HSIB

HEALTHCARE SAFETY INVESTIGATION BRANCH

21/22

Healthcare Safety Investigation Branch

Annual Review 2021/22

Keith Conradi
Chief Investigator

Foreword from the Chief Investigator

It is my great pleasure to introduce HSIB's Annual Review for what will be my last time. As with most years in our short history there have been many important improvements during 2021/22 and it has paved the way for even more significant organisational change for the year ahead. Two particular events characterise this:

1 The introduction of the Health and Care Act 2022 which will move our organisation onto an independent and statutory footing as the Health Services Safety Investigations Body (HSSIB) and provide powers for it to investigate far more efficiently. I have been campaigning for many years for this change and am delighted to see this introduction which will align us more closely with transport investigation legislation and should bring about the safety improvements long since evidenced in that sector.

2 The announcement to create a Special Health Authority for our maternity investigation programme. After several years of relationship building with individual trusts and regulators, this programme has come of age and is delivering safety improvements across England. Having its future secured will allow the maternity sector to fully exploit the benefits of independent investigation entirely dedicated to learning lessons from the most tragic events.

Investigations continued at pace throughout the year despite the various pressures created by the COVID-19 pandemic. The maternity programme completed 706 investigation reports and 22 national investigation reports were published, which included a thematic review of our first 22 investigations since our launch in 2017. This raised, among other things, the principle of safety management systems as a concept for the healthcare system, something that has been successfully adopted in other sectors.

This year has also seen the development of our Investigation Education Team. As well as providing internal safety science development, they have trialled and are now rolling out training courses to trust investigators and senior decision makers. Perhaps more than anything else, this will serve to establish the culture of safety investigations at scale throughout the NHS and hopefully beyond.

We trialled a model of investigating localised patient safety incidents in the NHS. This enabled us to look at events which would have been beyond the scope of any individual trust but where there weren't necessarily any identified national themes. Some of these reports have been published and a full evaluation of the trial will take place next year.

Last summer saw the standing up of our Citizens' Partnership after a great deal of work by its design and delivery group. This partnership, which is led by Professor Patrick Vernon OBE, is a long-term venture to ensure that the public's perspective is included in all our work.

Two of our long-standing executive directors, Kevin Stewart and Steve Drage, moved on this year having given HSIB the benefit of their experience in its formative years.

And finally, I shall be retiring in the summer of 2022 having taken HSIB from its very beginning, through the hard yards of initial development to being an embedded part of healthcare safety culture. I wish it the very best in both its future guises and give my sincere thanks for all those who have supported the concept and its delivery.

Keith Conradi
Chief Investigator

Contents

Advisory Panel

The Advisory Panel is a group of independent people with a blend of expertise in family advocacy, citizen leadership, clinical practice, education, policy and professional investigation. Our primary role is to provide external scrutiny of HSIB's operational independence while it is a division of NHS England and NHS Improvement (NHSE/I).

As we end the fifth year of these arrangements, the concerns we first expressed in 2019 regarding operational independence have deepened. NHSE/I continues to have senior management oversight of HSIB but is also the recipient of a third of all HSIB safety recommendations. In the absence of any non-executive governance arrangements the potential conflict of interest is clear to see. NHSE/I is also the only regulator that has not provided data and information as part of HSIB national investigations, despite repeated requests and escalation to Chief Executive level.

The Advisory Panel is now actively working with the Department of Health and Social Care (DHSC) and the Chair of the Health and Social Care Select Committee to ensure that a range of issues raised with the Advisory Panel regarding operational independence are thoroughly understood. It is vital for the credibility of HSIB's work that a proper distance from NHSE/I, as the system regulator, is maintained. The year ahead will be one of complex transition and we look forward to supporting a new set of collaborative, arms-length relationships with NHSE/I and DHSC as HSSIB is developed in shadow form.

During 2021/22, the Advisory Panel made significant efforts to lobby for amendments to the primary legislation, based on the recommendations arising from scrutiny by the Joint Committee of both Houses of Parliament. Success in key areas around the prohibition of disclosures to coroners and the Parliamentary and Health Service Ombudsman has been achieved. However, some principles that were previously accepted by government, specifically relating to limiting the powers of direction and regulation of the Secretary of State, have not been fully integrated into the final legislation.

In conclusion, the Advisory Panel wishes to acknowledge the incredibly hard work of all HSIB staff during another turbulent year. They have continued to deliver high-quality professional investigations and develop innovative educational programmes to improve safety in the NHS in England with great commitment. We thank and applaud them all.

Professor Murray Anderson-Wallace, Chair

Advisory Panel members

Professor Murray Anderson-Wallace JP, Chair

Steve Clinch MNM

Dr Mike Durkin OBE

Farrah Pradhan

Professor Joe Rafferty CBE

Jennie Stanley RN

Professor Patrick Vernon OBE

Richard von Abendorff

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

Our vision

To be a global leader and educator in healthcare safety investigations

Our mission

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

About HSIB

Our organisation

We are dedicated to improving patient safety, and we conduct effective and 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 and hosted by NHS England and NHS Improvement, but we operate independently.

Our work

Most harm in healthcare results from problems within the systems and processes that determine how care is delivered. Our investigations identify the contributory factors that have led to harm or have the potential to cause harm to patients.

Through safety recommendations to specific organisations we aim to improve healthcare systems and processes, 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 investigation approach

Our investigators and analysts have diverse experience of healthcare and other safety-critical industries and are trained in human factors and safety science. Human factors looks at the interactions between humans, the tools and equipment they use in the workplace, and the environment in which they operate. Safety science is the study of how to increase safety in different types of systems.

We consult widely to ensure that our work is informed by appropriate clinical and other relevant expertise.

Our investigations – national and maternity

We conduct our investigations through two programmes – national and maternity investigations. They are different in terms of how referrals are made and how we report on our findings. For both types of investigation:

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

Our investigation criteria – national investigation programme

We select our investigations by reviewing referrals and gathering and analysing data from a wide range of sources.

The information is then assessed against agreed criteria, which are summarised below, to determine the value of undertaking an investigation. The criteria are based on international patient safety research and approaches to system-level investigations in other industries.

There is more information about our **national healthcare investigation criteria** on our website.

- We assess the scale and severity of the actual or potential harm that an issue represents.

- We review the system-wide risk associated with safety issues including how widespread they are across the healthcare system.
- We consider whether the investigation and its safety recommendations are likely to lead to meaningful safety improvements.

HSIB criteria for national investigations

Outcome impact

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

Systemic risk

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

Learning potential

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

Our investigation criteria – maternity investigation programme

We have set criteria which make incidents eligible for maternity healthcare safety investigations. These criteria include:

- 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 – where the baby died within the first week of life (0 to 6 days) of any cause.

- Severe brain injury – where the baby was diagnosed with severe brain injury in the first 7 days of life.

More detailed information about our **maternity investigation criteria** is available on our website.

We also investigate maternal death where women have died while pregnant or within 42 days of the end of pregnancy. This can be from any cause related to, or aggravated by, the pregnancy or its management, but not from accidental or incidental causes. We do not investigate cases involving suicide.

For more detail about the differences in our approach to national and maternity investigations **see appendix 1**.

Our education programme

We develop and provide education programmes to the NHS delivered by professional healthcare safety investigation experts. Our courses aim to improve local patient safety investigations in NHS trusts, and to give strategic decision makers and senior leaders an overview of the principles which sit behind modern healthcare safety investigations.

Our education programme has been developed using expertise drawn from our own experience as well as specialists from around the country, all of whom are professionals in areas such as human factors, psychology, education and investigations. The curriculum is based on the training we provide to our national investigation and maternity investigation teams and combines safety science, investigation skills and the investigation process.

Our strategic goals

We have five strategic goals which frame our business and which are supported by our values.

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

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

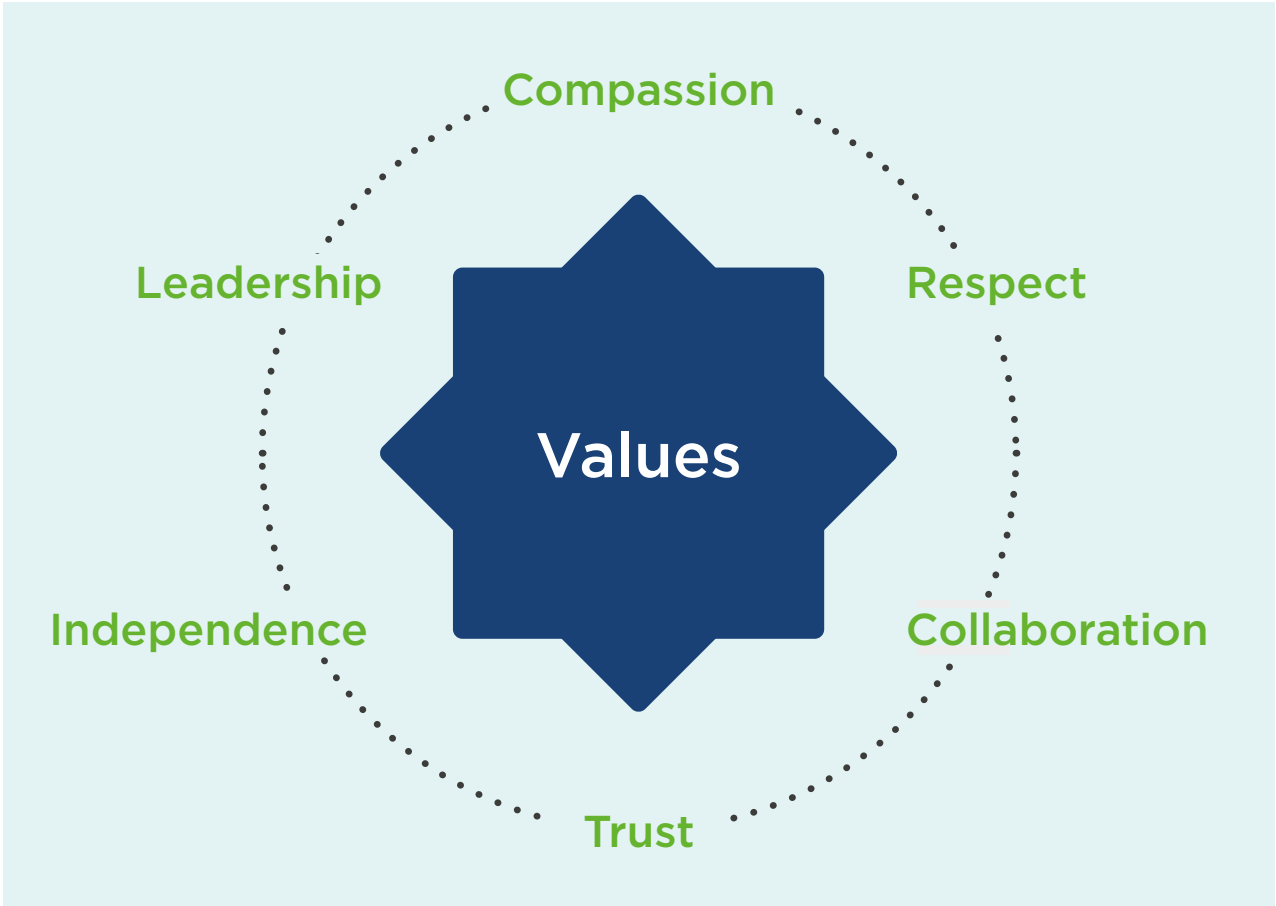
Strategic goal 2
Value and prioritise professional development for staff that includes internationally renowned safety investigation techniques and cutting-edge technology.

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

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

Our values

Our values are important to us. We began an exercise with staff in March 2022 to develop a series of behaviour statements to underpin our values. This exercise concluded in spring 2022 and is outside the timeframe for this review. However, information about the outcome of this activity, which is intended to strengthen our values and make them more meaningful to our staff, is available on the **values page** on our website.



Highlights and achievements 2021/22

The COVID-19 pandemic continued to impact the usual way we would complete our investigations, but our staff worked hard to ensure important safety investigations continued at pace. We ensure patients and their families are always kept as a central focus for all our reports as we continue to improve patient safety through professional safety investigations.

These are just some of our highlights during 2021/22.

1,015
NHS staff enrolled on HSIB safety investigation training from January to March 2022

22
national investigation reports published

73
national safety recommendations issued to **28** organisations

1,258
people attended our Healthcare Safety Investigations Conference

1,740
maternity safety recommendations made

706
reports produced by the maternity team

National investigations

Over the last 12 months our team of national investigators have published 22 investigation reports and issued 73 safety recommendations.

We have made sure that any impact of the COVID-19 pandemic on our investigations has been minimised, and where interviews could not be done in person they were conducted via video call.

As an organisation we continue to 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, coroners' prevention of future death reports).

We also identify risks through:

- horizon scanning – looking at potential safety risks by analysing serious incidents
- thematic reviews – which involve working through information and literature to identify themes from our investigations.

Family engagement in national investigations

Most national investigations use a real incident, known as a reference event, to explore a patient safety issue. Where this is the case, we engage with the patient who was involved in the reference event and obtain their consent for the initial scoping investigation. Their perspective on what happened to them is important evidence to HSIB. We will often seek the views of their family who offer insight into the care they were receiving.

In the case of reference events where a patient has died, we will seek the family's consent to investigate their care for the scoping investigation. We will also seek to understand the family's views on the issues raised by the investigation.

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

HSIB

National reports completed and/or published during 2021/22

Ordered by date	HSIB report title
1	Wrong site surgery – wrong tooth extraction
2	Outpatient appointments intended but not booked after inpatient stays
3	Management of chronic asthma in children aged 16 years and under
4	Wrong site surgery – wrong patient: invasive procedures in outpatient settings
5	Oxygen issues during the COVID-19 pandemic*
6	Suitability of equipment and technology used for continuous fetal heart rate monitoring
7	HSIB maternity programme year in review 2020/21
8	Timely detection and treatment of cauda equina syndrome
9	A thematic analysis of HSIB's first 22 national investigations
10	Intrapartum stillbirth: learning from maternity safety investigations that occurred during the COVID-19 pandemic 1 April to 30 June 2020*
11	Missed detection of lung cancer on chest X-rays of patients being seen in primary care
12	Surgical care of NHS patients in independent hospitals*
13	Treating COVID-19 patients using continuous positive airway pressure (CPAP) outside of a critical care unit*
14	Incorrect patient identification: Local integrated investigation pilot 1
15	Recognition of the acutely ill infant
16	Incorrect patient details on handover: Local integrated investigation pilot 2
17	Weight-based medication errors in children
18	Maternity pre-arrival instructions by 999 call handlers

Ordered by date	HSIB report title
19	Unintentional paracetamol overdose in adult inpatients with low bodyweight
20	Emergency neonatal blood transfusion at birth following acute blood loss during labour and/or delivery
21	Transfer of a patient who had suffered a stroke to emergency care: Local integrated investigation pilot 3
22	Clinical decision making: diagnosis and treatment of pulmonary embolism in emergency departments

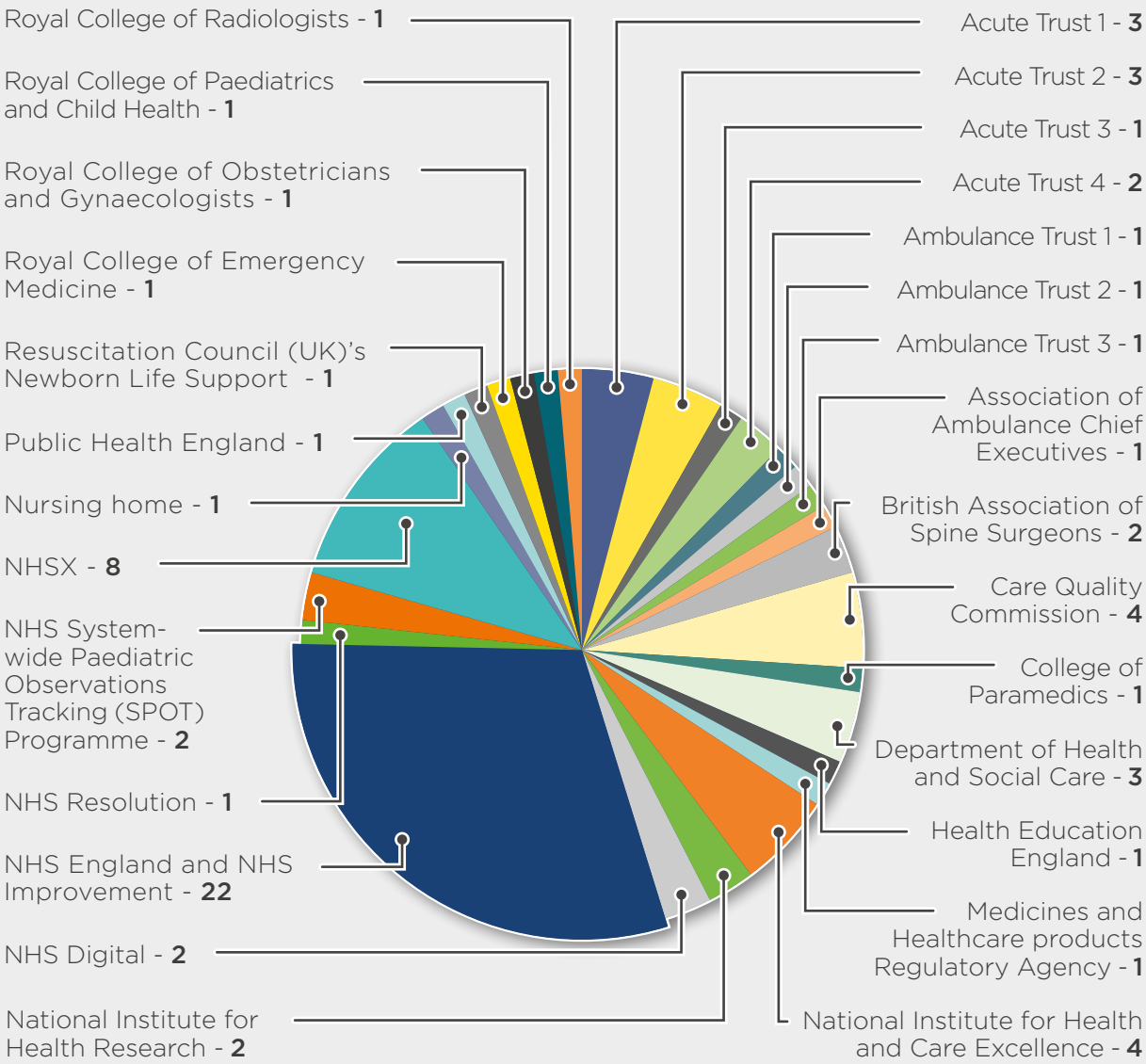
* Investigations launched as a direct result of the COVID-19 pandemic

Ongoing national investigations commenced but not completed during 2021/22

Investigation title
Provision of care for children and young people when accessing specialist gender dysphoria services
Unintentional overdose of morphine sulfate oral solution
Decontamination of surgical instruments
Medicine omissions in learning disability secure units
Administering high strength insulin from a pen device in hospital
HSIB maternity programme year in review 2021/22
NHS 111's response to callers with COVID-19 related symptoms during the pandemic
The use of an appropriate flush fluid with arterial line
Evaluation of local investigation pilot
Management of preterm labour and birth
Risk assessments during the maternity pathway
Community mental health teams
Variations in the delivery of palliative care services to adults in England
Impact of ethnicity on jaundice detection in newborn babies
Perimortem caesarean section during the management of cardiac arrest in pregnancy
Safety risks associated with central venous catheters used for haemodialysis treatment
Harm caused by delays in transferring patients to the right place of care
Identification of critical patient information at the bedside – Do Not Attempt Cardiopulmonary Resuscitation (DNACPR)
Safety risks associated with the selection and insertion of vascular grafts in haemodialysis patients
Invasive procedures in patients with sickle cell disease
The assessment of venous thromboembolism risks associated with pregnancy and postnatal
Risks associated with medication delivery via ambulatory syringe pumps

National report safety recommendations to different organisations in 2021/22

We made 73 safety recommendations to the 28 organisations shown below. A full list of these safety recommendations can be found in **appendix 2**, and more information about each investigation is available in the **investigations and reports** section of our website.



Our impact

Since HSIB was formed in April 2017 we have produced a total of 68 national investigation reports, and made 200 safety recommendations, 155 safety observations and 50 safety actions to 53 organisations in the healthcare system and beyond.

Many of the organisations which were the focus of our national safety recommendations during 2021/22 are still working on enacting them. Any safety recommendations we make support the healthcare system to revise and address system-wide issues, and may include changes to existing procedures and practices. It is currently not within our Directions (the legislation under which we operate) to monitor the implementation of safety recommendations. There are ongoing discussions about where this function should sit following the establishment of HSSIB.

However, we have started to catalogue the impacts that our reports and safety recommendations have delivered. Here is a small selection of the work undertaken by some of our stakeholders as a result of our national safety recommendations.

Outpatient appointments intended but not booked after inpatient stays

(report published April 2021)

The event which triggered our investigation involved a patient who was discharged from hospital on two separate occasions with a plan for follow-up in outpatient clinics. Neither of the outpatient clinic appointments were made.

Patients referred to hospital for non-urgent conditions should start treatment within a maximum of 18 weeks from referral. Similar standards and guidance do not clearly exist for follow-up outpatient appointments that fall outside of this standard.

The investigation made two safety recommendations to improve patient care. As a result, NHS England and NHS Improvement (NHSE/I) worked with NHSX to free up capacity to oversee patient appointments, while supporting organisations to prioritise patient lists. In addition, NHSX updated its What Good Looks Like programme to ensure organisations are responsive to HSIB reports and safety recommendations.

Management of chronic asthma in children aged 16 years and under

(report published May 2021)

We were notified by the Department of Health and Social Care (DHSC) of a safety risk identified in three prevention of future deaths reports by coroners. The reports highlighted missed opportunities to recognise asthma as a chronic and life-threatening condition in children.

Formal diagnosis of asthma in children under 5 years old can be challenging and its symptoms can be confused with those of other respiratory diseases.

The event which triggered the investigation involved a child aged 5. The child had had numerous planned and unplanned hospital visits with respiratory symptoms, before suffering a near-fatal asthma attack. Before this, the child had no formal diagnosis of asthma.

Our investigation made seven safety recommendations to improve patient care. Our impacts included NHSE/I and the British Paediatric Society ensuring health systems are provided with standardised templates to support the delivery of high standards of care for children and young people with asthma. NHS Digital also made changes to the supporting information in the NHS Pathways system relating to breathlessness in children aged 5 to 11 years, to include chest recession (an indrawing of the chest which may indicate breathing difficulties).

Suitability of equipment and technology used for continuous fetal heart rate monitoring

(report published July 2021)

After a review of HSIB maternity investigations into stillbirths, neonatal deaths and babies born with suspected brain injury we identified issues with the suitability of equipment and technology used to monitor a baby's heart rate during labour.

Many methods and types of equipment are used to monitor fetal wellbeing during labour and birth. This complexity can cause safety issues such as inability to interpret the fetal heart rate, and staff understanding the equipment and its purpose.

We reviewed 39 completed HSIB maternity investigations and this identified a theme relating to continuous fetal monitoring. A further review of 138 investigations identified 238 findings which referred to issues with cardiotocograph (CTG) monitoring.

The impacts of this investigation included NHSE/I amending the Saving Babies' Lives Care Bundle, the Clinical Negligence Scheme for Trusts Maternity Incentive Scheme, and core competency framework to include the requirement for training and competency checks of all maternity staff on the use and functionality of CTG equipment.

Timely detection and treatment of cauda equina syndrome

(report published August 2021)

The cauda equina is a group of nerves located below the spinal cord. Cauda equina syndrome (CES) is a rare and severe type of spinal stenosis (a condition where the space around the spinal cord narrows, compressing a section of nerve tissue). CES causes all the nerves in the lower back to become suddenly and severely compressed. It can be caused by disc protrusion, a tumour or trauma. It disrupts motor and sensory function to the lower extremities and bladder. If CES is not diagnosed and treated in a timely way it can lead to permanent incontinence, sexual dysfunction and even paralysis.

The event which triggered the investigation involved a patient who had had visited GPs and their local hospital several times before CES was diagnosed. Once an MRI scan identified the cord compression, there were further barriers to receiving timely emergency surgery to alleviate the compression.

The results of our investigation should help ensure patients with suspected CES receive a timely MRI scan, and have resulted in the National Institute for Health and Care Excellence (NICE) improving its guidance on relevant issues.

A thematic analysis of HSIB's first 22 national investigations

(report published September 2021)

We reviewed our first 22 national investigations and identified that similar issues were arising, even when investigations were focused on different clinical fields. Our analysis identified the following three recurring patient safety themes:

1 access to care and transitions of care (when patients move between care providers or care settings)

2 communication and decision making

3 checking at the point of care.

These three themes represent the most significant threats to patient safety that we have found based on our investigations so far.

The thematic analysis looked at the 85 safety recommendations made in those first 22 investigations. The safety recommendations were grouped into one or more of six categories. The categories were chosen as they represent the fundamental safety management activities used across safety-critical industries:

- identification of patient safety hazards
- improving the management of known patient safety risks
- monitoring of patient safety performance
- evaluation of patient safety interventions
- training and education for patient safety
- promotion of patient safety.

The outcome of our work suggests it may be beneficial for the NHS to explore how the application of safety management principles could build on the foundations developed by the NHS Patient Safety Strategy. A greater adoption of the principles of a safety management system in the NHS may support more effective responses to our safety recommendations.

Safety management systems help to mitigate threats to safety before they result in undesirable outcomes.

Missed detection of lung cancer on chest X-rays of patients being seen in primary care
(report published October 2021)

Lung cancer is the third most common cancer diagnosed in England, but accounts for the most cancer deaths. Five-year survival rates of those diagnosed with lung cancer are among the lowest in Europe. The low survival rate reflects the fact that two-thirds of patients with lung cancer are diagnosed when the disease is at an advanced stage, which means treatment to cure it is no longer possible. Chest X-ray is the first test used to assess for lung cancer. However, about 20% of lung cancers will be missed on X-rays resulting in a delay in diagnosis and this will potentially affect a patient's prognosis.

The event which triggered the investigation involved a patient who had seen their GP on multiple occasions and had had three chest X-rays where the possible cancer was not identified. This resulted in an 8-month delay in diagnosis and potentially limited the patient's treatment options.

The investigation:

- sought to understand the context and contributory factors influencing a delay in lung cancer diagnosis in a patient repeatedly attending primary care with non-specific symptoms

- identified the system-wide factors that help or hinder the detection of lung cancer on chest X-rays

- considered the utility of chest X-ray to assess for lung cancer in symptomatic patients being seen in primary care

- identified the implications of the findings for mitigating the risk of delayed diagnosis of lung cancer.

The investigation has had a number of impacts so far which include NICE reviewing its current safety-netting advice to healthcare professionals with respect to the investigation of possible lung cancer, and NHSX along with the Royal College of Radiologists and the Society and College of Radiographers developing guidance to support better identification of lung diseases such as cancer.

Surgical care of NHS patients in independent hospitals
(report published October 2021)

We received a referral from a member of the public describing concerns about the ability of independent hospitals to treat patients who previously would have only been cared for within an NHS hospital.

There has been a history of collaboration between the NHS and independent hospitals. The COVID-19 pandemic placed increased pressure on the NHS which resulted in independent hospitals providing more care for NHS patients, including urgent NHS elective (planned) surgical care and delivery of cancer care.

The event which triggered the investigation involved a patient with a diagnosis of bowel cancer. He was booked to undergo keyhole surgery to remove part of his bowel in an NHS hospital. He subsequently underwent open surgery in an independent hospital as a result of arrangements made because of the COVID-19 pandemic. After surgery, the patient's health started to deteriorate and he was transferred to the local NHS hospital. He died later the same day as a result of sepsis following a complication of his surgery.

The investigation:

- explored safety issues associated with the establishment of surgical services in independent hospitals to support the NHS and, in particular, the specialist services that are in place to deliver patient care

- considered the assessment of patients before surgery to identify their risk and suitability for an operation and where the operation was to be undertaken; this included identification of patients who were physically frail.

The impacts of our investigation so far include NHSX expanding its work programme to improve the transfer of information between the NHS and the independent sector to support safe care delivery, and the Care Quality Commission updating its inspection framework documentation to ensure patient transfer between NHS and independent providers is inspected.

Local integrated investigation pilot

(first report published in November 2021, second report published in January 2022, third report published in March 2022)

We conducted a pilot to see whether the experience gained from our maternity and national programmes could be combined and applied to the investigation of individual incidents, to enhance learning within local trusts/organisations and across healthcare systems locally. The intention was to contribute further to improvements in patient safety at local, regional and national levels.

We engaged with several acute hospitals and ambulance trusts who were asked to refer incidents that involved cross-boundary care (for example, where patients were cared for by ambulance services, acute hospitals, and primary care services).

Below are examples of two of the three investigations we undertook. The associated safety recommendations were made specifically to the organisations involved in the investigation. The organisations were anonymised.

First local investigation

This investigation examined the issue of incorrect patient identification where a patient who was admitted to hospital following an ambulance transfer had the wrong patient identification used for their care. This meant they were prescribed medicines intended for another patient.

Some of our impacts have included the hospital developing and implementing a standardised approach to patient identification in the emergency department, including checking three identifiers when confirming a patient's identification, and both the acute and ambulance trusts implementing a standardised approach to verifying and confirming a patient's identification during the handover process.

Second local investigation

This investigation looked at incorrect patient identification where the details of a patient who was admitted to hospital following an ambulance transfer were noted incorrectly, which led to a new patient record being created. This meant their existing patient record and medical history were not available when the patient underwent surgery.

The emergency department staff were unable to find the patient's details on the digital patient management systems available. A new patient record was created with the incorrect patient details.

Our impacts so far have included identification of improvements in patient verification between acute trusts and ambulance trusts including a formal emergency booking-in policy.

Recognition of the acutely ill infant
(report published December 2021)

We were notified of an incident involving the detection and treatment of an acutely ill child.

Infants and children who have a fever without an apparent cause are of particular concern to healthcare professionals because it is especially difficult to distinguish between simple viral illnesses and life-threatening bacterial infections.

It is also very difficult to identify early signs or symptoms that could lead to sudden deterioration in unwell infants and children. Unlike adults, infants and children are able to cope with potentially overwhelming infections for a period of time without showing any signs that they are seriously ill or getting worse.

Recognition of acutely unwell infants and children is complex and quick diagnosis is important as their health can deteriorate rapidly.

The event that triggered the investigation involved an infant aged 3 months who was admitted to a hospital and discharged 4 hours later. The infant was re-admitted less than 4 hours later and sadly died of meningococcus (serogroup B).

The investigation:

- focused on understanding and describing circumstances in which the acutely ill infant is not recognised and/or acted upon
- explored how clinical information is communicated along with the transfer of information between people; this included the voice of the parent/carer and handover of information between staff
- considered the system and environmental influences that impact on the decision-making process.

Our impacts from this investigation have so far ensured that the Association of Ambulance Chief Executives, community NHS 111 providers and primary care services are integral to the NHS System-wide Paediatric Observations Tracking (SPOT) Programme. In addition, the College of Paramedics will work with Health Education England to provide e-learning for all paramedics which will include further paediatric information as well as education material representative of people with darker skin tones.

Investigations related to the COVID-19 pandemic

Oxygen issues during the COVID-19 pandemic
(report published June 2021)

We identified a safety risk arising from an increased demand for oxygen gas in hospital wards during the COVID-19 pandemic. COVID-19 can cause severe inflammation of the lungs, which affects people's ability to breathe and get enough oxygen into their bloodstream. As a result, more patients have required oxygen therapy.

The event which triggered the investigation involved an acute hospital trust declaring a major incident when demands on its oxygen supply led to patients being diverted to different hospitals and a need to transfer patients between clinical environments. The trust had sufficient supplies of liquid oxygen but its piped oxygen system was unable to deliver the volume of oxygen gas required to meet all of its patients' needs.

Our impact includes the updating of healthcare technical memorandum guidance to ensure all appropriate members of hospital staff attend medical gas committees. In addition, the Care Quality Commission is updating its inspection guidance to ensure the way organisations manage their estates is reviewed with respect to oxygen delivery.

Treating COVID-19 patients using continuous positive airway pressure (CPAP) outside of a critical care unit

(report published November 2021)

We became aware of a safety risk involving the use of continuous positive airway pressure (CPAP) outside of critical care and high dependency units during the COVID-19 pandemic.

A significant proportion of people going to hospital with COVID-19 need help with their breathing. Often this takes the form of oxygen therapy which is given through a face mask or through little tubes that sit in the nose. Despite oxygen therapy, some patients still struggle to take in enough oxygen to breathe on their own and become exhausted. This is known as respiratory failure. Patients' breathing may be assisted with the use of a special device which delivers a flow of oxygen-enriched air at a constant pressure, and is connected to a mask or hood worn by the patient. This is known as CPAP.

The event that triggered the investigation involved a patient with COVID-19 using CPAP, who was found on the floor of a side room having called for assistance. The CPAP tubing had become disconnected from the patient's mask, meaning their breathing was not supported. Sadly, the patient died.

The investigation:

- aimed to understand the contextual factors surrounding the care of people with coronavirus requiring CPAP in hospital
- described the system-wide factors influencing the risks associated with using this form of non-invasive respiratory support during the pandemic
- identified whether recent national guidance addressed identified safety issues.

The investigation did not make specific safety recommendations to improve patient care as national bodies had recently published guidance. However, the investigation report highlighted six questions to help local organisations when considering the risk. These included questions about operational policy, whether CPAP devices have capability for remote monitoring, and whether staff have the required training to care for patients who need non-invasive respiratory support.

Looking ahead

Over the next year the focus of the national investigation team remains the publication of high-quality, systemic safety investigations. Our multidisciplinary team of national investigators continues to apply and adapt cutting-edge safety investigation techniques developed in academia and other safety-critical industries to fully analyse the factors that contribute to harm across healthcare and conduct no-blame and no-liability investigations.

We continue to explore our potential role relating to organisations' responses to our safety recommendations. Currently we review all responses received to make sure there is sufficient detail on the intended actions planned. This information is published on our website. The national programme is conducting work to ascertain the feasibility of HSSIB having a monitoring role in relation to safety recommendation implementation in the future.

We are currently evaluating the local integrated investigation pilot (**see page 31**) and we will publish the results in a national report later in the year. We will then consider how this model of investigation could be incorporated into our work in the future, as part of a broader review of our systems, structure and operating model, to ensure a sustainable and responsive national investigation programme.

Maternity investigations

Our maternity investigation programme is part of a national action plan to make maternity care safer.

Since the launch of the maternity programme in 2018 we have completed 2,247 investigations with the aim of recommending improvements to providers of maternity services across England.

Our reports are prepared for the trust and also for the family involved in the incident. We do not apportion blame and this helps to ensure that we discover the truth behind an incident, which in turn helps us develop safety recommendations and ensure learning takes place.

Maternity investigation impacts

During 2021/22 we completed 706 investigation reports and made 1,740 safety recommendations. All the reports and safety recommendations were shared with both the family and the trust. While investigation reports are not published, we do develop reports based on emerging themes coming from our investigations.

If a report makes safety recommendations, it is the healthcare provider's responsibility to make improvements.

Below are some improvements that have been implemented across maternity services in England as a result of our investigations and safety recommendations.

Improvements to telephone triage process

A trust was asked to ensure that its telephone triage risk assessments supported a consistent questioning approach to enable full consideration and documentation of the whole clinical picture and identification of risks. This will ensure that advice given to mothers is clear with detailed timeframes and actions.

The trust built a proforma in its electronic health records system to help staff undertake systematic risk assessments when triaging mothers over the telephone. The aim was to capture the full clinical picture and identify risk in a way that is clearly visible in the mother's notes. The trust shared tip sheets on how to use this function with all staff and highlighted the change to staff in its weekly 'big 4 safety messages' newsletter.

Introduction of safe gestational ranges for induction of labour

We recommended that a trust make sure that an individualised risk assessment for mothers who require induction of labour (IOL) considers the most suitable venue and plan of management for their ongoing care.

Following this recommendation the trust made sure that, as part of booking an IOL, all women are individually risk assessed. Using national and local guidance, a safe gestational range is allocated for undertaking IOL.

This allows for safe oversight of booking and improved management of capacity across both areas for induction. All staff are provided with 'Safe gestational range' cards to support decision making and to identify situations where escalation to a more senior colleague or specialist team may be needed.

Placental histology

Placental histology (the analysis of tissue from the placenta) can give important information in cases of adverse perinatal outcome, which can be used to plan appropriate care for a mother's subsequent pregnancies. In one of our investigations, the trust did not always send a placenta for histology when a baby was born requiring additional care including therapeutic cooling. We recommended that the trust review national guidance and ensure all staff know the clinical events that indicate a need to send a placenta for histology.

Following this safety recommendation, the trust has put posters in treatment rooms to remind staff at every possible opportunity to send for placental histology. The trust is planning to add a reminder to send the placenta for histology to the Situation Background Assessment Recommendation (SBAR) handover tool, which is used when babies are transferred to a neonatal unit.

These are just a few of the improvements which have been introduced by trusts following safety recommendations made by the maternity programme. Information about other improvements adopted by maternity care providers across England is available on the **maternity pages** on our website.

Newsletter

We piloted a **newsletter for the maternity programme** in the London region in 2021 and adopted a 'we said, you did' approach.

The newsletter came about because a number of trusts had approached us asking if other organisations had been given similar HSIB safety recommendations and how they were dealing with them. The aim of the newsletter is to share learning between trusts in order to make further improvements.

As the first edition received a positive response from trusts and external stakeholders, we extended the newsletter, inviting contributions from all four HSIB regions in England. As the volume of contributions increased, we grouped the entries under themes.

Examples of good practice may be mentioned during quarterly review meetings between HSIB and trusts, and trusts are encouraged to submit their improvements for sharing in the newsletter.

Examples of learning have included changes that have been made to maternity triage services, ways of supporting staff to undertake fetal monitoring successfully and initiatives to improve the escalation of concerns about a mother and baby. Trusts have shared examples of tools that may be useful to others including redesigned cardiotocography (CTG) stickers, posters and checklists.

Maternity Quality Improvement Team (MQIT)

This has been the first full year of operation for our Maternity Quality Improvement Team (MQIT), which was set up to support improvement projects across maternity investigations. The MQIT brings teams and individuals together to work on quality improvement (QI) projects which will enhance our approach to maternity investigations.

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

Looking ahead, the MQIT is continuing to work on four key QI projects that started in 2021/22 and is aiming to move these towards completion in 2022.

Webinars

With the continuing restrictions caused by the COVID-19 pandemic and advances in the ease of hosting and attending webinars, we were delighted to use technology to share our work with our stakeholders during 2021.

Change to ambulance service safety learning webinar

In collaboration with NHS Ambulance Services we ran a joint webinar with our maternity and national teams, which took place in June 2021. The aim was to help ambulance services to understand how our experience is making a difference to frontline healthcare.

We explored the differences between a maternity and national investigation. Findings were shared from the national investigation report into the emergency response to heart attacks, and the safety recommendations from a recent maternity investigation involving aspects of an ambulance service were discussed.

The webinar included an interactive question and answer session on HSIB's investigation approach and explored in greater depth the safety recommendations we have given to ambulance services to improve safety and optimise patient outcomes.

Joint webinar with medical defence organisations

In November 2021, in partnership with medical defence organisations, we delivered a webinar primarily aimed at doctors in training. The webinar, entitled 'Who, what and why?', explored the maternity programme and answered questions about HSIB maternity investigations. It was attended by clinicians from different professional backgrounds, mainly from those working within maternity and neonatal services.

The maternity programme during the COVID-19 pandemic

In response to the COVID-19 pandemic the maternity team initiated different approaches to working with families and trusts.

Working with families using virtual platforms has been challenging, particularly when they are sharing experiences with our investigators. Where we have visited families, we have made sure these visits have been thought through and assessed to ensure everyone's safety.

The importance of supporting a family to have a voice and share their experiences in a way that meets their needs is fundamental to our work. Since the start of the pandemic the approaches we have taken have demonstrated our commitment to maintaining and fulfilling this ambition.

We recognise that trusts have been under significant pressure in response to COVID-19 and we have seen the impact of this across England at different times. We have worked closely with trusts to reduce the burden of taking part in our investigations and have considered different approaches.

An example of this is where trusts walk our teams remotely through a mother's journey in hospital. This has enabled the teams to understand the changes that have been implemented to support the safe care of patients during the pandemic. An important part of our work going forward is to revisit all trusts and take time to walk through the maternity services and understand changes that have been made.

In addition to their role at HSIB, many of our maternity investigators have supported the NHS through frontline clinical work and by supporting the vaccination programme.

Family engagement

Maternity investigations

% of families engaging with our maternity investigations during 2021/22

Meaningful engagement with and involvement of families and patients continues to be a priority within our maternity investigation programme. Over the last year 86% of families engaged with our maternity investigations. Work to better understand why some families decide not to be involved has been ongoing. This includes families who do not agree for their contact details to be shared with HSIB, meaning we are not able to speak to them. It also includes families who agree to initial contact, but, after having the process explained to them, decide they do not wish to be involved, or for us to access their medical records. The reasons for not wishing to be involved included:

- families stating that they are happy with the care they received and do not see the value of an investigation
- families who do not feel able to participate due to the distress caused by what has happened.

There are also a number of families who have not replied to any contact.

To make sure that information provided to families is as complete and accessible as possible, we undertook a full review of family resources. This was to ensure that the information provided will help families to make an informed choice about their involvement. The review has resulted in additional resources being made available in different formats and additional languages. Videos

were also developed in which families explain, from their perspective, why they agreed to be involved and shared their experience of the process and the difference it made to them.

To ensure accessibility and inclusivity for families, a pilot was carried out where, with the agreement of the family, their particular needs were identified. This enabled us to adapt our approach to these families and make sure that the information provided or requested was the most suitable. Where the needs identified by the family sat outside of the investigation process, appropriate signposting was given. Support for investigators in this work included further information, resources and signposting information.

We have conducted a review to reflect on the experience of tripartite meetings that are held following a maternity investigation. These are meetings where HSIB, the family, and the trust meet to discuss next steps following an HSIB investigation. The meetings enable the family to ask the trust questions about areas that may sit outside of the investigation, and enable the trust to discuss what steps have already been taken or are planned following any safety recommendations. In collaboration with a trust, we are drafting a resource for families to help set clear expectations as to the purpose of these meetings.

The expertise we have developed in our work involving families within investigations is now being used in a joint project with NHS England and NHS Improvement. The intention is to develop central guidance to support and inform how the NHS engages with families in all patient safety responses. Feedback from families continues to inform our processes and provides opportunities for review and development.

Analysis of this feedback shows consistent positive themes that included:

- families feeling included in the investigation and able to participate
- investigators demonstrating sensitivity and excellent communication skills
- families thanking HSIB and investigators for the work they are doing
- families understanding the facts of what happened as a direct result of the investigation.

In addition, over the last year emerging positive themes included:

- families feeling the investigations were timely, especially given the impact of COVID-19 restrictions
- families recognising the value of tripartite meetings at the end of the investigation
- families saying that the language used within reports was clear and that they welcomed any terminology being explained.

Feedback over the last year has shown that families think our reports are thorough, independent and that they can make an impact to prevent further harm. Areas for development include ensuring families are made aware of what is being asked of them when the draft report is shared so that expectations are managed appropriately.

Feedback from families over the last year

"I cannot fault the MI's [maternity investigator's] communication at all, she was frequently in touch at each step of the investigation, and she would always be in touch on the exact date she said she would, we were never left wondering what was happening."

"We have been so impressed by the empathic and inclusive manner in which we were contacted."

"Although we appreciate that HSIB has to maintain a balanced approach, we were extremely happy with how our views were taken into consideration and the level of sensitivity that the investigator showed listening to and reporting our situation."

Feedback from families over the last year

"The communication was excellent with regular updates and much valued understanding and sensitivity. We were surprised how many of those involved were traced and interviewed and the professional approach throughout. We were always informed of progress and what was to come which generated great confidence in the process."

"I knew something wasn't quite right about my labour and birth however I feared that because of my young age, nobody would take me seriously and my voice would not be heard. HSIB involved me massively in the investigation which led to the findings being more accurate."

"The report has helped us to move forward in the grieving process and to feel that my baby's death has been given the due care, attention and diligence it deserves, not only uncovering the facts, but also helping to prevent any future incidents. This provides us with some comfort and adds even more meaning to such a short precious life. These reports are invaluable, and we would be in a totally different place without it."

Looking ahead

In January 2022, the Secretary of State for Health and Social Care announced a plan to establish a Special Health Authority to continue the HSIB maternity investigation programme.

The Special Health Authority will be established from April 2023. This will enable continuous learning to be achieved and will equip NHS trusts with the expertise, resources, and capacity to take on maternity safety incident investigations in the future.

This means that during 2022/23 work will be undertaken to establish the Special Health Authority and to take forward what we have learned over the last 4 years.

One area of development that remains core to the work we undertake is our approach to family engagement and making sure that it is accessible and reflects the diversity of the population.

In addition, there are areas of investigation which we would like to explore using the expertise we have developed across our teams. Opportunities for collaboration and joint working to enhance system-wide learning need further consideration to make sure that, as an organisation, we reduce the burden on the frontline teams delivering care.

Investigation education

Our Investigation Education, Learning and Standards Team has three core functions which are aligned with HSIB's strategic goals:

- education, which aims to develop and deliver investigation science education and training
- standards and methodology, which aims to establish and promote standards for professional healthcare safety investigation
- education promotion, which aims to promote inclusive safety investigation practice.

We draw on a variety of experience across a broad range of professional disciplines that feed into investigation science, including education, human factors, psychology, sociology, healthcare, legal, engineering, and other safety-critical industries.

This year was extremely busy and exciting for the team. It was also a landmark year for the provision of safety investigation education in the NHS. During 2021 the team designed and piloted courses with a number of trusts. These were well received and showed both the need for and the value of this education in developing professional healthcare safety investigators. Feedback from the pilots helped to inform and refine our education content ready for wider delivery to the NHS.

In January 2022 the wide-scale roll-out of courses began, and in the 3-month period from January to March 2022 we enrolled 1,015 NHS staff on our safety investigation courses. There were early challenges to providing education to such a large number of participants, but these were managed and we will undertake a comprehensive evaluation programme to provide assurance of the learning experience.

The education is delivered by the team's faculty of educators, who have specialist knowledge in safety science and safety investigations. Such in-depth safety investigation training has never been provided before to the NHS and is a key component in HSIB's strategic goal of professionalising healthcare safety investigations.

For our larger courses which accommodate hundreds of students, the teaching and learning is multi-method and online. It includes pre-recorded and live sessions, to provide flexibility for busy NHS staff who may not be able to

commit to set times each week. These courses also provide an opportunity to collaborate with co-learners to look at the practical application of investigation science in healthcare. During the courses participants explore the aspects of safety science, investigation processes and investigation skills which provide the foundations of a professional safety investigator.

In addition to these courses, we have developed two stand-alone live courses:

Investigation science for strategic decision makers and senior leaders in healthcare

This is a bespoke 2-hour course for small groups of senior NHS leaders. It is designed to give them an overview of the philosophical and methodological principles which sit behind modern healthcare safety investigations. This is to help promote and embed systems thinking into organisational learning and to ensure they know what to expect from investigations in the future. We have developed and delivered this training across the NHS to support the professionalisation of local investigations.

Investigative interviewing

This bespoke 2-hour course is for smaller groups of 30 staff who undertake healthcare safety investigations. The course offers an overview of the principles which underpin effective, supportive interviews and allows for interaction and discussion, directly relating learning to practice.

Evaluation and feedback

All courses have received a high level of interest and a waiting list has been created to manage the demand. We will be developing more courses throughout 2022 and, importantly, evaluating the impact of the existing courses on safety investigation in the NHS. This will include the involvement of patients and families in investigations, as well as a focus on improving the underlying systems that contribute to things going wrong, rather than a focus on individual staff. We will use a number of different methods in our evaluation and will be reporting our findings directly to the Department of Health and Social Care.

The first of these courses ran in January and we received positive feedback. It was particularly encouraging that staff felt able to translate their learning into practice, as well as use it to set a standard of practice for others. Here is just some of the feedback we have received so far:

Some of the feedback received over the last year:

"I am interviewing a member of staff tomorrow and the HSIB presentation helped me formulate how I would be conducting this tomorrow."

"I plan to ... introduce standards of practice for investigative interviews."

"I really enjoyed today's sessions ... it was great to start seeing how we can use the theory we've learned so far."

"Really passionate, engaging teachers who make sometimes complex concepts understandable."

"I have dyslexia and it's lovely to see process mapped out like this because it helps with understanding."

Details of all our current courses can be found in the investigation education area of our website.

In addition to these courses, we have committed to providing bespoke safety investigation education to a number of trusts during 2022.

Looking ahead

We will be supporting course participants to implement their learning in practice. To do this, the team is developing practical tools to be used during investigations. These tools are currently under development in collaboration with our colleagues in NHS England and NHS Improvement (NHSE/I) so that there can be a consistent, joined-up approach to investigations in the NHS.

To complement the formal education, the team is developing a competency portfolio. Those attending our courses will be able to apply to achieve an award in healthcare safety investigation. The portfolio is intended to be completed alongside live investigations ensuring that learning is related to, and reflected in, practice. Again, this is a milestone moment in healthcare investigation in the NHS, where investigators are established as requiring specialist knowledge and skills.

We are also working in partnership with NHSE/I to develop a guide for the assurance of safety investigation reports and safety recommendations. This will facilitate meaningful scrutiny and oversight of the output of future healthcare investigations.

Finally, the team's work on developing professional standards will continue. It will be informed by experts in safety investigation across the healthcare system and other safety-critical industries, nationally and internationally. The setting of professional standards, alongside a competency framework and the provision of investigation education, further supports the professionalisation of healthcare safety investigation.

Engagement

Stakeholder engagement

Stakeholder relationships are fundamental to our work and impact. Much of our strategic engagement during the past year has been driven by the Health and Care Bill, which will establish the HSSIB as a fully independent non-departmental public body from April 2023, and the planned transition of the maternity investigation programme to a new Special Health Authority of the Department of Health and Social Care (DHSC), also to begin operating from April 2023.

A key focus has been to make sure that our stakeholders understand the implications of the provisions for the functioning of the HSSIB, particularly for the prohibition on disclosure, commonly known as 'safe space' of our investigation evidence and materials.

As part of our transition to these two separate organisations, during the coming year we will consult broadly with stakeholders and the public to make sure that:

- our translation of the Health and Care Act 2022 legislation into policies and guidance is transparent, and encompasses patient, family, clinician and broader public expectations of the HSSIB as a fully independent public body, and

- the remit, approach and operations of the Special Health Authority for maternity investigations, which will be set in forthcoming secondary legislation, reflect the views and experiences of NHS trust maternity units and their staff, and national organisations with responsibility and interest in patient safety for maternity services.

Contributing our expertise to inform policymaking

Sharing our expertise and the learning from our independent investigations is important for demonstrating the value of our work for improving patient safety. During the year we contributed written submissions to the Health and Social Care Select Committee inquiries into cancer services and NHS litigation reform, which are due to report in the coming year. We also contributed knowledge and experience about patient safety from our national and maternity safety investigations, in written responses to government policy consultations including:

Lead agency	Consultation
Department of Health and Social Care	Establishing the office of the independent patient safety commissioner
Department of Health and Social Care	Women's health strategy: call for evidence
Medicines and Healthcare products Regulatory Agency	The future regulation of medical devices in the UK
National Institute for Health and Care Excellence	Guideline on inducing labour
National Institute for Health and Care Excellence	Guideline on intrapartum care
Independent	Essex Mental Health Inquiry

Stakeholder engagement to build strong relationships

Regular engagement with our key stakeholders across the NHS patient safety landscape evolved and expanded further during the year, and we continued to build strong relationships to support our intelligence about patient safety risks in the NHS.

Some examples of the organisations we have interacted with during 2021/22 across both national and maternity investigation programmes include:

- the DHSC and its arm's length bodies including NHS England and NHS Improvement (NHSE/I), the National Institute for Health and Care Excellence, the Medicines and Healthcare products Regulatory Agency, NHS Digital, NHS Resolution, the National Guardian's Office, and Health Education England

- healthcare sector and professional regulators including the Care Quality Commission, General Medical Council, Professional Standards Authority, the medical royal colleges, College of Paramedics and the Academy of Medical Royal Colleges

- patient advocacy and family representation organisations including Action Against Medical Accidents (AvMA), and the Parliamentary and Health Service Ombudsman

- professional and trade bodies such as the medical unions including the MDU, Medical Protection Society and the MDDUS, the British Association of Perinatal Medicine and NHS Providers

- NHS trusts who participate in our maternity investigation programme and have provided reference events for our national investigations

- associations and academic institutions with expertise in human factors and patient safety such as Loughborough University and the University of Nottingham.

These meetings build an ongoing dialogue between HSIB and our stakeholders around emerging patient safety risks, potential themes for future investigations, the development of effective safety recommendations, and sharing learning and insight from our current investigations. In the coming year we will continue to expand these relationships to encompass a broader range of stakeholders, and continue to build awareness of our role in the system.

Stakeholder surveys to help improve our work

We commissioned our first independently conducted external reputation survey during September and October 2021 with Opinion Research Services. This involved in-depth interviews of 25 of our key stakeholders that explored their perceptions of the quality of our work, effectiveness, impact, and value to the patient safety system.

Key findings from the research established:

- Stakeholder knowledge of HSIB and its remit are good, and most consider us to be open and transparent, willing to take on board their feedback, and they would speak highly of us and our work.

- Our investigations are conducted professionally with integrity and respect for confidentiality, with appropriate involvement of patients, families and healthcare staff.

- We produce useful learning to help improve patient safety and are perceived to add unique value to the NHS patient safety system through our independent investigations that focus on learning not blame.

- We can improve the impact of our reports by engaging more closely at earlier stages in our investigations to ensure our safety recommendations are targeted at the most appropriate organisations to make the needed changes to policy and guidance.

- To help improve the visibility of our work, it would be helpful to communicate more widely and in more targeted ways about our reports and safety recommendations.

- Stakeholders recognise that we are still a developing organisation, with scope to evolve and grow further in what we focus on and how we operate.

We also conducted in-house surveys of trusts and staff that participate in our maternity investigation programme. This provided useful feedback to inform the programme's continuous improvement activities. The in-house survey showed that our maternity investigations are valued by trusts and staff as professional, open, transparent and independent, providing useful learning and insight to support improved safety of care and safety culture in maternity services, both locally and across the NHS.

Our maternity investigation findings and safety recommendations are also becoming more integrated into internal patient safety governance and assurance processes for trusts' maternity services.

The results of both surveys will help to inform our strategic and operational development, including our preparedness for fully independent status, and improved stakeholder engagement throughout all HSIB's investigations functions, activities and outputs.

Citizens' Partnership

Our **Citizens' Partnership** (CP) was formally established in September 2021. It followed a design phase informed by a group of external lay people. Their work laid the ground for the terms of reference, which were approved at the CP inaugural meeting. The group also did valuable work in making improvements to our investigation process.

The membership of five people plus the Chair (Patrick Vernon OBE) is diverse and represents a range of expertise and networks. The executive lead member is our Director of Corporate Services who led the establishment of the CP and works closely with the Chair to set the business agendas and lead on the CP's work planning and priorities. Since being in operation, the CP has already begun making recommendations to add value to HSIB investigations using its members' specialist backgrounds. An equality impact assessment process for each investigation is being explored in conjunction with a member of the CP. Diversity awareness is also being undertaken by the Chair of the CP in

investigations and in interactions with staff. CP members have been involved in providing feedback on the website and other products from the public perspective as well as actively participating in task and finish groups, and focus groups with investigators.

During 2021/22 the CP continued its engagement with external patient safety and learning organisations. This work began in January 2022 when an introductory round table meeting was held with a range of organisations. The meeting covered topics around the journey of HSIB to become the HSSIB, the issue of 'safe space' in investigations, accountability, health inequalities, and the process of healing and rebuilding trust in the health system which is required when harm has occurred.

HSIB Safety Investigations Conference 2021

During the year we have continued to engage the healthcare system in our work with considerable success, using social media, HSIB news alerts, videos, press attention in trade and national media and also by hosting webinars.

On 16 September 2021 we marked World Patient Safety Day by hosting an international webinar and learning event on healthcare safety investigations. More than 1,200 people took part, dialling in from as far away as America and Australia.

Programme highlights included an overview of our maternity and investigation education programmes, along with an in-depth look at our COVID-19 related investigations. You can **watch the conference in full** on our YouTube channel.

Memoranda of understanding to support collaboration

We hold memoranda of understanding (MoUs) with our key stakeholders, which frame commitments and set the terms of engagement between our organisations, our respective roles and responsibilities for patient safety, and how we will work together. This may include sharing of relevant data and information, with appropriate safeguards, on patient safety risks. Current MoUs include:

- 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
- Loughborough University Enterprises Limited
- Medicines and Healthcare products Regulatory Agency
- NHS Improvement
- NHSX
- Parliamentary and Health Service Ombudsman
- Powys Health Board
- Royal College of Obstetricians and Gynaecologists.

During 2022/23, as the HSSIB and the maternity Special Health Authority are established, we will update these MoUs, and continue to expand our formalised partnership working with more of our key stakeholders.

Staff engagement

Over the last year our Staff and Wellbeing Group has been developing initiatives relating to health and wellbeing, trauma risk management (TRiM) and peer support as well as our charity and social activities.

HSIB has recognised the challenges for staff in the work they are involved with, and over the last year has continued to invest in supporting colleagues with several initiatives, including our peer support team trained in TRiM.

Due to the nature of our work our staff are often exposed to potentially traumatic events. The TRiM peer support team helps colleagues by listening and offering practical advice and assistance.

During the year staff received updates on what TRiM can deliver and they could reflect on their needs for peer support. In addition, our commitment to the REACT mental health programme, which helps all our staff to have supportive conversations with each other about their mental health, will expand access to peer support across the organisation by recognising the effect of cumulative exposure to traumatic events.

We have refreshed our Health and Wellbeing Strategy. This strategy aims to create a healthy and psychologically safe environment for all our employees and will include an offering to maximise the wellbeing of our people, acknowledgement of the difficulties that some people have faced and also the offer of additional support during challenging times.

Staff nominated Mind as the chosen charity for the organisation and a representative from the mental health charity spoke to all staff about its priorities and activities.

The Staff and Wellbeing Group benefits from open dialogue around issues of communication and culture in the organisation, raising concerns, challenges and suggestions for improvement. It is a valuable forum enabling voices from across the organisation to be heard. It also benefits from synergy with Equality, Diversity and Inclusion (EDI) Champions (**see page 61**) and Freedom to Speak up Guardians (**see page 60**). It actively supports actions from staff surveys and will play an important role in supporting actions resulting from the recommendations of the King's Fund cultural review (see below).

Cultural review

A cultural review took place in the summer of 2021 to better understand our culture and how it was being experienced within the organisation by our staff. All staff had the opportunity to take part and the outcomes and analysis were shared with us in the autumn.

The findings have given us the opportunity to shape a programme of cultural transformation by building on what has gone well over the last few years and changing the things that have not worked so well.

Our response and actions will prepare us for our transition into two new organisations, HSSIB and the maternity Special Health Authority. Some of the initiatives we have rolled out during the year include:

- 'Learning bursts' that incorporate training and essential updates to support staff with various HR-related topics.

- ‘Confident Conversations’ training sessions were held for all staff. This training has equipped staff with the skills to engage in a difficult conversation when required.

- A 360-degree feedback tool was launched for staff to gain honest feedback from colleagues and peers, allowing for self-reflection and improvement.

- ‘Progressing Conversations about Race’ – small groups of staff meeting with the Chair of the CP who is a trained coach and advisor in this area.

Moving into 2022/23 an action plan and recommendations will be rolled out as part of our ‘Together Towards Tomorrow’ campaign, which aims to continuously improve our culture.

Training

Bespoke training has been delivered throughout the year with staff having the opportunity to undertake courses for their personal development plans. We also held a successful ‘learning at work week’ which gave staff access to a range of classes.

Civility and respect will be at the core of our work which includes training and workshops on subjects such as EDI, race awareness and cultural intelligence to embed a culture of inclusion within the organisation. Regular and short ‘pulse’ surveys will be conducted, and our managers will benefit from specialist coaching and support with HR matters.

Recruitment

As part of the recruitment process we have been examining the employee journey with the aim of creating a more compassionate and inclusive culture. We have also been working on embedding our values into our recruitment processes.

Improvements have been made to many of our operational HR documents including absence management documentation, recruitment guidance, and appraisal documentation. Our policies have been reviewed and harmonised to ensure accuracy and clarity.

Irrespective of role or background, we take steps to be an inclusive employer that proactively embraces diversity.

Looking ahead, we will be welcoming the creation of our new Board who will oversee the strategic direction of our organisation while ensuring a commitment to developing a compassionate, inclusive leadership culture at HSIB.

Freedom to Speak Up

Freedom to Speak Up (FTSU) is an initiative run by the National Guardian's Office to support health and care staff to speak up about anything that doesn't feel right in the workplace. We have two FTSU Guardians who undertook training by NHSE/I FTSU and the FTSU National Guardian's Office. They are part of a network of about 60 Guardians within NHSE/I.

Over the last year our Guardians have worked hard to raise the profile of Speaking Up by introducing FTSU to all staff at our all-branch meeting, as well as setting up a new SharePoint page and providing virtual training to most of our staff, with the remaining staff doing online training.

During the year the Guardians have dealt with 14 cases in total across a wide range of subject matters, including concerns about fair recruitment and concerns for the wellbeing of colleagues. The Guardians are currently working on training for all staff which will be delivered during 2022/23.

Equality, diversity and inclusion

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.

Last year we published HSIB's 'Equality, diversity and inclusion strategy and action plan 2021-2023' and a stocktake of progress against actions will form a 1-year report on this strategy. This will remain iterative especially as we transition from HSIB to the HSSIB and the Special Health Authority.

Our 'Equality workforce report 2020-21' was approved for publication in March 2022. It provides a complete breakdown of data on protected characteristics (for example, age, disability or religion) for our intake of staff that year and for the whole organisation. Understanding the profile of the organisation enables the leadership to see where to focus efforts to address gaps in order to make sure our workforce reflects the population we serve. More work is needed to improve disclosure rates on protected characteristics, our ethnicity intake and understanding of the requirements around disability. Actions to address this are included in the equality, diversity and inclusion (EDI) strategy and action plan.

We have a cohort of EDI Champions who have been raising awareness and helping educate the organisation about EDI. Over the last year they have continued to play an important role and have increased their visibility in different working groups, including around race equality. They have supported recruitment from shortlisting to appointment (38 recruitments within the year) and are an asset to ensure EDI perspectives are actively considered. In collaboration with HR staff, EDI Champions have reviewed all recruitment documentation and processes to ensure EDI is given due regard and acted upon.

The inclusion of an EDI objective in all staff appraisals became a mandatory requirement from February 2022.

EDI Champions also support awareness raising for all staff. Examples include planning an all-staff briefing to mark Black History Month, a video on dyslexia, raising awareness of bullying and discrimination, and hidden disabilities, and extensive sharing of resources via a variety of internal media and webinars. In 2022, EDI Champions began workstreams around specific protected characteristics, prioritising race, disability and LGBT+.

Training on areas around EDI has continued with the work to accredit two staff members to cascade training on cultural intelligence and, to avoid further delay, a series of sessions entitled 'Progressing Conversations around Race'. These sessions were rolled out in the first months of 2022 by Patrick Vernon OBE, who is Chair of the HSIB Citizens' Partnership (**see page 55**). During the sessions, the trainer shared his lived experience with all staff in open, safe conversations about the language used in discussing race and how to recognise racism and allyship. The sessions received positive feedback for their format and content. This type of intervention is just one response to the recent King's Fund cultural review (**see page 58**).

We regularly network with EDI forums in a variety of organisations and formal groups to make sure best practice and ideas can be captured to share across the organisation.

EDI in investigations

A cross-branch race equality group was created in 2021. Because of their involvement with families, our maternity investigation teams are uniquely placed to explore, report and learn from family experiences where race has been a factor in our investigations. Families are able to contribute to the development of more informed safety recommendations which promote positive change.

We also aim to identify how we can optimise the data we hold and increase our understanding of health inequalities, taking account of individual needs. This work will inform staff development and ensure we improve staff understanding in this area.

We have ensured that there are no barriers to communication for patients and families in our investigations. We continue to invest in a language service and have provided a mix of language services which include translation (318 pieces produced in year) and interpreting (374 sessions, mostly video interpreting). Language services were delivered in 36 languages plus audio, British Sign Language and easy read. This service will continue through to HSSIB and the Special Health Authority.

We have arrangements in place to ensure we can access Experts by Lived Experience (people who have experience of certain health conditions or who have experience of using health and care services) in investigations wherever appropriate.

Governance

Responsibilities, accountability, and independence

We are accountable to the Secretary of State for Health and Social Care, to whom we report on our performance every year through this Annual Review. We also publish it on our website.

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

- The National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) Directions 2016. These 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.

In July 2021 the government introduced the Health and Care Bill, which included legislation to create the Health Services Safety Investigations Body (HSSIB) as a fully independent non-departmental public body with enhanced investigatory powers. The Bill became the Health and Care Act in April 2022. A transition board led by the Department of Health and Social Care will oversee the establishment of the two new bodies, HSSIB and the Special Health Authority, which will become operational in April 2023.

Information governance

The Data Security and Protection Toolkit (DSP)

The DSP is an online self-assessment tool that enables organisations to measure and publish their performance against the National Data Guardian's 10 data security standards.

All organisations that have access to NHS patient data and systems must use this toolkit to provide assurance that they are practising good data security and that personal information is handled correctly. HSIB provided its toolkit submission in June 2021 and submitted another in March 2022.

The impact of this toolkit submission being successfully approved means that HSIB, and later the HSSIB and the maternity Special Health Authority, will continue to be able to process, analyse and manage critical personal data.

Information requests

During the period April 2021 to March 2022:

- 19 subject access requests were received by the Information Governance Team. All requests were responded to within the timeframe set by the General Data Protection Regulation 2018.
- 8 Freedom of Information (FOI) requests were received by the Information Governance Team. All requests were responded to within the timeframe set by the Freedom of Information Act 2000.
- 167 requests for copies of interviews conducted during HSIB investigations were received and processed.
- 48 requests for information from coroners were received and processed.

Independent inquiries

We are currently assisting two independent inquiries: The Nottingham University Teaching Hospitals Thematic Review, and the East Kent Independent Inquiry, headed by Dr Bill Kirkup.

Looking ahead

The Information Governance Team will be working on a large-scale project which involves redesigning and updating all policies and procedures with regards to information governance/records management. These updated policies and procedures will be required for the new HSSIB and maternity Special Health authority from April 2023 onwards.

The transition will provide HSSIB with new powers which will require the development of new policies and procedures, and updates to the maternity programme policy and procedures in line with the forthcoming secondary legislation for the Special Health Authority.

Risk management

HSIB's self-service risk management system continues to monitor and map risks effectively. Our business continuity plans enabled staff to continue their work while working from home during the pandemic.

Essential requirements to visit trusts for investigation purposes were conducted under COVID-19 secure arrangements by first assessing arrangements with robust risk assessments.

Financial performance

During the year we kept within our funding allocation. Our net expenditure for the year was £18,678,000.

	2021/22	2020/21
Target: Funding allocation	£20,011,000	£19,800,000
Performance: Net expenditure	£18,678,000	£18,224,000
Performance: Capital expenditure	£178,000	£456,000

Main categories of revenue expenditure

	2021/22	2020/21
Revenue	-	£(1,000)
Staff	£16,387,000	£15,744,000
Purchase of goods and services	£2,142,000	£2,218,000
Other operating income	£149,000	£263,000
Total	**£18,678,000**	**£18,224,000**

(As at time of publication, the above amounts are unaudited)

In addition to the expenditure above, £178,000 of information technology hardware and software were capitalised in the year (2020/21: £456,000).

The largest area of spend was workforce costs, representing an increase to 88% of net expenditure in 2021/22 from 86% in 2020/21.

Purchase of goods and services relates to training, business travel, IT, communications and professional fees (including the fees of experts on specialist matters) and premises. Other operating expenditure is the cost to HSIB for the provision of back-office functions by NHS England and NHS Improvement.

Appendices

Appendix 1 Differences in our approach to national and maternity investigations

	National investigations	Maternity investigations
Start date	Programme began in April 2017.	Programme began in April 2018.
Number of investigators	12	127
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 3-week training programme as soon as they join, and they attend regular professional development workshops throughout the year.	All investigators attend a bespoke induction and training programme which includes the theory of patient safety and the practical application of these skills. Additional training and updates are provided throughout the year.
Referrals	Any person, group or organisation can refer a patient safety concern to us through our **website**. We also identify issues for investigation through research.	Individual NHS trusts refer incidents to us that meet the criteria.

	National investigations	Maternity investigations
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 a set HSIB criteria. In April 2020 (with DHSC's agreement) we made amendments to the programme criteria which remain in place as of 31 March 2022. Trusts continue to refer all cases in line with the existing criteria, and we have temporarily ceased investigations of cases relating to hypoxic ischemic encephalopathy (HIE) where a baby had received cooling therapy and there was no apparent brain injury. The exception to this is if the family or trust request we progress an investigation, in which case we will continue to do so.
Investigation status	Our investigation does not replace the local trust's investigation into the patient safety incident.	Our investigation replaces the trust's investigation into the maternity incident for those investigations that meet the criteria.
Reporting	We publish national investigation reports on our website.	Maternity investigation reports are shared with the family and trust. They are not published.

	National investigations	Maternity investigations
Safety recommendations	We make safety recommendations to relevant named organisations. Organisations are requested 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. In addition, themes can be developed into national learning reports in collaboration with the National team to support safety recommendations to national bodies.

Appendix 2 Safety recommendations issued during 2021/22

Please visit our website for the latest information on our **investigations, reports, safety recommendations and safety recommendation responses**.

Wrong site surgery – wrong tooth extraction
(April 2021)

R/2021/121 – HSIB recommends that NHS England and NHS Improvement should review the Never Events policy and framework and include content to explicitly define the criteria that need to be satisfied for any control to be considered a 'strong systemic protective barrier'.

Outpatient appointments intended but not booked after inpatient stays
(April 2021)

R/2021/122 – HSIB recommends that NHS England and NHS Improvement develops standards and an operating framework that describes the assurance required for all outpatient appointment booking processes, including after an inpatient stay. The assurance should include feedback mechanisms which provide safeguards that intended outpatient appointments are booked. Ideally, solutions will use technology and automation to create resilience and efficiency so that there is less reliance on staff vigilance.

R/2021/123 – HSIB recommends that NHSX's What Good Looks Like programme includes a requirement for organisations to be responsive to HSIB reports and safety recommendations within the 'Safe Practice' section of its guidance.

Management of chronic asthma in children aged 16 years and under
(May 2021)

R/2021/124 – HSIB recommends that NHS England and NHS Improvement, as a commissioning body, supports local systems to implement evidence-based interventions, such as standardised information and wheeze management plans, for the parents/carers of pre-school children. This will be undertaken in conjunction with the British Paediatric Respiratory Society.

R/2021/125 – HSIB recommends that NHS England and NHS Improvement reviews the safety recommendations arising from the National Review of Asthma Deaths to prioritise and ensure the implementation of safety recommendations that are outstanding.

R/2021/126 – HSIB recommends that NHS Digital reviews the supporting information for triaging the breathless child up to 16 years of age, to determine whether there are features of life-threatening breathing difficulty.

R/2021/127 – HSIB recommends that NHS England and NHS Improvement supports clinical experts to work with professional bodies to develop training competencies for healthcare professionals with responsibility for caring for children with suspected or confirmed asthma.

R/2021/128 – HSIB recommends that NHS England and NHS Improvement and NHSX identify and integrate data items into information technology systems to develop a greater understanding of the risk factors present in the community.

R/2021/129 – HSIB recommends that NHSX, supported by NHS England and NHS Improvement, implements a discovery programme into the roadmap for the digital personal child health record focused on developing support, self-reporting and alerting for asthma self-care.

R/2021/130 – HSIB recommends that Public Health England develops resources for young people and their parents/carers to raise awareness and enable them to self-manage asthma more effectively.

Wrong site surgery – wrong patient: invasive procedures in outpatient settings
(June 2021)

R/2021/131 – HSIB recommends that NHS England and NHS Improvement leads a review of risks relating to patient identification in outpatient settings, working with partners to engage clinical and human factors expertise. This should assess the feasibility to enhance or implement layers of systemic controls to manage these risks. It should also consider existing challenges relating to the usability and practice of including the NHS unique identifier in patient identification processes, and consider technological solutions to support its use.

Oxygen issues during the COVID-19 pandemic
(June 2021)

The first safety recommendation was made in an interim bulletin published in March 2021. Four further safety recommendations were made in the final report in June 2021.

R/2021/120 – HSIB recommends that NHS England and NHS Improvement urgently issue definitive guidance on the role, function, and key attendees of the medical gas committee. This guidance should identify and encourage key multidisciplinary relationships and board level reporting of medical gas issues.

R/2021/132 – HSIB recommends that NHS England and NHS Improvement review and further specify the key roles, responsibilities and competencies of individuals identified in the health technical memorandum (HTM) for medical gas pipeline systems, including identifying how the appointment and training of designated officers may be supported.

R/2021/133 – HSIB recommends that NHS England and NHS Improvement implement a process to provide ongoing assurance on the qualifications and experience of individuals identified in the health technical memorandum (HTM) for medical gas pipeline systems (MGPS), including how MGPS Authorising Engineers, or their subcontractors, are appointed by NHS trusts.

R/2021/134 – HSIB recommends that NHS England and NHS Improvement completes ongoing work to review, revise and reissue the health technical memorandum (HTM) for medical gas pipeline systems (MGPS). An updated HTM should reinforce multidisciplinary team working and include:

- Updated advice on the type and design of MGPS infrastructure recommended for NHS trusts.
- Enhanced processes to encourage shared working between clinical and nonclinical teams on MGPS issues.
- Specifications for the relevant levels of competence and training for NHS staff on MGPS.
- Any updated processes or guidance generated in response to the other safety recommendations specified in this report (R/2021/120, R/2021/132, R/2021/133).

R/2021/135 – HSIB recommends that the Care Quality Commission reviews and adapts its assessment model for NHS hospital estates to ensure greater scrutiny of estates-related safety concerns.

Suitability of equipment and technology used for continuous fetal heart rate monitoring
(July 2021)

R/2021/136 – HSIB recommends that NHS England and NHS Improvement amends the 'Saving Babies' Lives care bundle version 2' to enhance the role of the 'fetal monitoring lead' to include, training and competency checks of all maternity staff on the use and functionality of cardiotocograph (CTG) equipment.

R/2021/137 – HSIB recommends that NHS England and NHS Improvement amends the 'Saving Babies' Lives care bundle version 2' to remove specific references to Dawes Redman and instead use a generic term such as 'computerised cardiotocograph (CTG) analysis'.

R/2021/138 – HSIB recommends that the National Institute for Health and Care Excellence considers reviewing its telemetry recommendation as part of the current update of clinical guideline CG190, taking into account the existing evidence and the findings of this report.

Timely detection and treatment of cauda equina syndrome
(August 2021)

R/2021/139 – HSIB recommends that the British Association of Spine Surgeons, supported by the Royal College of Surgeons of England and the Royal College of Emergency Medicine, develops a decision-making tool to support the identification of patients who need an immediate MRI for suspected cauda equina syndrome (which may result in the patient being transferred for MRI if this is not immediately available at the assessing site).

R/2021/140 – HSIB recommends that guidance is developed by the Royal College of Radiologists, supported by the Society and College of Radiographers, stating that all hospitals should reserve the first MRI slot of the day for patients with suspected cauda equina syndrome who do not meet the criteria for an 'emergency'/immediate scan overnight.

R/2021/141 – HSIB recommends that the British Association of Spine Surgeons oversees the development of national guidance to identify how 'urgent' and 'emergency' requests for scans for suspected cauda equina syndrome are defined and prioritised.

R/2021/142 – HSIB recommends that the National Institute for Health and Care Excellence updates its current low back pain guideline to include the symptoms and initial management of cauda equina syndrome. This update should include a review of the role of supplementary investigations, such as bladder scanning, in patients with suspected cauda equina syndrome.

R/2021/143 – HSIB recommends that NHS England and NHS Improvement develops a national cauda equina syndrome pathway. This should define the safety-critical elements of the pathway and highlight areas that can be adapted locally.

Intrapartum stillbirth: learning from maternity safety investigations that occurred during the COVID-19 pandemic, 1 April to 30 June 2020 (September 2021)

R/2021/144 – HSIB recommends that NHS England and NHS Improvement leads work to develop a process to ensure consistency and clarity across national maternity clinical guidance.

R/2021/145 – HSIB recommends that future iterations of the Royal College of Obstetricians and Gynaecologists' guidance clarify the management of a reported change in fetal movements during the third trimester of pregnancy with due regard to national policy.

R/2021/146 – HSIB recommends that NHS England and NHS Improvement leads work to collate and act on the evidence on the risks and benefits associated with the use of remote consultations at critical points in the maternity care pathway.

R/2021/147 – HSIB recommends that NHSX develops specifications for electronic patient record (EPR) systems that require adherence to national interconnectivity standards for the exchange of core maternity healthcare information. The specification should include functionality to enable both pregnant people and professionals to add to the record, and also support alerting functionality.

R/2021/148 – HSIB recommends that the Department of Health and Social Care commission a review to improve the reliability of existing assessment tools for fetal growth and fetal heart rate to minimise the risk for babies.

R/2021/149 – HSIB recommends that NHS England and NHS Improvement leads the development of minimum operating standards for pre assessment maternity telephone triage services to support safe and consistent telephone triage to ensure reliable identification of risks.

R/2021/150 – HSIB recommends that NHS England and NHS Improvement develop minimum operating standards for interpretation services in maternity care which will include a communication risk assessment.

R/2021/151 – HSIB recommends that NHS England and NHS Improvement develop a framework to support trusts to anticipate operational risk in maternity services when delivering neonatal resuscitation.

Missed detection of lung cancer on chest X-rays of patients being seen in primary care
(October 2021)

R/2021/152 – HSIB recommends that the National Institute for Health Research assess the priority, feasibility and impact of future research to address whether low-dose computed tomography (CT) is clinically and cost-effective for the diagnosis of lung cancer in symptomatic patients seen in primary care and consider the most appropriate way of building up the evidence base on this topic.

R/2021/153 – HSIB recommends that the National Institute for Health and Care Excellence reviews its current safety netting advice to healthcare professionals with respect to the investigation of possible lung cancer. The wording of the advice should be amended as required to make it clearer what should be offered to patients with ongoing, unexplained symptoms who have had a negative chest X-ray.

R/2021/154 – HSIB recommends that NHSX, in collaboration with relevant stakeholders such as the Royal College of Radiologists and the Society and College of Radiographers, develops guidance to support independent benchmarking and validation of artificial intelligence algorithms for the identification of lung diseases such as cancer.

Surgical care of NHS patients in independent hospitals
(September 2021)

R/2021/155 – HSIB recommends that NHS England and NHS Improvement ensures that effective processes have been implemented in integrated care systems to identify local capability and capacity of their independent acute hospitals.

R/2021/156 – HSIB recommends that NHSX expands its work programme addressing the challenges associated with interoperability of information systems used in healthcare to include transfer of information between the NHS and independent sector in support of safe care delivery.

R/2021/157 – HSIB recommends that the Care Quality Commission reviews and appropriately develops its methodology for regulatory assurance of arrangements between NHS and independent providers for the provision of care across care pathways. This is to include any screening and risk management processes used to ensure the safe transfer of care between providers.

R/2021/158 – HSIB recommends that the Care Quality Commission incorporates regulatory assurance of surgical pathways between providers at a system level when developing its methodology for the regulation of integrated care systems.

R/2021/159 – HSIB recommends that NHS England and NHS Improvement reviews models of perioperative care for their value and impact. This should inform future work to support implementation of a standardised approach, based on evidence, across all healthcare providers that deliver surgical services.

R/2021/160 – HSIB recommends that NHS England and NHS Improvement establishes a process to ensure that findings of the National Institute for Health Research's policy research programme into frailty in younger patient groups are reviewed and acted upon.

Incorrect patient identification: Local integrated investigation pilot 1
(November 2021)

R/2021/161 – HSIB recommends that the Ambulance Trust develops and implements a standardised approach to patient identification in the emergency operations centre.

R/2021/162 – HSIB recommends that the Acute Trust develops and implements a standardised approach to patient identification in the emergency department.

R/2021/163 – HSIB recommends that the Acute Trust explores the barriers to checking three identifiers when confirming a patient's identification for their wristband, and takes appropriate action.

R/2021/164 – HSIB recommends the Acute Trust work with the Ambulance Trust to develop and implement a standardised approach to verifying and confirming a patient's identification during the handover process.

Recognition of the acutely ill infant
(October 2021)

R/2021/165 – HSIB recommends that the Chair of the NHS System-wide Paediatric Observations Tracking (SPOT) Programme ensures that the Association of Ambulance Chief Executives, community NHS 111 providers and primary care services are integral members of the NHS SPOT Programme.

R/2021/166 – HSIB recommends that NHSX develops national standards describing the electronic deployment of the NHS System-wide Paediatric Observations Tracking (SPOT) e-PEWS (the digital version of the Paediatric Early Warning Score tool), in collaboration with the NHS England and NHS Improvement SPOT Programme. This should include specifications for data capture, calculation of the score and escalation status, and also the display of the information and connectivity with other digital systems.

R/2021/167 – HSIB recommends that the Chair of the NHS System-wide Paediatric Observations Tracking (SPOT) Programme ensures that any resources produced include examples of children and young people with non-white skin showing signs of serious illness.

R/2021/168 – HSIB recommends that the Association of Ambulance Chief Executives works together with the ambulance services to share best practice in relation to paediatric training, education resources, frequency and types of training, and that it collates and shares areas of best practice.

R/2021/169 – HSIB recommends that the College of Paramedics works with partners and higher education providers to develop, agree and implement standards for paediatric education for the future ambulance service workforce.

Incorrect patient details on handover: Local integrated investigation pilot 2
(January 2022)

R/2022/170 – HSIB recommends that the nursing home implements a mechanism to use care records with the lowest risk of having incorrect personal identification data during interactions with the wider healthcare system.

R/2022/171 – HSIB recommends that the Ambulance Trust carries out additional personal identification data verification when a successful Patient Demographic Service search via NHS Spine has not been achieved.

R/2022/172 – HSIB recommends that the Acute Trust, in collaboration with the Ambulance Trust, develops and implements a formal emergency department booking-in policy.

R/2022/173 – HSIB recommends that the Acute Trust carries out additional personal identification data verification when an NHS number is not available.

R/2022/174 – HSIB recommends that the Acute Trust tests its positive patient identification procedure for patients with dementia in order to identify risks and support the development of effective mitigating controls.

Weight-based medication errors in children
(February 2022)

R/2022/175 – HSIB recommends that the Royal College of Paediatrics and Child Health identifies the best practice principles for effective paediatric ward rounds in relation to medicines, and disseminates them to its members.

R/2022/176 – HSIB recommends that the National Institute for Health Research assesses the priority, feasibility and impact of future research on processes for second checking medication, and considers the most appropriate way of building up the evidence base on this topic.

R/2022/177 – HSIB recommends that the Medicines and Healthcare products Regulatory Agency works with the manufacturers of electronic prescribing and medicines administration systems to provide guidance on their obligations under the Medical Devices Regulations 2002 (as amended).

R/2022/178 – HSIB recommends that NHS Digital and NHSX promote the organisational requirements for digital clinical safety, including organisations' responsibilities in terms of safety cases and clinical safety officers, to encompass system functionality and processes.

R/2022/179 – HSIB recommends that the Care Quality Commission (CQC) reviews whether a provider's assurance of its compliance with the Clinical Risk Management standard specific to electronic prescribing and medicines administration systems in healthcare, can form part of the CQC's developing regulatory model.

Maternity pre-arrival instructions by 999 call handlers (February 2022)

R/2022/180 – HSIB recommends that the Department of Health and Social Care commissions the National Institute for Health and Care Excellence to work with relevant stakeholders to develop guidance for maternity emergencies in the non-visual, non-clinician-attended environment.

R/2022/181 – HSIB recommends that the Department of Health and Social Care identifies a suitable regulatory mechanism to provide formal oversight of 999 maternity pre-arrival instructions across NHS-funded care in England.

R/2022/182 – HSIB recommends that NHS England and NHS Improvement develops the content of the patient safety incident investigation (PSII) standards to further support cross-boundary investigations.

Emergency neonatal blood transfusion at birth following acute blood loss during labour and/or delivery (March 2022)

R/2022/183 – HSIB recommends that NHS Resolution, working with relevant specialties through the clinical advisory group, amends the maternity incentive scheme guidance for year five to include the neonatal team as one of the professions required to attend multi-professional training.

R/2022/184 – HSIB recommends that the Resuscitation Council (UK)'s Newborn Life Support training course highlights that neonatal resuscitation teams should consider fetal blood loss in the event of neonatal resuscitation that includes chest compressions. In addition, this consideration should be included in the guidance to support the newborn life support algorithm.

Transfer of a patient who had suffered a stroke to emergency care: Local integrated investigation pilot 3

(March 2022)

R/2022/185 – HSIB recommends that Trust A and B update the information provided to the Directory of Service on the availability of stroke services once they have created a harmonised cross-trust stroke policy.

R/2022/186 – HSIB recommends that the Ambulance Trust works with Trust A and Trust B to ensure that their local stroke policies are aligned and direct ambulance crews to the most appropriate service.

R/2022/187 – HSIB recommends that Trust B works collaboratively with Trust A to develop a harmonised, cross-trust stroke policy with a clearly defined joint emergency department overnight stroke protocol for FAST-positive patients.

Clinical decision making: diagnosis and treatment of pulmonary embolism in emergency departments
(March 2022)

R/2022/188 – HSIB recommends that Health Education England works with appropriate professional bodies to develop and implement a strategy for supporting the education and training of clinical practitioners that can facilitate the development of decision-making skills. This strategy should consider the use of innovative approaches such as simulation and immersive learning.

R/2022/189 – HSIB recommends that the National Institute for Health and Care Excellence reviews the findings of this investigation in relation to its guidance NG158, 'Venous thromboembolic diseases: diagnosis, management and thrombophilia testing', and updates the guidance if required.

R/2022/190 – HSIB recommends that the Royal College of Emergency Medicine promotes best practice around diagnostic decision making with respect to patients with potential symptoms and signs of pulmonary embolism.

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HSIB
HEALTHCARE SAFETY INVESTIGATION BRANCH

Further information

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

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

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

Contact us

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

We monitor this inbox during normal office hours - Monday to Friday from 09:00 hours to 17:00 hours. We aim to respond to enquiries within five working days.

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