuries, and a set of criteria for maternal deaths defined by MBRRACE-UK[6]. Each Baby Counts is a national quality improvement programme of the Royal College of Obstetricians and Gynaecologists to reduce the number of babies who die or are left severely disabled as a result of incidents occurring during term labour.

Infant deaths/injuries

The defined criteria is eligible babies which includes all term babies (at least 37 completed weeks of gestation) born following labour who have one of the following outcomes:

- **intrapartum stillbirth:** where the baby was thought to be alive at the start of labour but was born with no signs of life
- **early neonatal death:** when the baby died within the first week of life (0-6) days of any cause
- **severe brain injury diagnosed in the first seven days of life, when the baby:**
  - was diagnosed with grade III hypoxic ischaemic encephalopathy (HIE), or
  - was therapeutically cooled (active cooling only), or
  - had decreased central tone and was comatose and had seizures of any kind.

The definition of labour for Each Baby Counts includes:

- any labour diagnosed by a health professional, including the latent phase of labour
- when the woman has called the unit to report any concerns of being in labour, for example (but not limited to) abdominal pains, contractions or suspected ruptured membranes
- induction of labour
- when the baby was thought to be alive following suspected or confirmed pre-labour rupture of membranes.

Babies whose outcome was the result of congenital anomalies are excluded.

CRITERIA FOR MATERNAL DEATHS

The death of a woman while pregnant or within 42 days of the end of the pregnancy from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes.

- **direct** deaths resulting from obstetric complications of the pregnant state (pregnancy, labour and puerperium), from interventions, omissions incorrect treatment or from a chain of events resulting from any of the above
- **indirect** deaths from previous existing disease or disease that developed during pregnancy and which was not the result of direct obstetric causes, but which was aggravated by the physiological effects of pregnancy in the perinatal period (during or within 42 days of the end of pregnancy)
- excluding suicides.

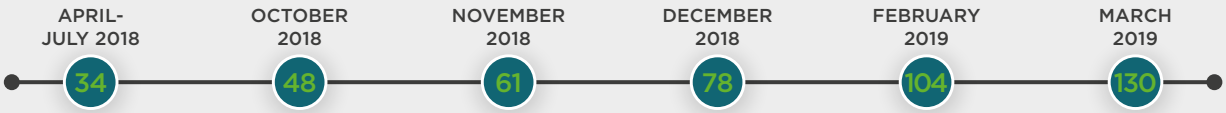
MATERNITY PROGRAMME ROLLOUT

We introduced a 12 month phased approach to working with over 130 maternity units across England to receive referrals across a regional footprint of 14 areas. HSIB expected to receive up to 300 referrals from May 2018 to March 2019 but the actual number was higher at 440 referrals.

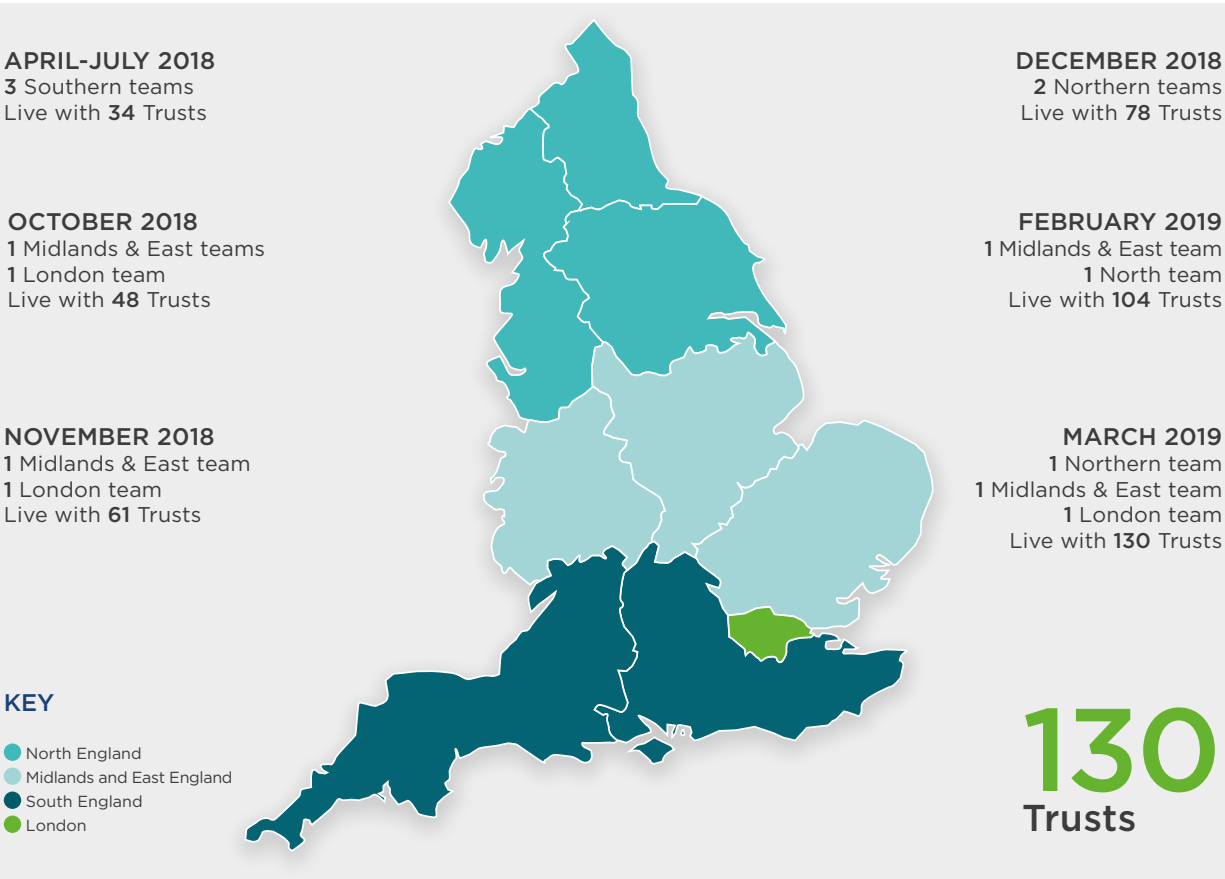
We began our maternity investigation programme in April 2018 with six maternity investigators joining HSIB. They completed an intensive training course before our first maternity investigations commenced in May 2018.

[6] MBRRACE-UK (Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK) runs the national Maternal, Newborn and Infant clinical Outcome Review Programme, which conducts surveillance and investigates the causes of maternal deaths, stillbirths and infant deaths.

MATERNITY ROLL OUT PROGRESS TIMELINE NUMBER OF TRUSTS 2018/19



MATERNITY ROLL OUT PROGRESS MAP 2018/19



A rolling recruitment programme continued throughout 2018 to build a flexible team of:

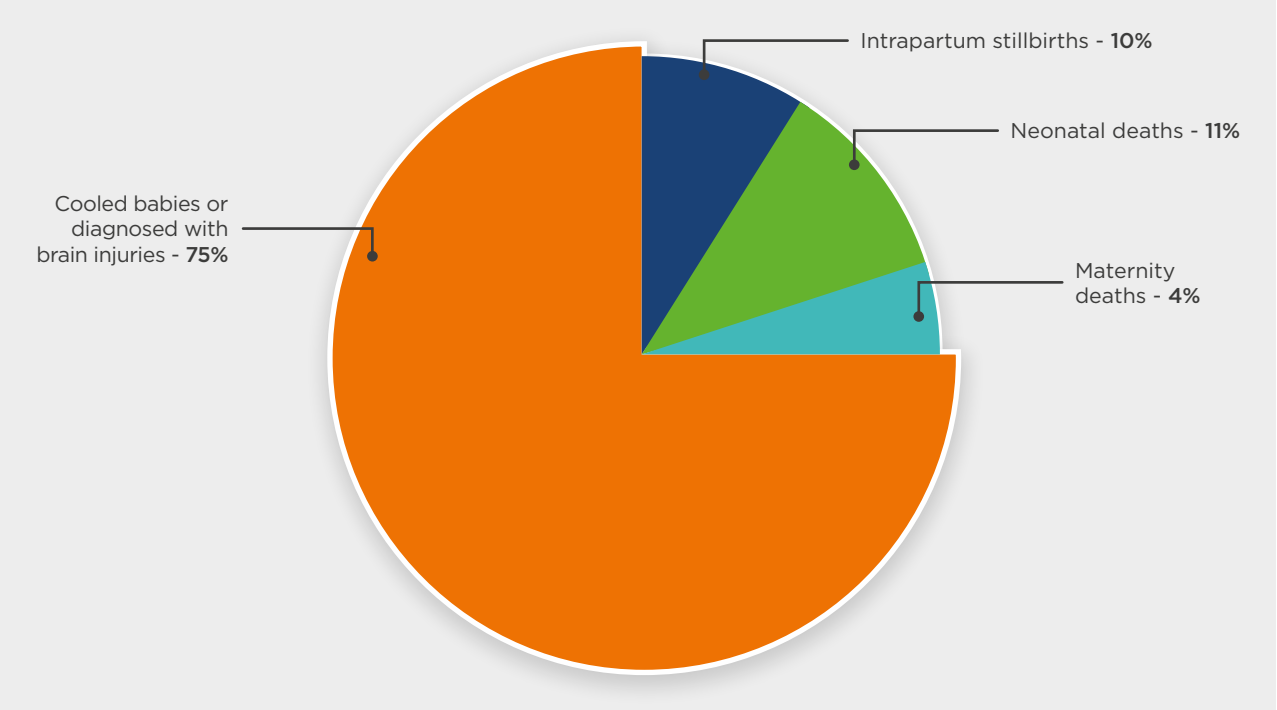
- Over 100 maternity investigators
- 14 maternity investigator team leaders
- A management leadership team of clinicians and non-clinicians
- A part-time team of clinical consultant advisors
- A bank of subject matter experts covering clinical, risk, human factors and other specialist skillsets

The final team of investigators were recruited in March 2019 and this was in parallel with the final region *'going live'* to enable all NHS funded maternity units in England to refer to HSIB from March 2019.

The full recruitment of the HSIB maternity workforce at the end of March 2019 will enable HSIB to manage expected referrals of circa 1000 for its first fully operational year across all English NHS maternity units (April 2019 to March 2020).

In April 2019, a further rolling recruitment programme commenced as the maternity investigator teams are predominantly secondees or fixed term contracts to enable a flexible workforce and funding model.

MATERNITY INVESTIGATION BY TYPES



OVERCOMING EARLY CHALLENGES

There have inevitably been challenges associated with the establishment of a new national programme, which has meant that at the end of March 2019 we were not completing our maternity investigations within the designated six-month timescale. However, our approach has evolved rapidly so we expect that we will be completing all but the most complex investigations well within the six-month deadline by the end of March 2020. We have ensured that families and trusts have been fully informed about progress throughout the investigations.

The early challenges have related to:

- the iterative learning and training required to develop our investigator teams
- the investigation methodology
- clarification of the scope of the Each Baby Counts criteria
- getting the processes right so that we are working in close partnership with trusts through the early stages of case handover, to ensure that all the appropriate information reporting, data governance and other considerations are fully met.

Trusts have been supportive through the transition phase. We are finding that in most cases the relationships with local maternity services and staff are strong, and that collaborative relationships based on trust, learning and improved communication are growing. This is fundamental to the success of the programme and will be a key priority for us through the coming year, as we start to share and work on themes at trust, regional and national level.

SHARING OUR LEARNING WITH TRUSTS AND ACROSS THE NHS

We are developing ways to share findings, recommendations and general themes from our investigations back to the trusts, to regional NHS local maternity systems and nationally, to ensure that we are helping to improve safety in a broader context. These include various methods of feedback throughout the investigation process.

- We provide immediate feedback to trusts if there are aspects of the care that we consider require urgent attention.

- We share regular feedback on the progress of cases and from next year will publish a summary of the themes identified from all referred cases.

- We share investigation progress reports with the trust's head of midwifery every two weeks.

- Once we have completed a number of investigations within a single trust, we hold a roundtable with that trust to share feedback on common themes, and raise actions that require immediate review to improve safety. This means trusts can take action without having to wait for our investigation reports to be completed.

BUILDING A PICTURE OF SAFETY RISKS ACROSS MATERNITY CARE

Our investigations are enabling us to identify and understand common themes that we find recurring in multiple trusts. We are already beginning to identify patterns and recurring themes which we are addressing in our recommendations to trusts, or which are emerging as underlying risks to safety at whole-system level and will require a national solution to address.

These themes include:

- Cases where women fall outside the normal expected pattern of labour or exhibit unusual or unfamiliar presentations. Hospitals, which are set up for optimal functioning, can this can find it hard to adapt in these cases. For example, the risk assessment, handling and management of women who present multiple times.

- Antenatal presentation concerns over inadequate risk assessment and attempt to normalise labour and not escalating appropriately.

- During labour, there are problems with escalation relating to teamwork and communication and diagnosing a decline in the mother baby.

LOOKING AHEAD: MATERNITY INVESTIGATIONS

Reporting on safety issues that occur across multiple investigations

In 2019/20 we will begin publishing reports on the thematic issues we have identified during our investigations. We expect to have our preliminary assessment of themes arising from the first 300 maternity investigations. We will publish an annual review setting out key themes based on this information.

Staying in touch with trusts

We will bring a programme of regular newsletters to all participating trusts and stakeholder organisations to keep them more regularly updated on the progress of the programme nationally, and to share learning.

Building investigation expertise within trusts

One of the key ambitions of the programme is that maternity investigators who complete their placement with HSIB will return to share learning about investigations and safety with in their own trusts.

SHARING LEARNING THROUGH NATIONAL PARTNERSHIPS

During the year we have worked closely with the regulators and professional bodies who can initiate change at a national level. These include the Royal College of Obstetricians and Gynaecologists' Each Baby Counts quality improvement programme, MBRRACE-UK and NHS Resolution.

At present these organisations have different remits which means there is often some overlap between our investigations and the work undertaken in these programmes. For example, MBRRACE-UK has a wider remit than the Each Baby Counts programme as it considers perinatal[7] mental health and late deaths.

Our aim is for our investigations to add learning and value to the work of other national maternity safety programmes, and we will continue to build on our work in this area in the coming year.

COMMUNICATING OUR MATERNITY INVESTIGATION WORK

In April 2019, following the complete roll out of our maternity investigations programme, we added a comprehensive new section to our website to explain this area of our work in more detail. The new content is aimed at families and the public, and the trusts and staff involved in maternity investigations. We regularly update the section to show progress, including the number of current maternity investigations and how many have been completed.

[7] Perinatal mental health problems are those that occur during pregnancy or in the first year following the birth of a child.

DEVELOPING OUR STAFF

STRATEGIC GOAL 2

Value and prioritise professional development for staff that includes internationally renowned safety investigation techniques and cutting-edge technology.

TO ACHIEVE THIS WE WILL:

1 develop and implement a workforce strategy and bespoke organisational development programme
2 develop and procure a bespoke safety investigation training programme with a recognised academic partner
3 develop and procure an expert IT partner to create a strategic transformation programme that exploits technological solutions that support an agile workforce.

TRAINING AND PROFESSIONAL DEVELOPMENT FOR INVESTIGATORS

As part of the establishment of our investigations function, we have made a significant investment in training and development for our investigators. They have all completed an intensive two to three week bespoke professional investigation training programme, which includes:

- a week at Cranfield University, which focuses on the importance of a human-factors based approach to investigation, considering all contextual, human and systemic issues relating to safety investigation

- a week at a local trust where trainee investigators consolidate their learning through the practical application of their skills on casework under supervision.

Learning from experts

Our investigators receive training in human factors, safety science and NHS services from leading experts in the country on these topics. We also ensure the ongoing professional development of our investigators through regular learning events and frequent engagement and advice from a team of subject matter advisors with expertise in obstetrics, neonatal care, midwifery, maternity nursing, and other relevant clinical specialities, when needed for a specific maternity or national investigation.

Working with patients and families

Maintaining a professional approach to all interviews or meetings is vital and HSIB investigators continue to display warmth and compassion to patients, families and staff. To maintain this high standard we will continue to ensure that each investigator is appropriately trained to conduct interviews in a sensitive and appropriate manner and is supported during challenging investigations to safeguard their wellbeing.

Reviewing training needs

In partnership with Skills for Health we have developed a transferable role template for a investigator. This is a document that defines the knowledge and understanding needed to perform the role. It also identifies performance criteria, to help us to measure investigators' effectiveness and competency. We can now use this to assist with our staff professional development and to review our training requirements.

LOOKING AHEAD: PROFESSIONAL SKILLS DEVELOPMENT

Improving our training

During 2019/20, we will build on the development of the maternity investigator role template by redesigning and facilitating the delivery of specific training requirements. We will work with other agencies where necessary to ensure our investigators have current knowledge, including in the area of family engagement.

SHARING LEARNING AND PROMOTING PROFESSIONAL SAFETY INVESTIGATIONS

STRATEGIC GOAL 3

Provide learning to the wider healthcare community and promote professional safety investigation.

TO ACHIEVE THIS WE WILL:

1 develop strategic alliances with academic, health and social care partners to diffuse our learning
2 develop and implement a communications and engagement strategy.

BUILDING RELATIONSHIPS AND CONTRIBUTING TO WIDER LEARNING

Our organisation is one part of a complex patient safety landscape across the NHS. Last year we continued to engage with other key organisations that aim to improve patient safety, to build awareness of our work and share learning.

Through our stakeholder engagement activities we are building strong working relationships with key strategic partners in the English healthcare sector including statutory and non-statutory bodies, health professions regulators and royal colleges.

We continue to receive many invitations to share our learning both across England's healthcare sector as well as the devolved nations. During the year our staff presented at academic safety courses, conferences and professional seminars. The audiences included clinical specialists, healthcare professionals and experts from industry, human factors and ergonomics.

The Intelligence Unit has been developing a clinical network and hosted an inaugural clinical network seminar to inform the healthcare community about professional safety investigation.

We are establishing memorandum of understanding agreements with the royal colleges, health and care professions regulators, the Department of Health and Social Care, NHS Improvement and others such as the Equality and Human Rights Commission. These documents are be published on our website and reviewed annually as part of our annual governance work plan.

LOOKING AHEAD: SHARING LEARNING AND PROMOTING PROFESSIONAL SAFETY INVESTIGATION

Exploring new ways of engagement

In the coming year we will expand our work to explore new ways of engaging with organisations in the context of both our maternity and national investigations. This is critical for ensuring we can obtain the support necessary to develop effective, evidence-based and implementable recommendations.

Continued global engagement

Our profile is growing internationally, and we are keen to continue engaging with other countries that are exploring how to establish safety investigation branches to share ideas and best practice. The World Health Organization's growing recognition of patient safety is an opportunity for HSIB to promote the benefits of patient safety investigation to a global audience of healthcare leaders. We will be exploring how we can work with patient safety world leaders over the forthcoming years and this will be set out in our new communications and engagement strategy that will be published in 2019/20.

International safety symposia

We intend to hold our first safety symposium in the forthcoming year. We will be sharing our early insights and learning from our national and maternity programmes. We will invite international safety leaders to share lessons from their work also, so that we support the expanding global movement for improving patient safety.

IMPROVING SAFETY INVESTIGATIONS

STRATEGIC GOAL 4

Improve investigation skills and techniques throughout the NHS by developing scientifically robust method-based principles learned from other industries and international research.

TO ACHIEVE THIS WE WILL:

1 improve the quality and consistency of NHS investigations
2 employ and train specialist investigators each year with a professional and world-renowned accredited safety training.

Supporting improved patient safety investigation across the NHS remains an important long-term priority for HSIB. To achieve this, considerable work needs to be done to improve the quality of safety investigations across the health service, and to improve the skills, methods and processes of safety investigation (Macrae and Vincent, 2014).

LAYING THE GROUNDWORK

In our first two years of operation we have focused on establishing our team of highly skilled investigators and developing the diversity of skills and knowledge needed for undertaking complex investigations in healthcare settings. This has involved working closely with subject matter advisers with expertise in areas such as human factors, and recruiting senior clinicians to our organisation, as well as continued professional development for our investigators in a wide range of investigation methodologies.

As we continue to learn and build our own specialised knowledge, we will seek opportunities to share our learning with healthcare professionals.

The focal point of this has been to create an innovation and learning hub to bring together and analyse feedback about our investigations from patients, families, the public, clinicians and trusts, and those involved in our investigations.

We are working towards the professionalisation of safety investigation, for example through the pioneering work we are have commenced with Skills for Health.

LOOKING AHEAD: PROFESSIONALISING SAFETY INVESTIGATION

The forthcoming NHS Patient Safety Strategy will provide an important framework for HSIB to consider as we take forward plans for developing the professionalisation of healthcare safety investigation in the NHS.

We will be recruiting a head of learning and development role to take forward this important objective.

EXEMPLARY GOVERNANCE

STRATEGIC GOAL 5

Be financially sustainable, well governed and legally constituted to support our independence.

TO ACHIEVE THIS WE WILL:

1 achieve non-departmental public body status by establishing the infrastructure to become a high performing independent organisation
2 develop robust governance, risk and assurance systems
3 establish a national HSIB citizens' panel.

ESTABLISHING OUR INFRASTRUCTURE

Since HSIB was established in April 2017 the organisation has grown rapidly from a small team of 27 people to 195 staff by the end of March 2019.

During 2018/19 we focused on building the high standard of corporate services and governance needed to support a fast-growing national organisation with a largely remote and highly mobile workforce.

To achieve this, we have:

- Developed a corporate governance work plan underpinned by the combined code of governance requirements for a well-governed and legally constituted public body. To support this, we worked closely with external experts, holding a series of workshops for our executives and senior management team.

- Evolved our decision-making processes in line with our expansion. A senior management team and a wider leadership team have been formed to devolve decision making to HSIB executives.

- Established robust governance assurance processes to clarify our relationship with our host organisation, NHS Improvement (NHSI). This has involved agreeing a memorandum of understanding with NHSI and associated service level agreements for corporate support functions.

- Developed our information governance[8] systems. We comply with NHSI's information governance policies and reporting procedures to help us identify and manage exposure to risk in relation to our data processing activities.

- Developed an IT transformation strategy so that we have a fit-for-purpose system for the future.

- Put in place systems to identify and manage risks to the organisation.

REPORTING ON OUR WORK

We report monthly to NHSI and to the Department for Health and Social Care (DHSC).

LOOKING AHEAD: EXTERNAL ORGANISATIONAL DEVELOPMENT REVIEW

As a learning organisation we will be working with external experts to review our functions and operating model to accommodate the requirements of the national and maternity investigation programmes as they mature.

[8] Information governance is the way in which an organisation handles information, in particular personal and sensitive information relating to individuals, such as patients and employees.

OUR PEOPLE

Recruiting and developing staff

In 2018/19 our organisational development focused on establishing workforce principles for the whole of HSIB, to enable a flexible rolling recruitment programme.

We established a training programme for the newly recruited maternity investigators. We successfully recruited a full complement of maternity investigators and management infrastructure. This enabled full coverage of all NHS maternity units in trusts in England by end of March 2019.

Throughout the year we held:

- an organisation-wide learning and § day
- a series of learning and feedback circles to support our continuous improvement journey
- in-house training programmes for all investigators to support their professional development
- quarterly learning events to support the maternity and national programmes
- equality, diversity and inclusion workshops
- emotional resilience workshops.

Staff Engagement Group

We have established a Staff Engagement Group (SEG) from across all our teams. The SEG has created a grass-roots programme of health and wellbeing activities such as team walks, virtual coffee mornings and charity bake-offs. It is looking to select a charity for future fundraising team and social events.

Peer support for investigation staff

We recognise that staff who engage with patients, families and other staff who have been exposed to traumatic incidents can be adversely affected.

Our peer support programme aims to enhance our staff wellbeing and employee assistance programmes. It provides a vital network for our staff to discuss their experiences and be provided help as required. To do this we have trained staff in Trauma Risk Impact Management (TrIM) to offer peer support.

LOOKING AHEAD: OUR PEOPLE

Developing our strategy and plans

During 2019/20 we will focus on organisational strategy development and workforce development, our corporate health and wellbeing plan and succession planning across the organisation to support improved business continuity and risk management.

Supporting the evolution of the Staff Engagement Group

We will develop our Staff Engagement Group further to broaden the membership and maximise opportunities for staff to be involved in a range of activities that support health, wellbeing and team building.

ESTABLISHING A CITIZENS' PARTNERSHIP

At its February 2019 meeting the HSIB Advisory Panel supported the establishment of a Citizens' Partnership to enable wider patient and public involvement in our work, and agreed the role of the Partnership Chair and members. Through the Citizens' Partnership, HSIB will benefit from the input of a group of individuals with diverse backgrounds, expertise and points of view. The Panel will provide the voice of the public as 'critical friends' who can influence and inform HSIB's work and ensure we receive feedback from wider networks on our initiatives and products.

LOOKING AHEAD: ESTABLISHING A CITIZENS' PARTNERSHIP

We will support and invest in the formation of the Citizens' Partnership, to be set up by the end of 2019.

We will be recruiting an independent chair to take forward this strategic priority.

OUR FINANCIAL PERFORMANCE

HSIB was formally established as a division of the NHS Trust Development Authority (NHS TDA).

The NHS TDA with Monitor operates as NHS Improvement.

The NHS TDA's financial performance and financial statements include those of HSIB. In note 3 of the NHS TDA's Annual Report and Accounts the HSIB is shown as a separate operating segment.

The HSIB is funded from parliamentary funding from the Department of Health and Social Care.

The financial obligation of the HSIB is to not exceed the agreed parliamentary funding allocation for the year.

HSIB FINANCIAL OBLIGATION

	2018/19	2017/18
Target: Funding allocation	£14,072,000	£3,800,000
Performance: Net expenditure	£11,922,000	£3,660,000
Obligation achieved	**Yes**	**Yes**

The accounts of the NHS TDA are prepared on a going concern basis.

FINANCIAL COMMENTARY

HSIB was directed by the Secretary of State for Health and Social Care to commence the maternity investigation programme in April 2018. As a result, the funding that HSIB received increased by £10,272,000 from £3,800,000 in 2017/18 to £12,273,000 in 2018/19.

The HSIB's net expenditure for the year was £11,922,000 (2017/18: £3,660,000). The main categories of expenditure are shown below.

MAIN CATEGORIES OF REVENUE AND EXPENDITURE

	2018/19	2017/18
Revenue	(£3,000)	-
Staff	£8,057,000	£2,355,000
Purchase of goods and services	£3,333,000	£975,000
Depreciation and impairment charges	£272,000	£130,000
Other operating expenditure	£263,000	£200,000
Total	**£11,922,000**	**£3,660,000**

The largest area of spend is staff costs, representing **68%** of net expenditure in 2018/19 (2017/18: 64%).

Purchase of goods and services relates to training, business travel, IT and communications, professional fees (including the fees of specialists on matters requiring expertise in particular fields) and premises.

Other operating expenditure is the cost to HSIB for the provision of back-office functions by NHS Improvement.

EQUALITY, DIVERSITY AND INCLUSION

STRATEGIC GOAL 6

To support and uphold equality across all our work areas, ensuring equitable and fair treatment, access and opportunity.

TO ACHIEVE THIS WE WILL:

1. develop and publish an HSIB equality strategy and action plan
2. invest in an equality, diversity and inclusion senior leader
3. work with the Equality Human Rights Commission to deliver mandatory public sector equality duty training to all staff
4. review our recruitment processes to ensure processes support equality of opportunity for all
5. review our information and communication materials to ensure they are accessible and that they meet plain English standards.

All public authorities in England, Scotland and Wales and bodies that carry out public functions must comply with obligations under the **Human Rights Act 1998** and the **Equality Act 2010**.

Complying with equality and human rights law is not only a matter of legal compliance, it improves patient safety and protects the rights of patients and their families and carers.

DEVELOPING OUR EQUALITY, DIVERSITY AND INCLUSION STRATEGY

In July 2018 we appointed an Equality, Diversity and Inclusion Officer who led the development of an equality, diversity and inclusion strategy.

The strategy will be reviewed both internally and externally before being published in 2019. It sets out:

- our current work to deliver on the objectives listed above
- our commitment to making equality and diversity part of all our decision making and policy
- future actions to work towards as the organisation prepares for arm's length body status.

The strategic plan will consolidate and advance activities that we have planned for, or that we have already started, including:

- exemplifying a strategic, sustainable and creative approach to equality and diversity in all our work, including decision making
- establishing policies and processes to prevent discrimination, and monitoring their implementation
- engaging with stakeholders, the public and staff through our work to promote diversity and tackle barriers to equality
- identifying and removing barriers that patients and families could experience during our investigations, for example, putting in place translation and interpretation and other formats for accessibility
- recognising and treating all people as individuals with their own experiences and needs
- collating and analysing data and evidence from investigations to gain insight into family experience before, during and after our investigations
- involving experts by lived experience in investigation teams
- synthesising feedback from the public and investigation process to inform learning for future investigations

- collating data on our workforce equality and diversity profile and understanding how we can improve this.

Our initial development of equality and diversity within HSIB has benefited from the advice and support of a range of bodies and individuals.

The Equality and Human Rights Commission (EHRC) has been instrumental in providing information, training and clarity on our duties under the Equality Act 2010.

This collaboration continues and a memorandum of understanding between the two organisations has been drafted pending confirmation of the EHRC's future direction following consultation on its business plan.

EQUALITY IN OUR WORKFORCE

We have produced the first HSIB report on equality in the HSIB workforce. It relates to the appointment of 174 HSIB staff in 2018/2019.

Data was provided by our host organisation, NHS Improvement (NHSI), which is responsible for HSIB staff recruitment processes, and the report follows the format of the NHSI Equality Report.

The report details recruitment according to the characteristics that are protected under the Equality Act (age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, and sexual orientation).

It is a requirement for HSIB to publish under:

'The provisions of the Equality Act 2010 (Specific Duties) Regulations 2011 require the NHS Trust Development Authority (including the HSIB), as a public body, to:

- *annually publish information to demonstrate compliance with the Public Sector Equality Duty (PSED). This information must include, in particular, information relating to persons who share a relevant protected characteristic who are its employees (provided the organisation has 150 or more employees) and other persons affected by its policies and procedures;'*

As we gather data year on year, we will be able to establish trends and obtain a deeper understanding of the issues affecting any of the protected characteristics in our workforce.

This will help us to ensure that our recruitment methods are fair and transparent for all and support us in our goal to recruit a workforce that is representative of the diverse population.

The training we provide to new staff and recruiting managers includes a session on unconscious bias.

Our job advertisements and interview questions underline our commitment to attracting a diversity of applicants and demographic spread as befits a public service organisation.

BUILDING OUR INCLUSIVENESS

Citizens' Partnership

One of HSIB's objectives is to establish a Citizens' Partnership to enable wider patient and public involvement in our work.

We anticipate that all Citizens' Partnership members will champion diversity for the organisation, and be empowered to challenge any areas where HSIB's products fall short of accessibility, or where equality and diversity are not reflected in our decision making.

Involving experts by lived experience

We routinely engage subject matter advisers in our investigations to provide clinical and technical expertise. However, our investigations will be more credible and accurate if we also involve experts by lived experience.

Experts by lived experience are people who are currently using or have used regulated health and social care services during the past five years. They are also family/carers of relatives who have used or are currently using regulated health and social services.

Their first-hand experience of using services means experts by lived experience can offer a unique perspective. Their contribution increases the scope of evidence gathering, providing a clearer picture of a service or related topic to give professionals a better understanding of how the needs of people using services can be met.

They can also help with the development and improvement of services and reduce barriers to open communication. Engaging with experts by lived experience is a priority for the coming year in our national investigations programme.

LOOKING AHEAD: EQUALITY AND ACCESSIBILITY

Gathering data to inform improvements
A staff survey has been conducted by an external supplier and the results of this will inform our future equality, diversity and inclusion work programme.

Monitoring equality in the context of maternity care
We will collect data to determine whether there is a link between poorer outcomes in maternity care and protected characteristics under the Equalities Act, to inform how we support safer maternity care.

Improving our online accessibility
We are funding a significant project to ensure the information on our website is accessible to all users, including those with disabilities, and that the website complies with all relevant accessibility guidelines.

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WWW.HSIB.ORG.UK
@hsib_org

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 submitting a safety awareness form.

@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 Fridays (not bank holidays) from 0900hrs to 1700hrs. We aim to respond to enquiries within five working days.

To access this document in a different format – including braille, large-print or easy-read – please contact **enquiries@hsib.org.uk**.