HSIB

HEALTHCARE SAFETY INVESTIGATION BRANCH

WWW.HSIB.ORG.UK

19/20

Healthcare Safety Investigation Branch

Annual Review 2019/20

Keith Conradi, Chief Investigator

Chief Investigator

Welcome to the Healthcare Safety Investigation Branch (HSIB) Annual Review 2019/20, which has been produced from deep within the confines of the COVID-19 lockdown. Although we are looking forward to returning to our core activity, it is perhaps an apt time to remind ourselves of what was achieved in the previous year and this publication aims to do just that.

The 15 national investigation reports published in this period received significant attention, both from the national bodies where the safety recommendations were directed and from the wider public and media. Nowhere was this more typified than the publication of our report 'Undetected button and coin cell battery ingestion in children', which identified measures to prevent similar tragic accidents happening in the future. These included a safety recommendation to the Department for Business, Energy and Industrial Strategy which, as a direct response, has commissioned a new specification covering household products and batteries to mitigate the risk of ingestion.

In fact, during the period of this Annual Review we have addressed 58 safety recommendations to 26 organisations and programmes as well as making 46 safety observations and 29 safety actions as a direct result of our investigations.

To fully monitor the progress of promised measures to improve patient safety, NHS England and NHS Improvement has established a Patient Safety Committee which will allow the HSIB to escalate any concerns about the quality of safety recommendation responses. I see this as a significant step towards the adoption of a wider healthcare safety management system with safety investigation playing a prominent role.

This period also saw a full year of HSIB maternity investigations across all maternity units in England. Analysis of the first 125 reports identified several underlying themes culminating in the publication of our report, 'Summary of Themes arising from the Healthcare Safety Investigation Branch Maternity Programme' in March 2020. Individual reports on each of the summarised themes will be published over the coming year.

Elsewhere we appointed Professor Murray Anderson-Wallace as the Chair of our Advisory Panel and Patrick Vernon OBE as Chair of our Citizens' Partnership. Patrick will now work with us to establish this new partnership, which will ensure that the patient and public perspective is fully embedded into all our investigations.

Finally, I want to mention the draft Health Service Safety Investigations

Bill, which received a second reading in the House of Lords before falling as a result of the December general election. I am excited that it remains a legislative priority and firmly believe that the status of the Health Service Safety Investigations Body (HSSIB) as an independent arm's length body is as crucial as ever.

There has been a huge amount of hard work from everyone within the HSIB during this period and I want to thank them and acknowledge the support of our stakeholders in the wider healthcare sector. The HSIB is now fully established as an integral part of the healthcare safety system.

Keith Conradi
Chief Investigator

Advisory Panel

Advisory Panel

The Advisory Panel is a group of independent people who, through professional or personal experience, have developed expertise in the fields of healthcare, patient safety and safety investigations.

Its core role as defined under section 9 (3) of the HSIB Directions is to ensure the independence of HSIB investigations.

In addition, the Advisory Panel has continued to use its broad range of knowledge to provide the HSIB with feedback and advice to strengthen the systemic impact of safety recommendations.

During 2019/20 the Advisory Panel has focused on three main priorities:

- Advocating for primary legislation and supporting the establishment of HSIB as an independent statutory body.

- Contributing to the development of the Citizens' Partnership as a primary means of widening participation and creating a stronger public voice in the strategic development of the HSIB. This included the appointment of the Chair of the Citizens' Partnership, a role now occupied by Patrick Vernon OBE, who also joins the Advisory Panel as a full member.

- Continuing to provide feedback on HSIB operations from the panel's professional and personal networks.

In anticipation of a transition towards a more independent future, the Advisory Panel contributed to an external review of HSIB's operating model and governance. In the absence of progress towards the establishment of a shadow non-executive board, the responsibility for oversight and performance management of the HSIB remains with NHS England and NHS Improvement and the Department of Health and Social Care. The Advisory Panel uses its position to ensure external challenge, critique and comment on the status, operation and outputs of the HSIB to ensure greater professional, public and patient perspectives of the HSIB's work.

The Advisory Panel will continue to strongly support the establishment of the HSIB as an independent statutory body, and very much hopes to see significant progress during 2020/21. In the meantime, the Advisory Panel will continue to support the HSIB in whatever ways it can, within the constraints of its mandate.

Professor Murray Anderson-Wallace, Chair

Advisory Panel members

Professor Murray Anderson-Wallace, Chair

Steve Clinch

Dr Mike Durkin OBE

Farrah Pradhan

Dr Joe Rafferty CBE

Dr Suzanne Shale

Jennie Stanley

Patrick Vernon OBE

Richard von Abendorff

Visit our website for more information about the **Advisory Panel**.

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

HSIB

Contents

About the HSIB

Our organisation

We are dedicated to improving patient safety, and 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 England and NHS Improvement [1], but we operate independently.

Our work

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 have the potential to cause harm to patients. Through safety recommendations to specific organisations we aim to improve healthcare systems and processes, in order to reduce risk and improve patient safety. We share our findings through effective communications and engagement across the wider health and social care system, as well as internationally.

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 and maternity investigations.

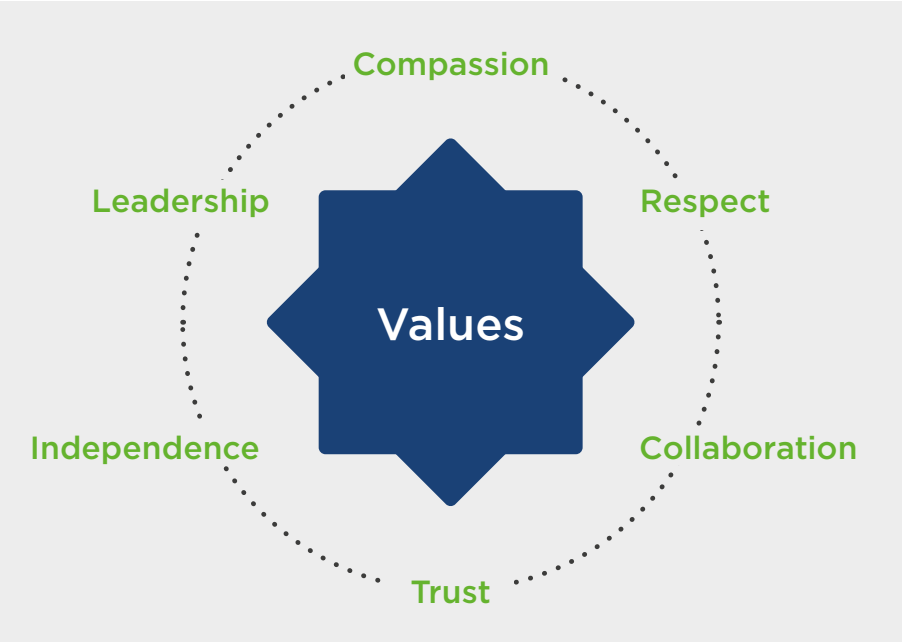
National investigations: Concerns about patient safety in any area of NHS-funded healthcare in England can be referred to us by any person, group or organisation. We review these concerns against our investigation criteria to decide whether to conduct a national investigation. National investigation reports are published on our website and include safety recommendations for specific organisations. These organisations are 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 [2] and MBRRACE-UK [3]. 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 March 2020 we published our first maternity National Learning Report [4] which summarises the themes arising from the HSIB maternity investigation programme. In-depth learning reports will be published on some of the themes identified, with others progressing into national investigations.

Our values

Our values were developed with staff and align with the NHS Constitution.



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.

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.

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.

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.

Leadership

- We have a workplace 'just culture' [14] that values people and relationships, ensuring all the HSIB staff have the ability to speak openly and honestly but retain accountability.
- We are accountable for our conduct and our decisions.

Our highlights 2019/20

Family engagement

Family information has now been developed and is available in over

20 languages to ensure greater inclusivity

Intelligence Unit

109

patient safety referrals received

Maternity investigations

515

maternity reports completed

National investigations

58

national safety recommendations made

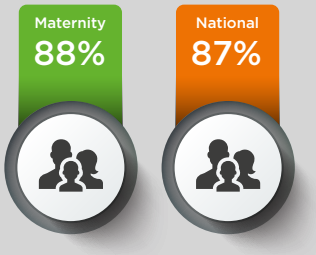
Equality, diversity and inclusion

The HSIB Citizens' Partnership will promote and advocate the voice of patients and the public around safety investigations in the NHS.

Patrick Vernon OBE appointed as Chair of the HSIB Citizens' Partnership

Maternity/national investigations

% of families engaging with our investigations



Communications and engagement

100%

of national investigation reports appeared in national, regional, local or trade press

Our people

91%

of staff took part in our first staff survey

Responsibilities, accountability and independence

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

Through this Annual Review we report every year to the Secretary of State on our performance in meeting our core functions. We also make our annual reviews available on our website.

Our functions and responsibilities were established in two sets of secondary legislation [5] 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 Bill, which would establish a new, fully independent body to investigate healthcare safety incidents in the NHS in England.

The Bill began its journey through Parliament last year, receiving its first reading in the House of Lords on 15 October 2019 and its second a fortnight later. The early general election of December 2019 restarted the process and means the Health Service Safety Investigations Bill will need to go through Parliament again before gaining Royal Assent. The Bill will make us independent in legal terms, provides the powers to conduct effective investigations and sets out the provisions for protected disclosure (commonly known as 'safe space'). As a statutory body, we will be governed by an executive and non-executive board.

Our strategic goals and objectives

Our organisation has five strategic goals underpinned by a suite of specific and measurable objectives.

The five goals are:

Strategic goal 1
Undertake independent safety investigations with objectivity, underpinned by competence, credibility and integrity.

Strategic goal 2
Value and prioritise professional development for staff that includes internationally renowned safety investigation techniques and cutting-edge technology.

Strategic goal 3
Provide learning to the wider healthcare community, and promote professional safety investigations by improving investigation skills and techniques throughout the NHS.

Strategic goal 4
Be financially sustainable, well governed and legally constituted to support our independence.

Strategic goal 5
To support and uphold equality across all our work areas, ensuring equitable and fair treatment, access and opportunity.

Our strategic goals underpin everything we do and act as a framework for this Annual Review as we set out our achievements, activities and finances from 1 April 2019 to 31 March 2020.

We are one of the first organisations in the world to conduct independent investigations into patient safety concerns.

Our mission is 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.

Throughout the year we have continued to develop our processes and have become more streamlined and efficient, particularly in the production of national and maternity reports.

Our five strategic goals reflect our responsibilities as set out in law and in our agreements with the Department of Health and Social Care and with our host organisation, NHS England and NHS Improvement. Each goal is underpinned by actions required to achieve it.

The 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:

- operate as an exemplar within safety investigation
- carry out up to 30 national investigations per year
- carry out approximately 1,000 maternity investigations per year
- not apportion blame or liability within our investigation reports
- influence improvements in quality, safety and patient experience through professional investigations that identify systemic learning
- involve patients and families in investigations, as far as practicable and appropriate
- 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 to 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.

Table 1 shows at a glance the differences in our approach to national and maternity investigations.

Table 1 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	12	130
Number of investigations	We were set the task of carrying out up to 30 investigations per year.	We were set the task of completing around 1,000 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.	All investigators attend an intensive three-week training programme and additional training and updates are provided throughout the year.
Referrals	Any person, group or organisation can refer a patient safety concern to the 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 in Each Baby Counts or MBRRACE-UK (see [2] and [3]).
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. We ask organisations to 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. The trust 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

We identify 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 [6]
- thematic reviews, which involve starting with a theme 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 (which are summarised in figure 1) are based on:

Outcome impact

We assess the scale and severity of the actual or potential harm that an issue represents. 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 issue has 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 and persistent across the healthcare system. Some events that occur within very different healthcare settings share 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. For example, we might decide not to investigate an issue that has already been extensively investigated and for which robust recommendations for improvement already exist. On the other hand, we have initiated national investigations on a number of safety issues that have already received a lot of attention (such as some recurring Never Events [7]), but where existing interventions are clearly not robust enough, or correctly directed, to prevent an issue from recurring.

Figure 1 HSIB criteria for a national investigation

National Investigation Team

The National Investigation Team comprises three principal national investigators and 12 national investigators working across England, with a head office base in Farnborough and a regional base in Derby.

We have many subject matter advisors with clinical and non-clinical backgrounds who we can call upon at any given time. We have a bank of experts by lived experience, who can also support our investigators. Table 2 lists the reports published in this Annual Review period.

Table 2 National reports published

Investigation number	HSIB reports in order of publication
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
I2019/003	Wrong patient details on blood sample
I2018/020	Management of chronic health conditions in prisons
I2018/018	Electronic prescribing and medicines administration systems and safe discharge
I2018/025	Detection of retained vaginal swabs and tampons following childbirth
I2019/001	Lack of timely monitoring of patients with glaucoma
I2017/002b	Delayed recognition of acute aortic dissection
I2018/022	Potential under-recognised risk of harm from the use of propranolol
I2018/021	The diagnosis of ectopic pregnancy
I2018/026	Undiagnosed cardiomyopathy in a young person with autism
I2020/001	Summary of Themes arising from the Healthcare Safety Investigation Branch Maternity Programme – National Learning Report [4]

In addition to the national reports we have already published, the following investigations are ongoing, but not completed for 2019/20.

Table 3 Ongoing national investigations

Investigation number	Investigation title
I2020/003	Severe brain injury, early neonatal death and intrapartum stillbirth associated with group B streptococcus infection – National Learning Report
I2020/004	Neonatal collapse alongside skin-to-skin contact – National Learning Report
I2018/023	Management of venous thromboembolism risk in patients following thrombolysis for an acute stroke
I2018/019	Identifying and reducing high-risk prescribing errors in hospital
I2020/005	Risks associated with larger babies – National Learning Report
I2020/007	Giving families a voice: HSIB's approach to family engagement during investigations – National Learning Report
I2019/008	Unplanned delayed removal of ureteric stents
I2019/007	Administering insulin from a pen device in hospital
I2019/009	Procurement, usability and adoption of 'smart' infusion pumps
I2019/013	Residual drugs in intravenous cannulae and extension lines
I2019/006	Placement of nasogastric tubes
I2019/004	Medicine omissions in learning disability secure units
I2019/011	Outpatient appointments intended but not booked after inpatient stays
I2018/024	Recognition of the acutely ill infant
I2019/012	Emergency response to heart attack
I2020/006	Healthcare Safety Investigation Branch report on Never Events – National Learning Report

Investigation number	Investigation title
I2019/018	Wrong patient surgery
I2019/017	Wrong tooth extraction
I2019/016	Timely recognition and treatment of suspected pulmonary embolism in inpatients
I2020/009	Prescribing insulin from a pen device in hospital
I2019/015	Timely detection and treatment of spinal nerve compression (cauda equina syndrome) in patients with back pain
I2019/020	Delays to intrapartum intervention once fetal compromise is suspected
I2019/010	Management of chronic asthma in children

Published national reports and safety recommendations 2019/20

Inadvertent administration of an oral liquid medicine into a vein (April 2019)

R/2019/028 - It is recommended that **NHS Improvement**, through the National Patient Safety Alert Committee, set standards for all issuers of patient safety alerts which make clear that alert issuers should assess for unintended consequences of the actions in the alert, the effectiveness of barriers created by these actions, and provide appropriate advice for providers on implementation, including ongoing monitoring.

R/2019/029 - It is recommended that **NHS Improvement** support the development of necessary knowledge, skills and capacity for the effective operationalisation of hazard identification and risk analysis at a national, regional and local level, as an integral part of the National Patient Safety Strategy.

R/2019/030 - It is recommended that the **Royal College of Physicians**, in collaboration with the Royal Pharmaceutical Society, British Pharmacological Society, Royal College of General Practitioners, Royal College of Paediatrics and Child Health, NHS Improvement, the professional bodies for the professions regulated by the Health and Care Professions Council, Royal College of Nursing and Royal College of Midwives, provide leadership in recommending the postgraduate learning needs and activities to standardise professional development in medicines safety processes.

R/2019/031 - It is recommended that **NHS Improvement** undertake a formal evaluation of banding, time and resource given to the Medication Safety Officer role across England and publish its findings and mandate minimum resources and standards.

Recognising and responding to critically unwell patients (April 2019)

R/2019/032 - The **Royal College of Physicians** NEWS advisory group continues to evaluate the implementation and use of NEWS2 [8], including but not limited to:

- the use of NEWS2 in practice, in particular the consistency of recording, the consistency of response, and the communication of patient measurements between healthcare professionals
- the effectiveness of NEWS2 in identifying a patient's level of acute illness in different care settings and patient groups
- the presentation of NEWS2 information and how this supports clinicians to identify trends, particularly in electronic records
- the guidance and training on the use of NEWS2 as part of clinical assessment and patient monitoring.

R/2019/033 - **NHS England/NHS Improvement** should expand the remit of the Cross-System Sepsis Programme Board to include physical patient deterioration, involving additional stakeholders as required.

Undetected button and coin cell battery ingestion in children (June 2019)

R/2019/034 - It is recommended that the **Department for Business, Energy and Industrial Strategy** develops a strategy to improve button/coin cell battery safety, to include producing a fast-track standard covering/ considering battery design, product casing, packaging and safe retailing practices.

R/2019/035 - It is recommended that the **Royal College of Paediatrics and Child Health** develop a key practice point within a decision support tool for suspected or known ingestion of button/ coin cell batteries, and to be supported in this development by the Royal College of Emergency Medicine.

R/2019/036 - It is recommended that the **Association of Ambulance Chief Executives** agrees guidance that can inform its members on the competency and authority for staff to convey, refer and discharge children under five years who are subject to 999 calls.

R/2019/037 - It is recommended that the **College of Paramedics** develops supervision guidance for paramedics, applicable to all relevant practice settings.

R/2019/038 - It is recommended that the **Department for Business, Energy and Industrial Strategy** highlights to the general public the dangers of button/coin cell batteries.

Failures in communication or follow-up of unexpected significant radiological findings (July 2019)

R/2019/039 - It is recommended that the **Royal College of Radiologists**, working with the Society and College of Radiographers and other relevant specialties through the Academy of Royal Medical Colleges, develops:

1 principles upon which findings should be reported as 'unexpected significant', 'critical' and 'urgent'

2 a simplified national framework for the coding of alerts on radiology reports

3 a list of conditions for which an alert should always be triggered, where appropriate and feasible to do so.

R/2019/040 - It is recommended that **NHS England and NHS Improvement's** patient safety team takes steps to ensure providers are aware of the safety recommendations in this report and act to implement the key findings regarding risk controls such as a monitored acknowledgement system for critical, urgent and unexpected significant findings.

R/2019/041 - It is recommended that **NHSX** develops a method of digitally notifying patients of results. This should be used to inform patients of unexpected significant radiological findings after an agreed timeframe. It should be developed in conjunction with the Royal College of Radiologists. The notification system should be tested and evaluated.

R/2019/042 - It is recommended that the **Care Quality Commission** amends all appropriate core service frameworks to include risk controls identified in this report, to mitigate the risk of significant abnormal findings not being followed up.

Management of acute onset testicular pain (September 2019)

R/2019/043 - It is recommended that the **National Institute for Health and Care Excellence** revises the content and accessibility of its Clinical Knowledge Summary on testicular torsion.

R/2019/044 - It is recommended that the NHS England/ Improvement **'Getting It Right First Time'** programme ensures that testicular torsion/ acute testicular pain is included on the checklist of emergency pathways to be considered by the newly established Urology Area Networks across England.

R/2019/045 - It is recommended that **NHS England/Improvement** works with relevant stakeholders to develop guidance for handling telephone advice/triage in primary medical care settings.

Wrong patient details on blood sample (September 2019)

R/2019/046 - It is recommended that **NHSX** should take steps to ensure the adoption and ongoing use of electronic systems for identification, blood sample collection and labelling systems in NHS trusts.

Management of chronic health conditions in prisons (October 2019)

R/2019/047 - It is recommended that the **Care Quality Commission** amends its inspection criteria to ensure that interprison transfer processes are fully encapsulated within the inspection schedule to assure the provision of care throughout.

R/2019/048 - It is recommended that the **National Prison Healthcare Board for England** oversees work to implement interoperability between SystmOne and the Prison National Offender Management Information System, enabling sharing of essential information across the prison service which does not impinge on the confidentiality requirements of either system.

R/2019/049 - It is recommended that the **NHS England/ Improvement** health and justice national commissioning team review how they monitor and assure the provision of healthcare in prisons to reduce variability in standards, particularly in the areas of incident reporting and investigations.

Electronic prescribing and medicines administration systems and safe discharge (October 2019)

R/2019/050 - It is recommended that **NHSX** develops a process to recognise and act on digital issues reported from the Patient Safety Incident Management System.

R/2019/051 - It is recommended that **NHSX** supports the development of interoperability standards for medication messaging.

R/2019/052 - It is recommended that **NHSX** continues its assessment of the ePRaSE pilot and considers making ePRaSE a mandatory annual reporting requirement for the assessment and assurance of electronic prescribing and medicines administration safety.

R/2019/053 - It is recommended that the **Department of Health and Social Care** should consider how to prioritise the commissioning of research on human factors and clinical decision support systems, particularly in relation to the configuration of software system alerting and alert fatigue, to establish how best to maximise clinician response to high-risk medication alerts.

R/2019/054 - It is recommended that **NHS England and NHS Improvement** include in the Medication Safety Programme shared decision making and improved patient access to medication information across all sectors of care, to ensure a person-centred approach to safe and effective medicines use.

R/2019/055 - It is recommended that **NHSX** produces guidance for configuring the electronic discharge process, and how electronic prescribing and medicines administration systems should be interfaced with such a process.

Detection of retained vaginal swabs and tampons following childbirth (December 2019)

R/2019/058 - It is recommended that **NHS England/Improvement** carries out its intention to commission and publish an independent evaluation of its alternative design for swabs and tampons. The evaluation should also consider other solutions or technologies and include usability, cost/benefit analysis and the impact on reducing harm.

Lack of timely monitoring of patients with glaucoma (January 2020)

R/2020/059 - It is recommended that the **Royal College of Ophthalmologists**, working with relevant stakeholders, develop models and review workforce required for the optimal delivery of glaucoma care. The models should be tested and evaluated.

R/2020/060 - It is recommended that **NHS England/Improvement** require commissioners to agree, under their service contracts, the action that providers will take to ensure compliance with the Portfolio of Indicators for Eye Health and Care follow-up performance standard. Where the standard has not been met, there should be a requirement for providers to demonstrate that they have reviewed individual pathways and taken action to mitigate risk, as well as to understand the causes.

R/2020/061 - It is recommended that **NHS England/Improvement** commission NHS Digital to publish reports of hospital eye services' compliance with the follow-up appointments performance standard

included in the Portfolio of Indicators for Eye Health and Care.

R/2020/062 - It is recommended that **NHS England/Improvement** review the payment for the ongoing management of patients with glaucoma, regardless of setting. Pricing should reflect the complexity and costs of follow-up appointments and encourage new ways of working.

R/2020/063 - It is recommended that **NHS Digital** include provision for identifying, prioritising and monitoring patients at risk of developing sight loss within the next version of the national Commissioning Data Set. Provision should include the ability to record a risk rating and the recommended follow-up date for each patient, meaning these are mandated data items for collection by hospital eye services. This should be carried out in consultation with key stakeholders such as the Royal College of Ophthalmologists and patient administration system suppliers.

R/2020/064 - It is recommended that the **Royal College of Ophthalmologists** agree criteria for the risk stratification of patients with glaucoma so that practice can be standardised across NHS hospital eye services.

R/2020/065 - It is recommended that the **International Glaucoma Association** facilitate the funding of research into the development and evaluation of an automated, predictive risk stratification tool.

Delayed recognition of acute aortic dissection (January 2020)

R/2020/066 - It is recommended that the **Manchester Triage International Reference Group** considers the addition of 'aortic pain' to the Manchester Triage System as a discriminator for chest pain, to raise awareness of acute aortic dissection as a potential cause.

R/2020/067 - It is recommended that the **Royal College of Emergency Medicine**, together with the **Royal College of Radiologists**, develops, deploys and evaluates a national evidence-based process to detect and manage patients with acute aortic dissection presenting to emergency departments. The process should form part of a wider strategy for managing non-cardiac chest pain in the emergency department.

Potential under-recognised risk of harm from the use of propranolol (February 2020)

R/2020/068 - It is recommended that the **British National Formulary** reviews and updates guidance on the use of propranolol in the treatment of anxiety and the advice provided for beta blocker overdose.

R/2020/069 - It is recommended that the **National Institute for Health and Care Excellence** reviews and updates guidance on the use of propranolol in the treatment of anxiety and migraine, with particular reference to the toxicity of propranolol in overdose.

R/2020/070 - It is recommended that the **Royal College of General Practitioners** supports its members in identifying the potential risk of prescribing propranolol to patients in at-risk groups.

R/2020/071 - It is recommended that the **Royal Pharmaceutical Society** supports its members in identifying the potential risk of prescribing propranolol to patients in at-risk groups.

R/2020/072 - It is recommended that **PrescQIPP CIC** supports its subscribers to identify the potential risk of prescribing propranolol to patients in at-risk groups.

R/2020/073 - It is recommended that **NHS England/NHS Improvement** evaluates current approaches to the clinical oversight of overdose calls within ambulance control rooms and leads on work to develop a national framework to describe the requirements for appropriate clinical oversight of overdose calls.

R/2020/074 - It is recommended that the **Association of Ambulance Chief Executives** works with the National Poisons Information Service to review its guidance on the treatment and transportation of patients known to have taken an overdose of propranolol or other beta blocker medication.

The diagnosis of ectopic pregnancy
(March 2020)

R/2020/075 - The **National Institute for Health and Care Excellence** should review and revise the clinical knowledge summary for 'urinary tract infection (lower) – women' to include ectopic pregnancy as a category under 'alternative or serious diagnoses'.

R/2020/076 - The **Royal College of Emergency Medicine** should provide standardised discharge information for clinicians to offer to women following discharge from the emergency department with a problem in early pregnancy and while awaiting further assessment by early pregnancy services.

R/2020/077 - The **Royal College of Obstetricians and Gynaecologists** should provide guidance on the information that should be provided during referral to early pregnancy units to standardise and improve the flow of information required to identify those most at risk from ectopic pregnancy and any consequent deterioration.

R/2020/078 - It is recommended that the **Care Quality Commission** Services Framework for Gynaecology and Termination Services includes an assessment of early pregnancy services, using as a reference the National Institute for Health and Care Excellence Guideline 126, Ectopic pregnancy and miscarriage: diagnosis and initial management.

Undiagnosed cardiomyopathy in a young person with autism (March 2020)

R/2020/079 - It is recommended that the **Royal College of Anaesthetists** convenes a working group to provide additional guidance regarding the responsibilities for obtaining consent for MRI and other non-invasive diagnostic and/or therapeutic procedures under general anaesthetic in children.

R/2020/080 - It is recommended that the **Royal College of Anaesthetists** reviews standards for pre-assessment services, including their purpose, the required observations and examinations, and competencies of staff undertaking this work.

R/2020/081 - It is recommended that **NHS England and NHS Improvement** strengthens its 'Learning disability improvement standards for NHS trusts' by including metrics which enable organisations to assess their progress against the outcomes for specialist learning disability teams.

R/2020/082 - It is recommended that as part of the work to support the NHS Long Term Plan, **NHS England and NHS Improvement** should develop a role and competency framework for learning disability liaison nurses, to ensure that people with learning disabilities and autistic people receive optimal care which respects and protects their rights.

Undiagnosed cardiomyopathy in a young person with autism (March 2020)

R/2020/083 - It is recommended that **NHSX** develops a system for sharing care plans for patients with autism, learning disabilities or learning difficulties to enable reasonable adjustments to be made.

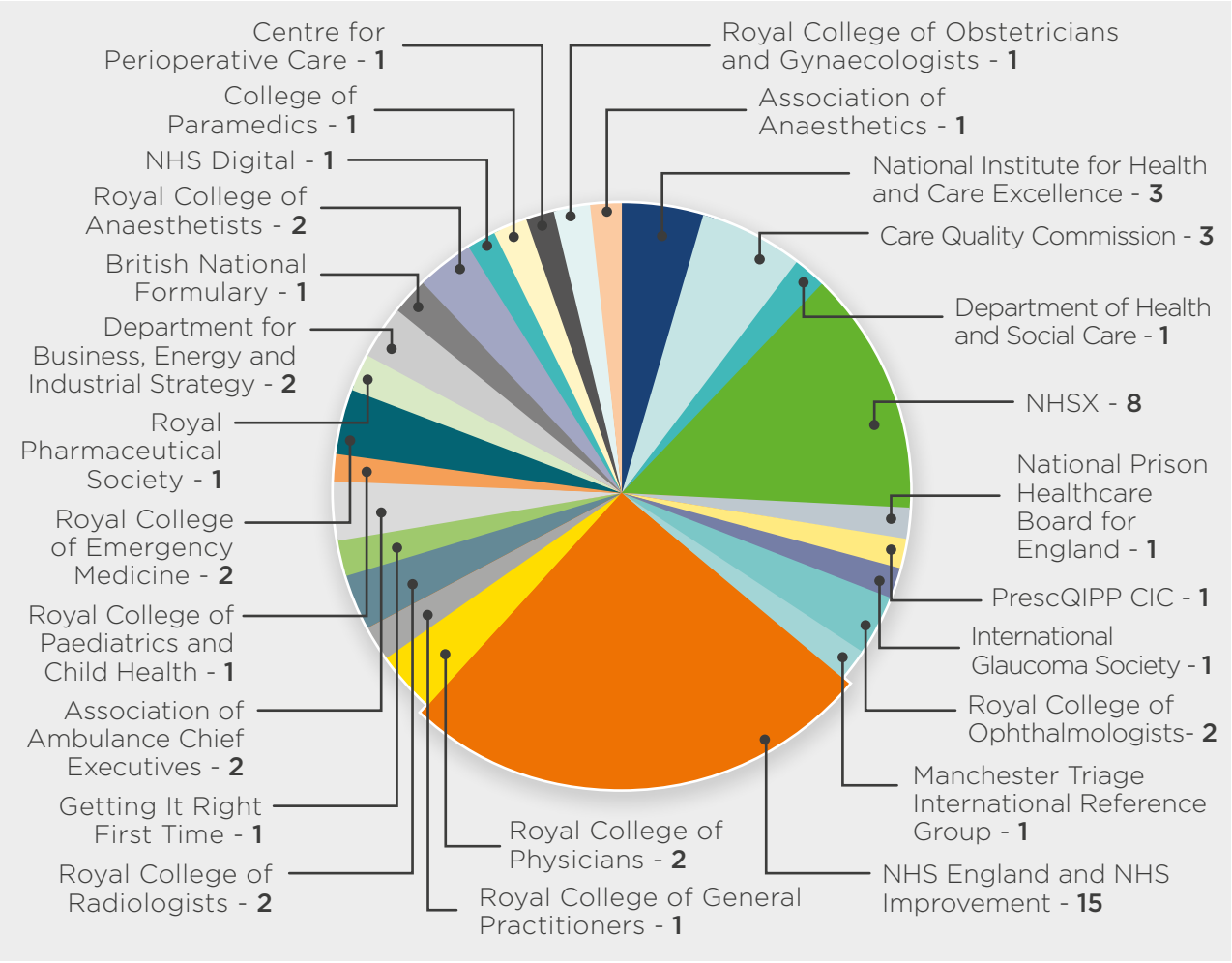
R/2020/084 - It is recommended that **NHSX** develops a standardised care passport, which should include sections to support patients with autism, learning disabilities or learning difficulties.

R/2020/085 - It is recommended that the **Centre for Perioperative Care** considers the remit of the National Safety Standards for Invasive Procedures (NatSSIPs) to cover the administration of general or regional anaesthesia for non-invasive diagnostic procedures.

R/2020/086 - It is recommended that the **Association of Anaesthetists** reviews the dissemination and implementation of its 'Quick reference handbook' on managing adverse events during anaesthesia.

Responses to our safety recommendations throughout 2019/20

Figure 2 Recipients of HSIB safety recommendations in 2019/20



We have had an excellent response to all the recommendations we have made during the year.

During 2018/19 we made 30 recommendations to 14 organisations, whereas in 2019/20 we have made 58 recommendations to 26 organisations and programmes (see figure 2) and have had a 100% response rate; a number of these recommendations have already been implemented.

This strong response is encouraging and demonstrates the positive benefits that other organisations believe the HSIB can bring to improving patient safety in the NHS and across the wider health and care system.

Over the following pages we highlight our journey over the last year and some of the recommendations and safety actions which have already been implemented during 2019/20 due to our reports.

Refining our approach

We have continued to refine our processes and the way we work. As a national investigation body it is important for us to improve and review our investigation process. During 2019/20 we have:

- enhanced our use of feedback from families and stakeholders to improve the quality of our investigations
- embedded a more formal debriefing stage as part of the investigation process
- routinely used information from feedback and debriefing to improve our processes
- created a specific forum to generate and monitor improvements to the investigation process (the Investigation Improvement Group)
- begun to populate an operational manual to describe our processes and standard operating procedures
- accelerated development of a case management IT system to align with current investigation processes and provide efficiencies.

Making change happen through our recommendations

Below are some examples of the broad range of safety recommendations and the outcomes from some of our national investigations.

Undetected button and coin cell battery ingestion in children

Our investigation into undetected button and coin cell battery ingestion in children concerned a reference event where a child died following the unknown and undetected ingestion of a coin cell battery. The report was published in June 2019 and we made five safety recommendations to national bodies. Their responses were published on our website in January 2020, and significant progress has been made in respect of all.

In summary:

- The Office for Product Safety and Standards commissioned the British Standards Institute to produce a Publicly Available Specification (PAS) for button and coin cell batteries and household products that use them. The new PAS will provide a guide to best practice for manufacturers and retailers of the batteries, and the household products in which they are used, with respect to packaging, product casing, labelling and disposal, to mitigate the risk of ingestion.

- The Royal College of Paediatrics and Child Health, supported by the Royal College of Emergency Medicine, is producing a Key Practice Point (KPP) on button battery ingestion in children. KPPs are comprehensive guides covering common signs, symptoms and critical care situations to help clinicians make the right decisions.

- The Association of Ambulance Chief Executives is bringing together partners to review the available evidence and undertake a case review. This is being undertaken to try and agree guidance that can inform its members on the competency and authority for staff to convey, refer and discharge children under five years who are subject to 999 calls.

- The College of Paramedics is in the process of drafting supervision guidance for paramedics working in all care settings. They are also working with the Association of Ambulance Chief Executives to produce supervision guidance for ambulance service staff. The intention is that the guidance produced for paramedics in other care settings will complement the advice provided for paramedics and other clinicians working in ambulance services.

Digital systems

The use of digital systems across the healthcare landscape continues to expand and it has been no surprise that we have completed several investigations that have identified where improvements in patient care could occur. Since its formation last year we have placed eight recommendations with NHSX [9]. The sharing of patient records with the appropriate care provider and the use of digital systems to support wider understanding were key attributes that were identified. These are highlighted in the following investigations:

- ‘Electronic prescribing and medicines administration systems and safe discharge’ (published in October 2019) identified that there were no standards for system interoperability for medication messaging and that system users needed guidance on configuring their respective electronic discharge processes. We also commented on electronic prescribing systems in ‘Potential under-recognised risk of harm from the use of propranolol’ (February 2020).

- ‘Wrong patient details on blood sample’ (September 2019), identified that steps to ensure the adoption and ongoing use of electronic systems for identification, blood sample collection and labelling should be taken.

- ‘Undiagnosed cardiomyopathy in a young person with autism’ (March 2020) identified that a standardised digital care passport (which should include sections to support patients with autism, learning disabilities or learning difficulties) should be developed. NHSX has piloted this functionality. It needs to be embraced across all healthcare settings to gain maximum effect.

- ‘Failures in communication or follow-up of unexpected significant radiological findings’ (July 2019) identified that a method of digitally notifying patients of results should be developed. This system would need to be a collaboration between different national bodies and needs to be tested and evaluated before being widely adopted.

Digital systems will continue to feature in many of our investigations, particularly as more digital systems are used to support care delivery and new ways of working and sharing information are identified. These need to be evaluated and embraced where appropriate, but can improve delivery of care.

For many patients their first contact with the health care system will be via the NHS 111 or 999 services. Both services have featured in the investigations we have completed this year and in ongoing investigations. Our investigation ‘Potential under-recognised risk of harm from the use of propranolol’ (February 2020) focused on an incident in which a young woman died due to an overdose. We highlighted that current approaches to the clinical oversight of overdose calls within ambulance control rooms need to be re-evaluated.

Safety improvements for placement of nasogastric tubes

In October 2019 we launched an investigation looking at implementation of safety improvements for the placement of nasogastric (NG) tubes. The investigation began after we

were notified of a patient who inadvertently had an NG tube inserted into his lung rather than his stomach. There is a risk of serious harm and risk to life if NG tubes are incorrectly placed into the lungs and feed is passed through them.

During the investigation of the reference event, boxes of non-CE marked [10] pH testing strips were still in circulation on critical care units, alongside the new enteral pH strips [11]. These two types of pH testing strips had different pH scales and used different colour coding schemes to represent the pH level. If the non-CE marked strip was exposed to a neutral substance such as a respiratory tract sample, and then inadvertently read against the CE marked enteral pH testing strip scale, it would read as strongly acidic, falling in the 2.0 to 3.0 range. A pH of 2.0 to 3.0 would indicate that the NG tube was correctly placed in the stomach.

As both these boxes of pH strips were kept together in the same area and the pH strips were very similar in appearance, it was possible that, in the reference event, the strip was compared to the wrong container, giving false reassurance that the NG tube was correctly placed.

Although most other providers will have transitioned to pH paper that has been CE marked for use on human gastric aspirate, the investigation identified risks related to the correct reading and interpreting of pH. These include:

- CE marked pH strips from manufacturers can have different pH colour coding scales.
- If a provider has more than one type of pH strip in circulation at the same time, there is a similar risk of error – comparing a pH strip from one manufacturer against a container that might have a different pH scale.
- A lack of understanding of how to read a pH strip. There is no standardised competency framework and delivery model for training and assessment in nasogastric tube placement and undertaking pH checks.
- While a reliable process when performed correctly, the result of a pH test of aspirate may be influenced by feed/medication once 24-hour feeding has commenced.

As we believed this issue may have represented a risk across other units, an interim bulletin was published in February 2020. It made organisations aware that there is not a standard scale or colour scheme across the different manufacturers. If organisations have CE marked enteral pH testing strips from more than one manufacturer in use at the same time, there is potential for error. The investigation is ongoing and will be published during 2020/21.

Management of chronic health conditions in prisons

We are not limited to guiding improvements in primary and secondary care settings, and we have been identifying improvements to other care delivery settings. Our investigation into the 'Management of chronic health conditions in prisons' (October 2019) placed a recommendation to the National Prison Healthcare Board for England. This requires it to enable sharing of appropriate information between the prison health electronic record system and the custodial services system. NHS Digital has been working with the Ministry of Justice to explore technical solutions to provide this information sharing, with due regard for patient confidentiality. They are anticipating testing new approaches in information sharing across the two systems from autumn 2020. This will be a significant milestone in providing end-to-end care for all people within the custodial system. The issue of electronic patient records not being shared appropriately has been a factor in many HSIB investigations, such as our investigation into 'Electronic prescribing and medicines administration systems and safe discharge' (October 2019).

Design and safe use of portable oxygen systems

After our report 'Design and safe use of portable oxygen systems' was published (November 2018) we were invited to discuss our findings with a manufacturer in February 2020. Our original report highlighted several issues including:

- variability in valve configuration after use
- the lack of a clear visual indicator that a valve is open or closed
- the integral valve design does not offer a clear indicator of the current state of the valve.

The manufacturer recognised that safety improvements could be made and reacted to the report. We were invited as part of a stakeholder group to comment on new concepts to improve safe delivery of oxygen to a patient. While this would result in improvements to one component of the end-to-end system, it should enhance overall safety in portable oxygen systems.

Additionally, an Australian consultant who contributed to our report has since developed a face mask which

has now gained a CE mark. The facemask indicates whether there is flow/no flow of medical gas to the patient – an improvement in safe delivery of oxygen to a patient.

Looking ahead

Throughout 2020/21 we will thematically analyse all the national investigation reports we have published in our first three years of operation. We will publish a National Learning Report that will identify common themes across our investigations and this will inform the future selection of HSIB investigations. Often investigations in different settings or circumstances can raise similar themes. For example, difficulties in monitoring vital signs and then summoning help seem to be common in healthcare safety incidents whether in maternity units, emergency departments or children's hospitals.

In collaboration with our maternity team we will also thematically analyse our maternity investigation reports to understand common risks that require further investigation by the national team. In these national investigations the 'reference cases' have already been investigated by the maternity programme and we will expand these investigations to explore the national aspects around guidance, service provision and regulation of services.

We continue to explore innovative ways of investigating safety incidents and we will explore areas such as the use of interview transcription and qualitative analysis software to maximise our use of interview evidence.

We are also mindful of the impact that the COVID-19 pandemic will have on our operations during 2020/21, due to the need to visit healthcare settings and observe staff at work, and to see their healthcare processes and workplace environment in real time.

The Intelligence Unit

The Intelligence Unit (IU) identifies safety risks and reference cases for national investigations that offer strong opportunities for system-wide learning and safety improvement.

To achieve this the IU:

- analyses a variety of intelligence sources to understand the healthcare landscape and systemic safety risks
- processes all new notifications to the HSIB, including engaging with patients, families, academics, clinical experts and healthcare professionals
- hosts the HSIB's links to safety research and relevant academic institutions
- continually updates and maintains a body of intelligence relating to healthcare issues in our Safety Intelligence Research (SIRch) database

Intelligence Unit highlights

We have extensive research knowledge and expertise in intelligence analysis and human factors [12], and team members are from a variety of backgrounds including clinical, operational and academia.

In 2019/20 the IU:

- received **109** patient safety referrals
- presented **30** intelligence review reports for consideration for national investigation
- developed a strategic approach to national investigation selection which includes defining three areas for particular investigation focus.

National investigation referrals in 2019/20

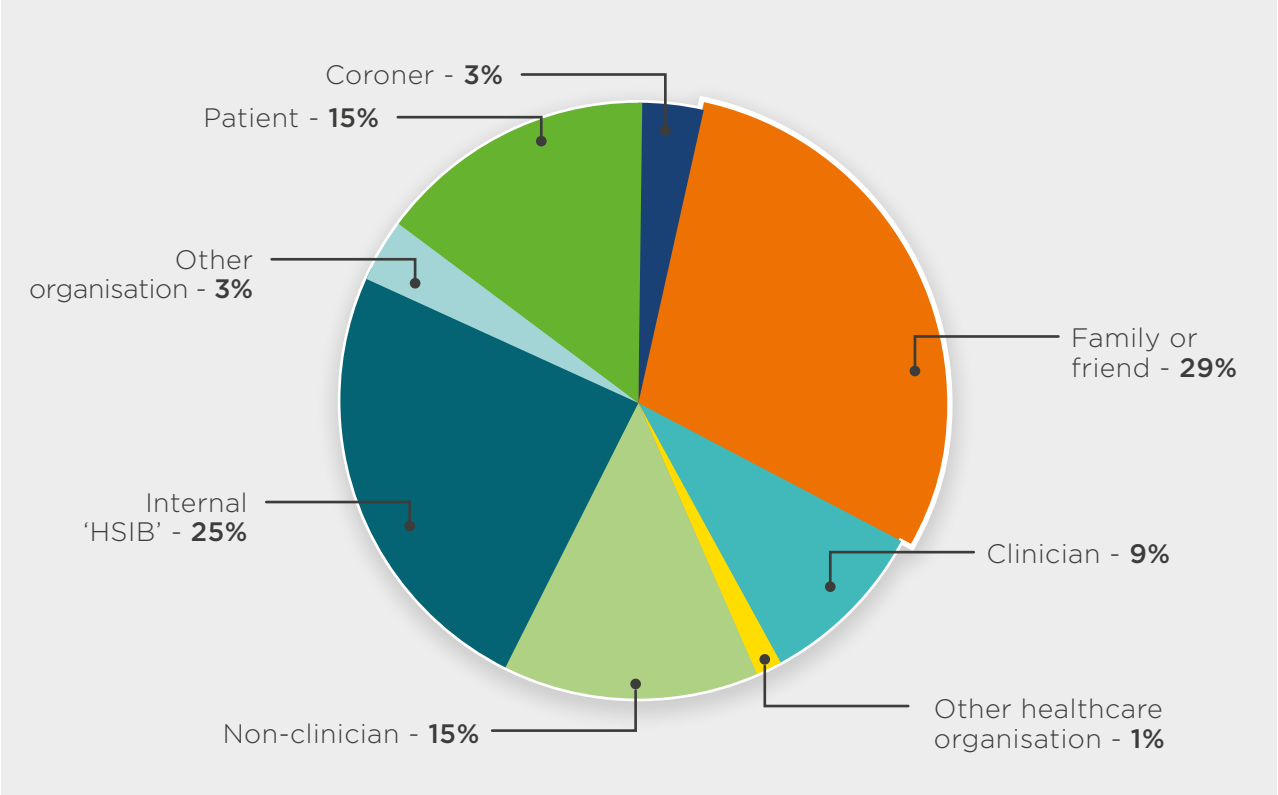
Notifying organisations/ individuals

We receive referrals via several routes (see figure 3). External referrers include healthcare professionals (clinicians), family members and other healthcare workers such as those working in safety, risk and governance roles. Internal referrals are either received from HSIB employees or are generated through our intelligence searches and monitoring.

Figure 3 Key

Clinician	A medical professional currently working in a clinical role
Other healthcare organisation	An organisation involved in healthcare but which does not provide direct services, such as clinical commissioning groups, Care Quality Commission, NHS England, Nuffield Trust
Non-clinician	Patient safety managers, governance leads, risk managers
Other organisation	A non-healthcare organisation, for example a solicitor, media organisation (journalist)

Figure 3 Referrals received during 2019/20 according to referrer type



National investigations by care setting

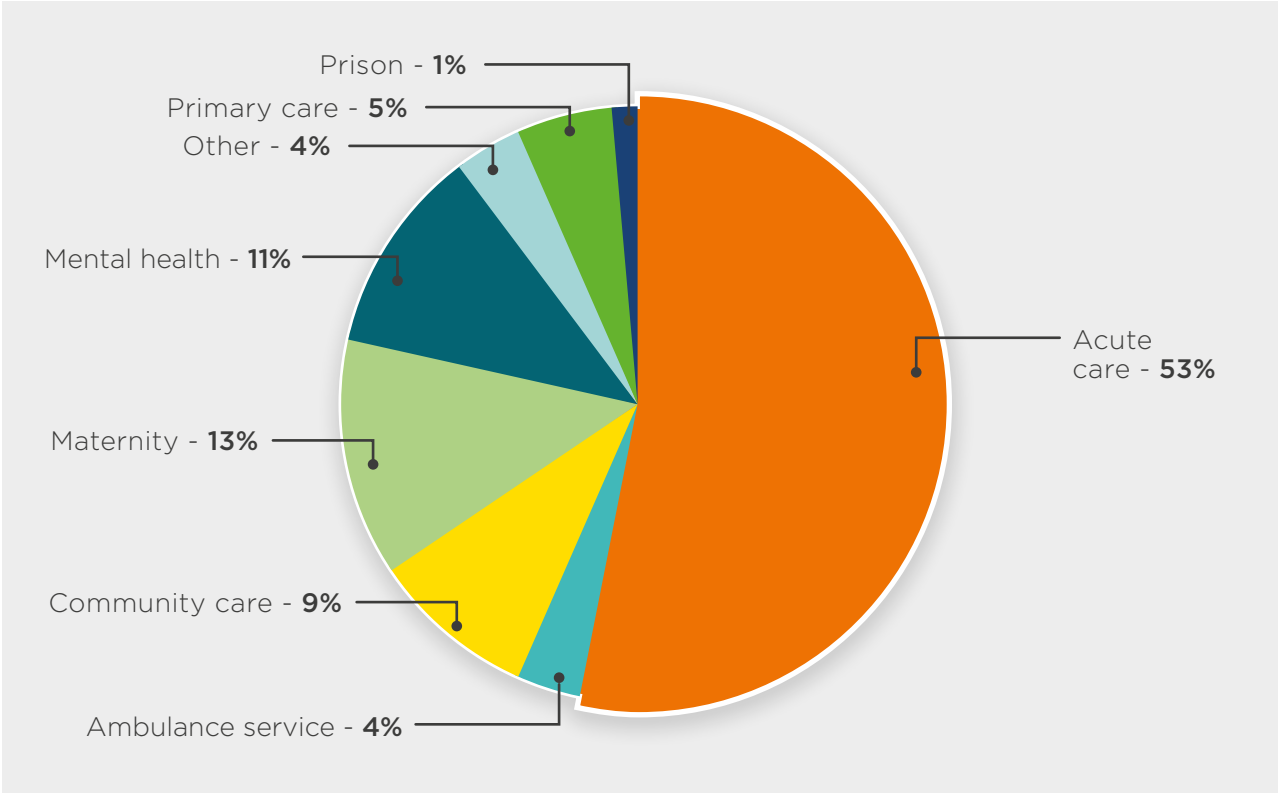
Our national investigations cover a range of NHS-funded care settings in England. While most of our national investigations are conducted within acute care, other settings include ambulance services, community care and maternity services. Figure 4 shows our referrals during the year according to care setting.

How national investigations are selected

We hold regular Scrutiny Panel meetings to make decisions regarding new national investigative work to ensure any investigation meets the organisation's national investigation criteria.

We develop intelligence review reports (IRRs) which summarise the intelligence we have gathered and the IRRs are then reviewed to aid the selection of investigations during the panel process.

Figure 4 Referrals received in 2019/20 according to care setting



Strategic approach to investigation selection

In 2020 we improved our approach to investigation selection. Our new approach involves investigating multiple incidents related to a particular 'focus area'.

The HSIB Scrutiny Panel is now divided into two parts:

Part I – responsive. It is important to remain responsive to external referrals therefore Part I reviews IRRs related to recent referrals that meet the HSIB's national investigation criteria.

Part II – focus areas (new for 2020). Review of IRRs related to a specific investigation focus area defined as part of a strategic approach to investigation selection.

This will enable us to explore and understand safety risks in greater depth over a 12-month period, building new learning from past reports across multiple investigations.

Specialist intelligence analysis

The IU is staffed with qualitative and quantitative research expertise to provide specialist intelligence analysis and inputs into all aspects of our work, including:

- leading on the development of an analysis framework for analysing maternity investigation reports to understand common themes
- assisting in the analysis of our survey work, particularly regarding family engagement and trust feedback
- contributing to our Investigation Improvement Group initiatives
- forging academic collaborations.

SIRch database

The IU manages and collates a large amount of incoming intelligence and has created the SIRch database. It is being used to provide a central location for collation of incoming HSIB intelligence and to inform the selection of national investigations.

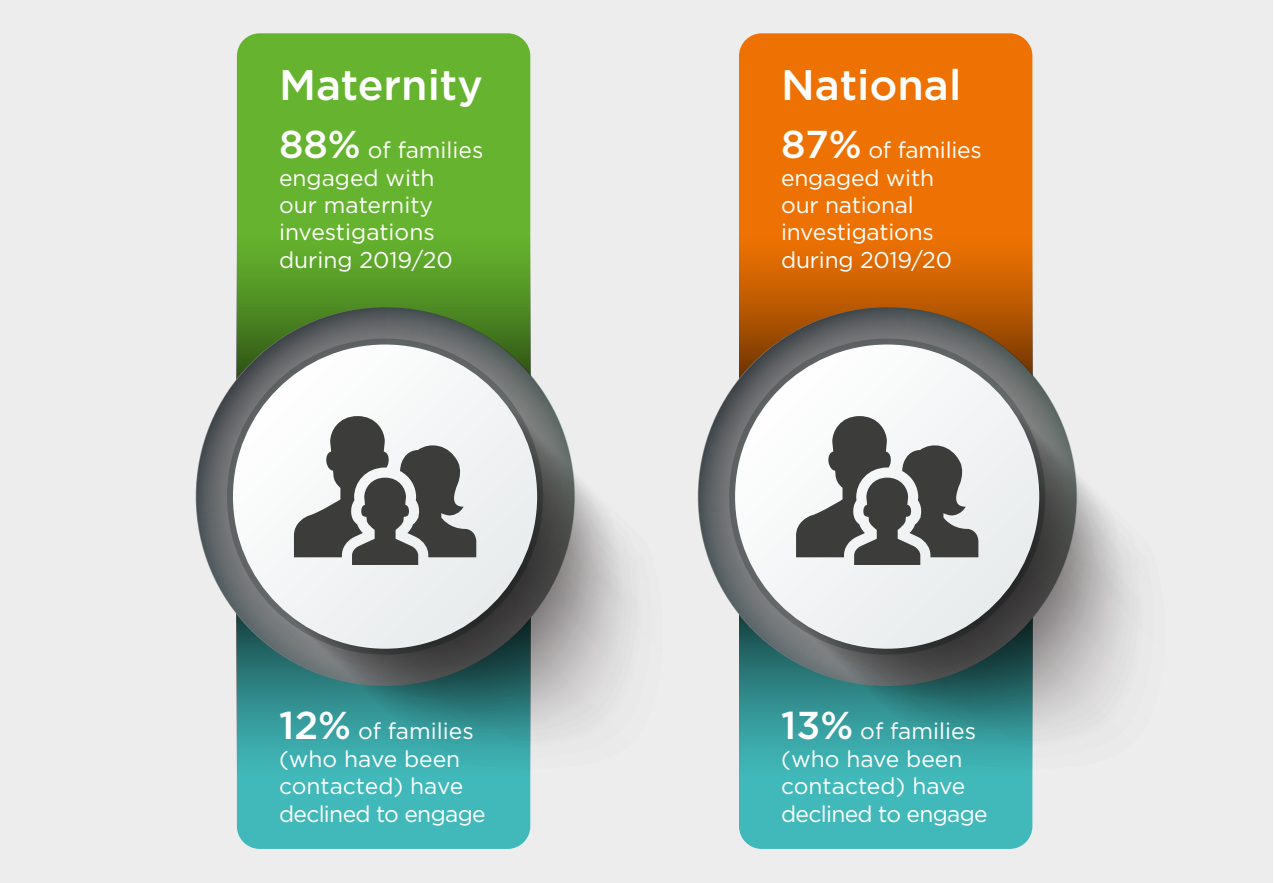
Focus areas for 2020/21

1. Prevention and management of inpatient falls during in-hospital stay.
2. Ensuring a safe environment for inpatients with mental health needs.
3. Minimising time between presentation, further investigation and onward management of cancer.

We anticipate that over the next two years we will publish up to three themed reports which will review learning emerging from national investigations into the defined focus areas.

We selected these three focus areas in January 2020. We acknowledge the impact COVID-19 is having on healthcare and so we will continue to review our focus areas for 2020/21 to ensure our national investigations reflect significant risks to patient safety.

Patient and family engagement



The way we conduct our investigations means we want to have a positive and open dialogue with the families who are central to our investigations.

Meaningful family engagement and the participation of patients, carers and family members continues to be a priority for our investigations. Successfully and sensitively working with families throughout the process can produce a high-quality investigation, valuable learning across the system and an improved investigation experience for all involved.

Our approach to family engagement encompasses the entire investigation process, aiming to facilitate involvement and support from an early stage.

We have designed several resources to help families understand aspects of our investigations. These resources are reviewed regularly. They include such items as an introductory card, a one-page guide explaining the 10 steps of a maternity investigation and a sample report to prepare families for what an investigation report may look like. These resources are available in different languages and can be produced in alternative formats.

We ensure families are treated as integral to our investigations, and we conduct training and development sessions specifically to assist investigators who are working with families.

Family feedback

Listening to the views and suggestions of those that we have worked with is an important aspect of ensuring we review and learn about our approach to family engagement.

With the help of some families who were involved in our earlier investigations, we developed a feedback process. All families are asked whether they would like to give feedback at the conclusion of their investigation. This process has been in place since July 2019. However, more recently, in January 2020, an opportunity to provide feedback earlier in the investigation was introduced.

A thematic analysis of feedback to date was conducted in October 2019 with the primary objective of collating insight and learning. This analysis identified three overarching themes:

- communication
- investigation process
- the HSIB as an organisation.

Communication

Families highlighted the importance of:

- being able to speak with a named investigator
- the compassion shown by investigators
- feeling listened to
- the inclusion of family members
- being kept up to date
- HSIB providing better signposting to other agencies for support.

Investigation processes

Views from families were:

- the investigation process was thorough
- it took too long to complete investigations.

A small proportion of families felt HSIB investigations should apportion blame.

HSIB as an organisation

- Families felt that HSIB investigations had the potential to improve patient safety.

In addition, any feedback received is reviewed and action taken where necessary. Families have been incredibly helpful with endorsing what works well, and have also made suggestions for new resources and improvements to current literature and processes.

Training our investigators

Family engagement induction training has continued for any new investigators joining our organisation. This training is supported by development workshops, which have covered topics such as:

- accessing language services
- assessing risk
- working with distressed families
- media and social media
- safeguarding
- working with families with additional needs
- best practice when sharing reports.

Additional professional development has been provided in the form of enhanced bereavement training, where we have worked with the stillbirth and neonatal death charity Sands and Cruse Bereavement Care.

Staff support

In recognition of the important and difficult role we ask of our staff, several investigators have been trained and accredited to deliver peer support. Wider opportunities to attend resilience training have been open to all staff with the aim of building their own resilience as well as supporting others.

Looking ahead

During 2020/21 we intend to publish a report which will provide an overview of our approach to family engagement in our investigations. The report will:

- describe our approach to family engagement in our investigations and what has informed our practice
- describe what has worked well in our approach to family engagement
- summarise what families and staff are telling us about our approach
- explain what we have learned and set out plans for future work.

What families say about our engagement

Thank you for all your dedication and hard work.

We are lucky to have HSIB.

I would just like to thank you and the team who worked on my case. Every step of the investigation was explained thoroughly, and she [the investigator] did it with a lot of compassion and sensitivity towards myself and my family. If I ever had any questions, she very promptly answered these and assured me I could contact her at any time. It is very reassuring and useful to have a report to look back on, and to understand exactly what went wrong that day and maybe feel a little bit more at ease that this won't necessarily happen again in future, I hope! I'd just like to thank her for such a thorough report, it's very clear a lot of time and effort went into producing it.

In such a horrible situation you have helped provide my husband and I with not only answers, but emotional support.

It was helpful for us to feel that our side of the story was heard and considered appropriately, which gave us confidence that the findings would be representative of the truth.

Absolutely fantastic. I just want to say a massive thank you for your hard work, patience and kindness. I will be forever grateful for the support and guidance you have provided to me and my family during this difficult experience.

Maternity investigations

Our maternity investigations began in April 2018, and we became operational in all 130 trusts with maternity units in England from March 2019. We have now received referrals from all of them.

Following referral, investigations are carried out through 14 teams of investigators across England, each team working closely with a designated group of trusts. The teams are overseen and supported by regional leads and clinical advisors with extensive midwifery and obstetric experience.

Maternity programme overview

Our maternity investigation programme is part of a national action plan to make maternity care safer. Our investigations meet the Each Baby Counts criteria for infant deaths and injuries [2], as well as those set out for maternal deaths as defined by MBRRACE-UK [3]. 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.

During 2019/20 we had **1,168** referrals and progressed **867** cases through to investigation. Where we did not progress a case to investigation this was either because we did not receive family consent, or the case did not meet our criteria for investigation.

As an organisation we have been tasked with carrying out maternity investigations because we are in a unique position as a national and independent investigating body. Our investigations follow a thorough, independent and impartial process and are focused on learning and not attributing blame. The involvement of the family is a key priority.

Our maternity investigations:

- identify the factors that may have contributed towards death or injury
- use evidence-based accounts to establish what happened and why
- make safety recommendations to improve maternity care both regionally and nationally.

Criteria for maternity investigations

Incidents that are eligible for investigation include those that involve term babies (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 but was born with no signs of life.

Early neonatal death

When the baby died within the first week of life (zero to six days) of any cause.

Severe brain injury

Diagnosed in the first seven days of life. These are any babies that fall into the following categories:

- diagnosed with grade III hypoxic ischaemic encephalopathy (HIE) [17], or
- therapeutically cooled (active cooling only), or
- had decreased central tone [18] and was comatose and had seizures of any kind.

The definition of labour in the Each Baby Counts criteria 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.

Incidents involving babies whose outcome was the result of congenital anomalies are excluded.

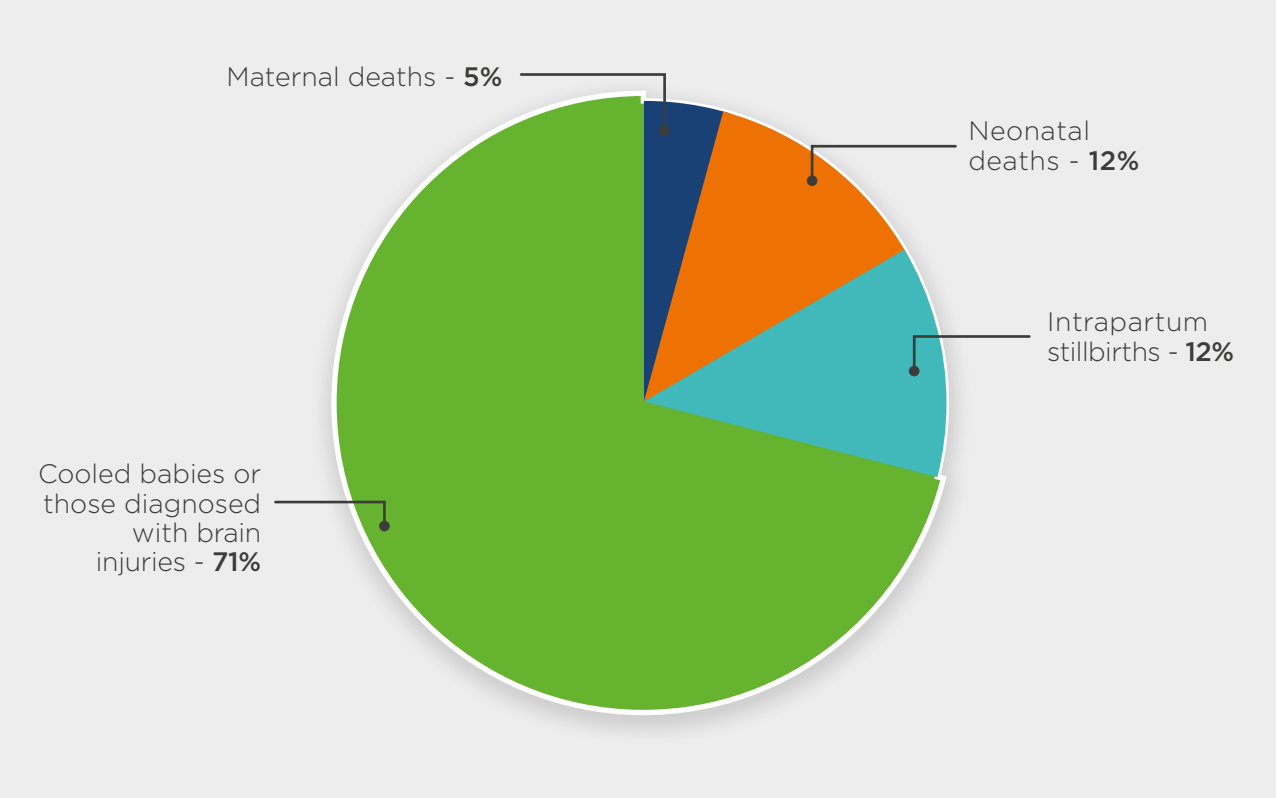
In line with our **maternity investigations** Directions we do not investigate neonatal cases where the mother has not gone into labour, for example, a caesarean section which was performed before the mother had started having contractions or her membranes were ruptured.

Criteria for maternal deaths

We investigate direct or indirect maternal deaths of women while pregnant or within 42 days of the end of pregnancy from any cause related to, or aggravated by, the pregnancy or its management, but not from accidental or incidental causes.

- Direct deaths are those resulting from obstetric complications of the pregnant state (pregnancy, labour and puerperium [13]), from interventions, omissions incorrect treatment or from a chain of events resulting from any of the above.
- Indirect deaths are 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).

Figure 5 Types of maternity investigation undertaken in 2019/20 (active and complete)



Our maternity investigations Directions exclude the investigation of cases where suicide is the cause of the mother's death.

Training our maternity investigators

All maternity investigators go on a bespoke course designed to give them specialist skills and tools to ensure they can conduct quality investigations.

Since the maternity programme began in April 2018, we have trained 187 investigators. For those who are seconded from trusts into the investigation team, on completion we are proud to support them returning to their particular trust and continuing their career with the knowledge and expertise required to carry on doing investigations to a high standard.

Developing our approach to investigations

Since April 2019 we have been improving our approach to maternity investigations. We have been developing collaborative relationships with trusts and the wider maternity system that supports the implementation of safer care for mothers and babies.

The relationships we have developed with trusts ensure that an organisation is immediately informed when there are safety concerns identified during an investigation. This enables them to implement actions that can prevent similar events from happening again. We have received positive feedback on this approach, and on completion of an investigation are able to reflect the actions already taken by the trust.

In addition, all trusts providing maternity care are invited to meet with our HSIB team on a quarterly basis. This is an opportunity for us to share information with the trust's senior clinical and leadership team about the themes developing across multiple investigations. This allows us to work together to focus on changes within the clinical environment that will support improvements in the care mothers and their babies receive. It is also an opportunity to provide trusts with information to support the allocation of resources across their maternity services.

Thematic learning

During 2019/20 we published a National Learning Report, **'Summary of Themes arising from the Healthcare Safety Investigation Branch Maternity Programme'** which reflects what we have learned during our initial completed investigations.

The summary highlights eight initial areas of learning:

- early recognition of risk
- safety of intrapartum care
- escalation
- handovers
- larger babies
- neonatal collapse alongside skin-to-skin contact
- group B streptococcus
- cultural considerations.

Each of these areas of learning are being taken forward to form in-depth HSIB National Learning Reports or are being progressed as part of two national investigations which are already underway, looking at:

- 'Delays to intrapartum intervention once fetal compromise is suspected'
- 'Safety risks associated with fetal heart monitoring'.

We have also become increasingly involved in the national Maternity Transformation Programme which implements the vision set out in **'Better Births'** the report of the National Maternity Review which was published in 2016 [16]. This supports the Secretary of State's ambition to halve the rates of stillbirths, neonatal mortality, maternal mortality and brain injury by 2025. As part of our involvement in this work we are working collaboratively with the representative group of stakeholders to support national learning and prevent duplication and burden to trusts.

Through this ongoing work we are developing our current relationships and building new ones with the regional chief midwives.

Looking ahead

We are continually innovating and improving our processes and ensuring we develop our maternity programme so we provide the best reports possible to mothers and fathers, families, and to trusts and their maternity staff.

During 2020/21 the maternity investigation programme will:

- continue to support families who have been affected by maternity care events that meet our criteria for investigation
- identify further themes for progression to national investigations and publish detailed National Learning Reports
- continue ongoing work to support trusts with different approaches to investigation
- provide trusts with information about the emerging themes we are seeing from investigations to support local learning and allocation of resources
- work collaboratively with key stakeholders to reduce duplication and burden on trusts
- continue to update our approach to support timeliness of investigation
- provide updated information for trusts and families through our website and publications.

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:

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

Organisational development

In February 2020 we produced an organisational development (OD) strategy and action plan. The strategy and two-year plan will ensure our workforce is equipped with the necessary knowledge, skills and behaviours required to meet our performance ambitions and those outlined in the **'Interim NHS People Plan'**.

Our four OD priorities for the next two years are:

- leadership
- workforce
- systems and processes
- culture (equality, diversity and inclusion).

Work has already begun on some of these areas and in February 2020 executives attended a cultural intelligence masterclass. This will be expanded and rolled out across the organisation during 2020/21. This work is important as it addresses comments made in the staff survey and enables our staff to be equipped with the latest support in understanding and working across different cultures.

Training and professional development for investigators

All investigators joining our organisation are enrolled on a bespoke and highly specialised training programme.

This is a significant investment but ensures that all investigators have the latest knowledge and expertise in the relevant fields.

All investigators complete an intensive three-week professional investigations training programme which includes:

- a week or more at Cranfield University, focusing on the importance of a human factors approach to an investigation, considering all contextual, human and systemic issues relating to safety investigations

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

- ongoing training with experts, clinicians and leaders in their field to ensure all investigators have the latest learning.

Learning from experts

Our investigators receive training in human factors, safety science and NHS services from leading experts in the country. We ensure the continued professional development of our investigators through regular learning events and frequent engagement and advice sessions from a team of clinical and non-clinical subject matter advisors.

Working with patients and families

We expect all our staff to maintain a professional, warm and compassionate approach in all situations.

Our investigators regularly meet staff, patients and families and we are often speaking to people at particularly difficult times in their lives, so it is important for us to ask sometimes difficult questions but in a way that shows respect and empathy. We also ensure that families are supported so that they do not encounter any barriers to communication.

To maintain the high standards expected, each investigator is trained appropriately to conduct interviews in a sensitive and appropriate manner, and we ensure they are supported during challenging investigations to safeguard their own wellbeing.

Ongoing training

With a full and stable complement of national and maternity investigators, ongoing training has played an important part in ensuring they are kept up to date. We have hosted regular external speakers and run training days and sessions exploring detailed clinical knowledge throughout the year. Ongoing training is an essential part of what we do, ensuring our investigators have the latest research-based professional knowledge.

IT

We have developed and implemented an IT strategy which enables our organisation to support operating environment standardisation and security enhancements. Our IT solution enables an agile workforce and has the capability to exploit any future technological benefits to support our corporate objectives.

Looking ahead

We are developing our training capabilities for both the national and maternity programme.

To ensure our investigators all have the latest human factors and safety science knowledge we have appointed a temporary acting Head of Investigation Education, Learning and Development. This role will ensure an ongoing suite of training sessions will be maintained for the benefit of staff over the coming 12 months.

Sharing learning - improving patient safety investigations

Strategic goal 3

Provide learning to the wider healthcare community, and promote professional safety investigations by improving investigation skills and techniques throughout the NHS.

To achieve this we will:

- develop strategic alliances with academic, health and social care partners to diffuse our learning
- improve the quality and consistency of NHS investigations
- develop and implement a communications and engagement strategy
- employ and train specialist investigators each year with professional and world-renowned accredited safety training.

Building relationships and contributing to wider learning

We have been a formative presence over the last year, completing multiple investigations and making a continual stream of safety recommendations to all levels and areas of the healthcare system.

We rely on excellent working partnerships with the Department of Health and Social Care, NHS England and NHS Improvement, and NHS trusts across the country as well as a wide range of other stakeholders including the royal colleges and NHSX.

Although we are just one organisation in a busy patient safety landscape, we are key to providing system-wide patient safety learning. One of our long-term priorities is to develop the skills of other healthcare colleagues across the system so they can improve their own patient safety investigations.

Stakeholder engagement

Our engagement activities have continued during the year, and we have continued to improve awareness of the value of independent patient safety investigations to healthcare. We have built and maintained our relationships with health professions, regulators and statutory and non-statutory bodies. We have done this as part of our communications and engagement approach to proactively developing our national and international stakeholder relationships in a strategic way.

We have developed the way we approach the media and engage with the press when we need to share our

national reports with a wider audience. We have had considerable success, with our reports featuring in national media outlets including the Guardian, the Times, the Daily Mail and the Health Service Journal, as well as many other trade, regional and local papers.

During the year we have shared our learning and our expertise widely across the country. We have presented at the highest level in government as well as at conferences and professional forums. We participated in the UK Foreign Office's Global Action on Patient Safety forum with leaders from national patient safety organisations across the world. We presented at the Intensive Care Society State of the Art Conference and the Annual Health Informatics Society of Ireland Conference, and many others. We presented at the Chief Nursing Officer for England's Summit and at the Baby Lifeline National Maternity Safety Conference, sharing early learning of themes from maternity investigations.

We continue to explore new opportunities to engage with NHS frontline medical and clinical staff and communicate more widely about our contribution to improving patient safety. For the first World Health Organization Patient Safety Day on 17 September 2019, we partnered with Loughborough University to bring human factors and healthcare professionals together to discuss learning and insight about patient safety from our investigations.

We have also begun to work on the commitment in 'The NHS National Patient Safety Strategy' to establish a national committee for oversight of national health organisation responses to our safety recommendations. This will be led by the National Director for Patient Safety and we will offer support.

Memoranda of understanding

Since HSIB was established we have set in place memoranda of understanding with 13 organisations (see table 4). These memoranda set out the framework for the working relationship between each of these organisations and the HSIB, as well as informing our staff and the public about how our organisations relate to each other and work together.

Table 4 Memoranda of understanding completed to date

Organisation
Cardiff Health Board
Care Quality Commission
Defence Accident Investigation Branch
Department of Health and Social Care
General Dental Council
General Medical Council
Health Education England
Human Fertilisation and Embryology Authority
Medicines and Healthcare products Regulatory Agency
NHS Improvement
Parliamentary and Health Service Ombudsman
Powys Health Board
Royal College of Obstetricians and Gynaecologists

Investigating for learning

The safety of people who use healthcare services in England is our biggest concern. That is why we are working towards the professionalisation of safety investigations, ensuring we have a bespoke set of criteria that defines the knowledge and understanding required to be a high-performing investigator.

We have brought together professional investigators from a wide range of backgrounds and disciplines to grow our national and maternity teams. Our investigations are built upon scientifically robust method-based approaches, a strong commitment to **'just culture'** [14] as well as a determination to make sure our investigations can direct transformation.

Looking ahead

Professionalising safety investigations

Over the year we have recruited academic and safety science staff as we design training programmes and look at exciting ways to work with universities and external training bodies. During our fourth year of operation, we want to grow our education, learning and development offer. This is the point at which we will be looking for ways to share our investigation skills and

techniques and to support healthcare services as they develop their own professional healthcare investigators.

Sharing safety recommendations

Our recommendations from national investigations will continue to improve safety by addressing system-level changes across the NHS.

The clinicians who work for our organisation have extensive experience in patient safety and clinical leadership in various local and national roles and ensure any recommendations are considered pertinent to frontline staff.

Healthcare Safety Investigation Conference

We planned to hold our first International Healthcare Safety Investigation Conference in September 2020, but had to postpone it due to the COVID-19 pandemic. When the conference takes place we will share our insights and learning from our national and maternity programmes, and invite contributions from international experts. We want to understand any potential lessons from other countries that are also focusing on healthcare safety investigations.

Sharing learning

During 2020/21 our Citizens' Partnership will be able to help us develop our networks with the public and those who can widen the impact of our reports and recommendations.

Our staff will continue to give tutorials and speak at seminars and conferences as experts in the field of human factors and safety science in an international arena.

Exemplary governance

Strategic goal 4

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

To achieve this we will:

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

Improving our governance

Since the HSIB was established in April 2017 the organisation has grown rapidly to the point where we have a steady complement of staff.

Over the last year we have continued to build on our governance principles and to build upon the high standards expected from our Corporate Services team.

With only two bases across the country, in Farnborough and in Derby, and with a remote and mobile workforce, the development of good, clear governance processes that are easy to understand and to follow have been essential for the smooth running of our organisation.

Over the last year we have:

- reviewed corporate governance and began the development of a workplan to review and prepare for the requirements to become a well-governed and legally constituted arm's length body
- continued to develop the executive team to ensure it functions in an effective and highly professional way
- ensured robust governance assurance processes have been maintained, and clarified our relationships with our key stakeholders NHS England and NHS Improvement, and the Department of Health and Social Care
- refined information governance [15] systems to ensure the highest level of compliance in terms of reporting, risk and data processing activities
- implemented an IT transformation strategy, and ensured we have an IT system which is futureproof and can support home working to a highly professional level

- built a system to identify and manage risk so that risk is mapped and addressed on an ongoing basis.

Reporting on our work

We report monthly to NHS England and NHS Improvement and to the Department of Health and Social Care.

Our people

During 2019/20 we have worked hard with staff to consider their development requirements and opportunities, and have improved the training programme for newly recruited investigators.

Across the year we have held:

- in-house training programmes for all investigators and staff to support their professional development
- learning and development events
- quarterly learning events for maternity teams to ensure the latest clinical knowledge is shared widely
- a masterclass in inclusive leadership through cultural intelligence
- emotional resilience workshops to support staff with their mental and emotional health, and which enable them to support others.

Staff survey 2019/20

We completed our first annual staff engagement survey in June 2019. We achieved a response rate of 91%, which was 11% above the benchmark. The Staff Survey Project Steering Group was set up to work with staff to formulate and suggest actions for improvement. We have been making improvements during the year including increasing the visibility of and access to the executive and senior management teams, and initiatives to strengthen relationships across the organisation.

Work in confidence

In response to the staff engagement survey, in November 2019 a mechanism was introduced to enable staff to speak up safely and anonymously on matters of concern to themselves and others, as well as to make suggestions to improve systems and processes.

Mandatory and statutory training

We ended the year with an overall compliance rate of 89%, up from 70% at the beginning of the year.

Peer support for investigation staff

We recognise that our investigators who engage with patients, families and other staff may well be exposed

to traumatic incidents, and could 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 to be provided with help as required. To do this we have trained staff in Trauma Risk Impact Management to offer peer support.

Citizens' Partnership

Following an open and transparent process, **Patrick Vernon OBE** was appointed as Chair of our Citizens' Partnership.

Patrick comes to us with a wealth of experience in a range of roles in health advocacy and health inequalities. During 2020/21, he will lead on phase two of setting up the partnership. This will involve collaborating with a small external and internal group of patient and public involvement experts to look at its remit and appoint members through another open process.

The Citizens' Partnership will work to ensure the public perspective is integral to everything we do and adds value to investigations from inception to completion. Our products, processes and inclusion of people with lived experience will all benefit from the insight and fresh eyes of this partnership. Patrick has also become a member of the HSIB Advisory Panel.

Staff Engagement Group

The Staff Engagement Group (SEG) has been instrumental in helping to improve organisational culture and connect staff working remotely across the country.

The SEG has co-ordinated the choice of a charity for the organisation, which has led to organisation-wide fundraising activities for **Alzheimer's Research UK**. The SEG will continue to support the action plan resulting from the staff survey and pursue the inclusion agenda so that all staff have an opportunity to be actively connected to our values and contribute to areas such as wellbeing and home-working initiatives in support of an agile workforce.

Our financial performance

HSIB was formally established as a division of the NHS Trust Development Authority (NHS TDA). The NHS TDA, with Monitor and NHS England, operate as NHS England and NHS Improvement. The NHS TDA's financial performance and financial statements include those of HSIB. In note 2 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 (see table 5).

Table 5 HSIB financial obligation

	2019/20	2018/19
Target: Funding allocation	£19,800,000	£14,072,000
Performance: Net expenditure	£19,287,000	11,922,000
Obligation achieved	**Yes**	**Yes**

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

Financial commentary

The HSIB was directed by the Secretary of State for Health and Social Care to commence the maternity investigation programme in April 2018. It was not until March 2019 that the maternity investigation programme was rolled out completely to all maternity units across England. As a result, the funding that HSIB received increased by £5,728,000 from £14,072,000 in 2018/19 to £19,800,000 in 2019/20.

The HSIB's net expenditure for the year was £19,287,000 (2018/19: £11,922,000). The main categories of expenditure are shown in table 6.

Table 6 Main categories of revenue and expenditure

	2019/20	2018/19
Revenue	-	(£3,000)
Staff	£14,904,000	£8,057,000
Purchase of goods and services	£4,086,000	£3,333,000
Depreciation and impairment charges*	-	£72,000
Other operating expenditure	£297,000	£263,000
Total	**£19,287,000**	**£11,922,000**

The largest area of spend is staff costs, representing 77% of net expenditure in 2019/20 (2018/19: 68%).

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 the HSIB for the provision of back-office functions by NHS England and NHS Improvement.

* Depreciation and impairment charges in 2019/20 were incurred by the NHS TDA's central ringfenced budget for depreciation and amortisation.

Equality, diversity and inclusion

Strategic goal 5

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

To achieve this we will:

- develop and publish an HSIB equality strategy and action plan
- invest in an equality, diversity and inclusion senior leader
- work with the Equality and Human Rights Commission to deliver mandatory public sector equality duty training to all staff
- review our recruitment processes to ensure they support equality of opportunity for all
- 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, but improves patient safety and protects the rights of patients and their families and carers.

Embedding equality, diversity and inclusivity

Embedding equality and diversity across our whole organisation, in its culture and in its investigations, processes, workforce and communications, has remained a key focus for us during the year.

The following are some examples of areas in which we have been endeavouring to make a difference to improve equality, diversity and inclusion (EDI) across our workforce.

Equality, diversity and inclusion strategy

The EDI strategy is a live document and is being revised for 2020/21 to take into account new initiatives and opportunities such as the establishment of EDI champions, analysis of our Equality Report and associated targets, and the role of the Citizens' Partnership in promoting equality and diversity through different parts of the organisation.

A key part of the EDI strategy is to ensure our staff are culturally aware

and that investigations adequately support families and staff during investigations.

As an organisation we have taken a holistic approach by organising cultural intelligence training for senior leaders followed by a roll-out to staff. This training covers areas of unconscious bias and cultural awareness to equip investigators in the field with intelligence in this area. It also develops leadership through inclusion and working across teams with different micro-cultures.

In all investigations, we have ensured there are no barriers to communication for families and those involved in investigations. A dedicated and timely translation and interpreting service is in place to cover the consent process, information for families and feedback opportunities. Other formats such as easy-read and audio are also available through the service to ensure accessibility. Families gave positive feedback about this support and noted that we had made it extremely easy for them to receive it.

We continue to emphasise the importance of the involvement of Experts by Lived Experience (EbLEs) in our investigations, and this will continue to be the case. The insight of those who are currently using, or have used, regulated health and social care services over the past five years is of great value to investigations. This involvement may also include family and carers of relatives who have used the regulated services in the past five years. Investigators access EbLEs through a dedicated service and their involvement may take the form of dialogue or a focus group. One investigator noted that the involvement of family insight opened a new line of enquiry which led to a safety recommendation and two safety observations being developed. Hearing from families has enhanced our investigation reports and allowed greater analysis of the evidence gathered for the case.

Equality and our workforce

Our **'Equality in our Workforce Report'** was published in November 2019. The data on the 174 staff who were recruited during 2018/19 was received from NHS Improvement, which is responsible for our staff recruitment processes. Our next report will also include workforce data across protected characteristics for appointments made in 2019/20 and consider any trends compared to the previous year.

In order to improve equality, diversity and inclusion among our workforce:

- We have initiated a drive for EDI Champions who will support the organisation nationally by contributing suggestions, enthusiasm and motivation among staff for the EDI agenda. EDI Champions will support the Head of Equality and Diversity to provide us with greater engagement in this area and share views on where improvements around EDI could be reflected across the investigation process.

- We have encouraged staff to update their employment records for declarations on disability, religion/belief, and ethnicity. This will help us to understand any support required. We finalised a process for examining any EDI aspects from exit interviews which could have been addressed but were not raised. This includes the possibility of sending in information anonymously, as well as after someone has left the organisation.

- We have set up a process to analyse shortlisting by protected characteristics against actual appointments. Although, we operate 'blind' recruitment, any possibility of unconscious bias needs to be ruled out via increased training. Conversely, leavers will be analysed by equality and diversity data.

- We have ensured our candidate interview format has been updated so that interview panels must include at least one person of different sex and/or ethnicity. Interview questions include equality and diversity questions, and interviewers are encouraged to keep equal opportunities and equality and diversity at the forefront of their thinking. Interview processes now include a stakeholder session across a range of staff representation to ensure wide feedback.

Reverse mentoring and talent management, as well as a focus on disability monitoring and 'disability confident' organisation schemes, are under review for 2020/21.

Keith Conradi, Chief Investigator

Looking Ahead

The HSIB is an exciting place to work. As an organisation we are committed to helping the NHS become as safe as it can be for the millions of patients it helps care for every year.

The results from our last staff survey demonstrate clearly how everyone in the organisation values what we are trying to do. This creates the drive to support our continual improvement. We welcome feedback, and are constantly looking at how we can do better and how the HSIB can respond even more effectively to patient safety issues as they arise.

We worked tirelessly to support the healthcare system's response to the COVID-19 outbreak. Assisting with the development of the new Nightingale hospitals, whilst also aiding Trusts across the country with issues where our expertise was considered essential, for example improving safety in oxygen supply systems and improving efficiency and safety at local, mobile and fixed coronavirus testing facilities for keyworkers and the public. We continue to do whatever we can, whether it is supporting local hospitals with early rapid learning from our investigations or providing insight, guidance or critical expertise to resolving issues for the wider healthcare system.

Due to the swift change in healthcare provision since April 2020 we established a rapid investigation model to aid with the COVID-19 effort. We also enhanced our suite of national reports by developing National Learning Reports and National Intelligence Reports. Both will provide essential insight, as well as helping make the NHS one of the safest healthcare systems in the world.

And while we work hard to make changes in a fast moving, dynamic healthcare landscape we are acutely aware that our staff are our biggest asset. That is why we have now established an investigation education programme to share professional investigation skills and experience between our staff, something which is being highly valued. We also hope we can share this professional investigation expertise across the system and cement our standing as a leader in safety investigation education.

Keith Conradi
Chief Investigator

Endnotes

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

[2] 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.

[3] 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.

[4] National Learning Reports are HSIB publications describing common themes and findings that arise from both our national investigation and maternity investigation programmes. We use the information from these reports to inform future HSIB investigations.

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

[6] Serious incidents are defined in the NHS England 'Serious Incident Framework' document (published in 2015) as events in healthcare where the potential for learning is so great, or the consequences to patients, families and carers, staff or organisations are so significant, that they warrant using additional resources to mount a comprehensive response.

[7] The Care Quality Commission's 2018 report 'Opening the door to change' defines Never Events as incidents with the potential to cause serious patient harm or death that are wholly preventable if national guidance or safety recommendations are followed.

[8] NEWS2 is the latest version of the National Early Warning Score (NEWS) which advocates a system to standardise the assessment and response to acute illness.

[9] NHSX is a joint unit bringing together teams from the Department of Health and Social Care and NHS England and NHS Improvement to drive the digital transformation of care.

[10] A CE mark is a manufacturer's declaration that a product meets EU standards for health, safety and environmental protection.

[11] Enteral pH strips are strips of reagent paper or plastic that react to gastric fluid and provide a colour-coded indication. This provides an indication that the NG tube is correctly placed in the patient's stomach.

[12] Human factors (also known as ergonomics) is the study of how humans behave physically and psychologically in relation to particular environments, products or services.

[13] The puerperium is the period of six weeks after childbirth during which the mother's reproductive organs return to their original non-pregnant state.

[14] A 'just culture' is where staff feel their organisation supports a culture of fairness, openness and learning by making staff feel confident to speak up when things go wrong, rather than fearing blame.

[15] 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.

[16] 'Better Births' is a report looking at the outcomes in maternity services in England.

[17] Hypoxic ischaemic encephalopathy (HIE) is a brain injury caused by an inadequate supply of oxygen to a baby's brain occurring during the antenatal, intrapartum or postnatal period. It occurs in 1.0 to 1.5 per 1,000 live births in the UK. A lack of oxygen to a baby's brain may result in HIE and other organ damage, which can lead to severe, lifelong disability or death. The UK total body cooling trial confirmed that 72 hours of cooling to a core temperature of 33C to 34C within six hours of birth for babies with moderate or severe HIE reduces death and disability at 18 months of age and improves neurodevelopmental outcome in survivors.

[18] Decreased central tone is where a baby has reduced muscle tone - or in layman's terms, is 'floppy'.

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

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