HSIB

HEALTHCARE SAFETY INVESTIGATION BRANCH

WWW.HSIB.ORG.UK

2021

Healthcare Safety Investigation Branch

Annual Review 2020/21

Keith Conradi, Chief Investigator

Foreword from the Chief Investigator

When I introduced last year's HSIB Annual Review from 'deep within the confines of the COVID-19 lockdown', I had very little anticipation that this year's review would also be produced in very similar circumstances.

Sadly, adverse events continued to occur within the remit of both our maternity and national programmes and we rapidly adjusted our investigation models to ensure minimum physical interaction with staff, families and healthcare facilities. This has been far from straightforward as face-to-face interviews with staff and families alike are a bedrock of our investigation process, as are observational visits. We also needed to achieve this without some of our key staff who, due to their specific skillsets, were redeployed to the frontline.

During this period, our maternity investigation teams completed 1,024 reports and have been working to keep all investigations within the agreed 6 months.

Almost all of these investigations were completed virtually, with just one or two visits to families when the benefits of a physical visit were deemed essential and were conducted in a covid-secure way. Feedback from families and trusts has

been overwhelmingly positive which is a remarkable achievement considering the restrictions imposed. Data from referrals and analysis of these investigations also led to COVID-19 themed investigations into unusual rises in maternal deaths and intrapartum stillbirths, intrapartum being the time from the onset of labour to immediately after a baby is born.

Cognisant of where we could add greatest value to safety in the pandemic, our national programme switched almost all its activity into COVID-19 related investigations. These included a prospective investigation into COVID-19 transmission in hospitals, oxygen supply concerns and use of early warning scores to detect deterioration in COVID-19 patients, among many others reported in this review. Our safety science expertise was also used to assist with evaluation of the Nightingale Hospitals and fixed and mobile COVID-19 testing centres. Despite the dramatic change in working conditions, the health sector has continued to work closely with our teams on the 39 safety recommendations we have made.

Importantly this year we have established an Investigation Education, Learning and Standards section which is described in more detail throughout this report.

This has always been an ambition of HSIB, as per our original Directions and we now consider we have the experience to start delivering this programme. Early trials suggest that this is a much-desired part of our work and we are refining the output before offering it to a wider audience in 2021/22.

We also delivered our first national seminar in September, aligned with World Patient Safety Day. Although this needed to be a virtual event, it was an opportunity to showcase work from the various sections of HSIB, and was well received by an international audience. Similar events will be planned to take place at the same time in the years ahead.

Finally, the journey for HSIB to become an independent body continues and looks set to progress this coming year, with the government's white paper published in February 2021 indicating that clauses to establish the Health Services Safety Investigations Body (HSSIB) will be included within the forthcoming Health and Care Bill*.

Alongside so many organisations, this has been a difficult year for HSIB. I consider the organisation to have shown extraordinary agility in adapting its operations and am extremely proud of the response from all my colleagues and the sector as a whole to delivering high-quality safety investigations, safety recommendations and their responses.

Keith Conradi
Chief Investigator

* At the time of publication of this Annual Review, the Bill has been introduced.

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Advisory Panel

HSIB's Advisory Panel brings together a group of independent people with a unique blend of expertise in the fields of patient and family advocacy, citizen leadership, clinical practice, healthcare policy, education and ethics, and professional investigation in other industries. Our members are all established and respected leaders within their fields, with significant track records of achievement. Although we have a purely advisory role, the diversity of opinion and experience makes for lively debate, and a level of healthy challenge with HSIB executives.

During 2020/21 we continued to provide a level of external scrutiny in relation to operational independence while the hosting arrangements with NHS England and NHS Improvement continue into a fourth year. Overall, we feel HSIB has maintained a good level of core independence, and we look forward to introduction of the Health and Care Bill* which will make HSIB an independent statutory body.

The Advisory Panel has significant experience in the field of patient and family advocacy and has taken a key role in supporting the ongoing design and development of the Citizens' Partnership. This formal network, under the leadership of Patrick Vernon OBE as Chair, is being established to ensure that the citizen voice – and particularly those most affected by healthcare harm – is at the heart of decision-making within HSIB and its successor organisation. This is a challenging task in the context of a professional investigation body, where technical skill is considered to be of central importance in providing high-quality outputs.

Finally, the last year has been one of great challenge and adaptation for HSIB. The Advisory Panel wishes to formally applaud the efforts of all its staff, who have responded professionally and effectively in extraordinary circumstances.

Professor Murray Anderson-Wallace, Chair

* At the time of publication of this Annual Review, the Bill has been introduced.

Advisory Panel members

Professor Murray Anderson-Wallace, Chair

Steve Clinch MNM

Dr Mike Durkin OBE

Farrah Pradhan

Professor Joe Rafferty CBE

Dr Suzanne Shale (resigned 4 January 2021)

Jennie Stanley RN

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

Our strategic goals

We have 5 strategic goals as set out below. Our Annual Review explains how we are delivering our goals throughout the reporting year 2020/21.

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.

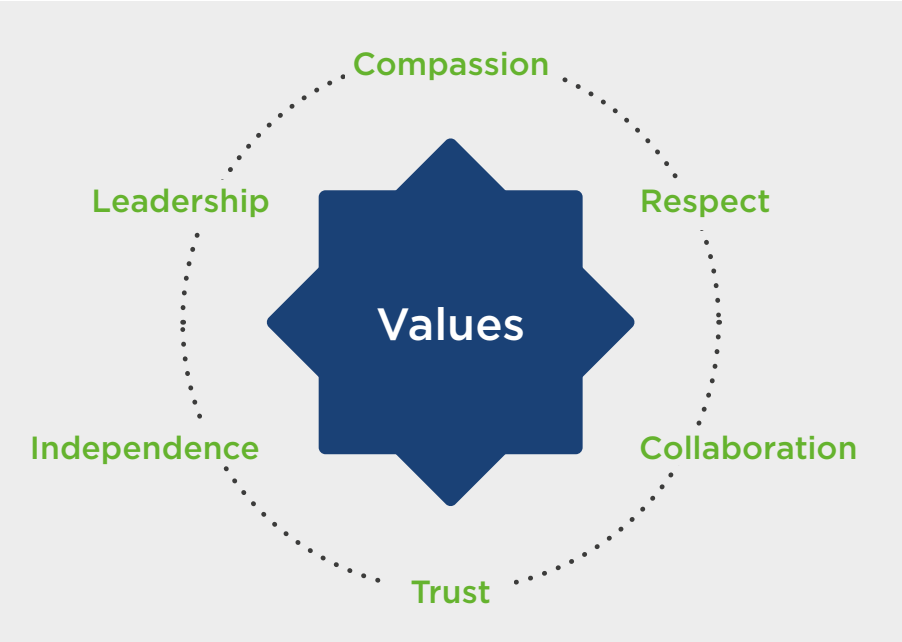
Strategic goal 2
Value and prioritise professional development for staff that includes internationally renowned safety investigation techniques and cutting-edge technology.

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 staff helped us develop our values and we are proud to evidence them in all the work we do.



Compassion

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

Respect

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

Collaboration

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

Trust

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

Independence

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

Leadership

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

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

HSIB

About the 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 (DHSC) and hosted by NHS England and NHS Improvement (NHSE/I), 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 Intelligence Unit (IU) informs the selection and conduct of our investigations by receiving referrals, and gathering and analysing data from a wide range of sources. The unit:

- Identifies safety risks and incidents for national investigations that offer strong opportunities for system-wide learning and safety improvement
- Identifies common themes emerging from analysis of the findings of multiple investigations in both maternity and national investigations
- Produces IU-led reports arising from such analysis
- Updates and maintains a body of intelligence relating to healthcare issues in our Safety Intelligence Research database.

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.

National investigations

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

Maternity investigations

We investigate incidents in NHS maternity services that meet criteria set out by two national maternity healthcare programmes, Each Baby Counts and MBRRACE-UK.

Each Baby Counts is a national quality improvement programme of the Royal College of Obstetricians and Gynaecologists to reduce the number of babies who die or are left severely disabled as a result of incidents occurring during term labour. MBRRACE-UK runs the national Maternal, Newborn and Infant clinical Outcome Review Programme, which conducts surveillance and investigates the causes of maternal deaths, stillbirths and infant deaths.

Incidents are referred to us by the NHS trust where the incident took place, and, where an incident meets the criteria, our investigation replaces the trust's own local investigation.

Our investigation report is shared with the family and trust, and the trust is responsible for carrying out any safety recommendations made in the report. From our maternity investigations we also identify important themes which then become the focus of a series of national reports.

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	15	130
Number of investigations	We were set the task of carrying out up to 30 investigations per year.	We were set the task of completing around 1,000 investigations per year that meet the criteria.
Training for investigators	Investigators attend an intensive training programme as soon as they join. They attend regular professional development workshops throughout the year.	All investigators attend an intensive training programme. 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 the criteria set out in Each Baby Counts and MBRRACE-UK. In April 2020 (with DHSC's agreement) we made amendments to the programme criteria which remained in place as of 31 March 2021. 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.

	National investigations	Maternity investigations
Reporting	We publish national investigation reports on our website. However, this year due to COVID-19 we undertook some investigations directly for NHSE/I and DHSC which we did not publish.	Maternity investigation reports are shared with the family and trust. They are not published.
Safety Recommendations	We make safety recommendations to relevant named organisations. We ask organisations to respond to the recommendations within 90 days and we publish the responses on our website. We may also make safety observations (where we consider our findings warrant attention but there is not enough information on which to make a recommendation) and identify safety actions that have been taken during an investigation to immediately improve patient safety.	We make safety recommendations for learning to the trust. The trust is responsible for putting them into action. We gather information about themes arising from our investigations to share learning across the health sector.

Highlights and achievements

During 2020/21 we had to change the way we worked. Some of the changes we made enabled us to undertake rapid investigations which provided valuable intelligence to help Trusts and frontline staff deal with COVID-19. Against the backdrop of the pandemic here are some of our highlights from the last year.

13
COVID-19 focused investigations launched to share learning swiftly across the NHS

22
national investigation reports produced, with **39** safety recommendations to **18** organisations

39
national safety recommendations issued to 18 different organisations to implement learning outcomes

1,024
maternity investigation reports completed

1,500
maternity safety recommendations to maternity units across England

700+
people attended our first online conference marking World Patient Safety Day 2020

New Investigation Education, Learning and Standards Team to develop and deliver investigation science education, and healthcare safety investigation training to the NHS.

Monitoring impact of our recommendations and results show improvement for areas such as: disease transmission in hospitals; oxygen supply; heart attacks; naso-gastric tubes; and, safety during mother and baby skin-to-skin contact. Adapted our investigation process and reports to maximise our ability to share intelligence and learning as swiftly as possible.

Continued to achieve exceptionally high levels of family engagement and positive feedback from our investigations.

The Chair of HSIB's Citizens' Partnership has actively supported our investigations focusing on the NHS response to COVID-19 and the transmission of covid within hospitals. For both, he chaired focus groups in a sensitive and empathetic way.

National investigations

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

- 'horizon scanning' – looking at potential safety risks by analysing serious incidents
- thematic reviews, which involve starting with a theme and working through information and literature.

National investigation criteria

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

Outcome impact

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

Systemic risk

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

Learning potential

We carefully consider whether our investigation and its safety recommendations are likely to lead to meaningful safety improvements. We are unlikely to initiate a national investigation if we cannot anticipate safety recommendations that could be implemented. For example, we might decide not to investigate an issue that has already been extensively investigated and for which robust recommendations for improvement already exist.

On the other hand, we have initiated national investigations into a number of safety issues that have already received a lot of attention, such as some recurring Never Events but where existing interventions are clearly not robust enough, or correctly directed, to prevent an issue from recurring.

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 recommendations
Value of intervention: adequacy and scope of safety actions by others; potential to develop local investigative capacity; potential to develop HSIB capacity and capability

National reports completed and/or published during 2020/21

Investigation number	HSIB report title
I2020/010	Investigation into oxygen supply concerns - (submitted to NHSE/I National Incident Response Board)*
I2020/013	Regional test sites (RTS) and Mobile test sites (MTS) review report (submitted to DHSC)*
I2020/003	Severe brain injury, early neonatal death and intrapartum stillbirth associated with group B streptococcus infection
I2020/019	Local test sites (LTS) review report (submitted to DHSC)*
I2020/012	Early warning scores to detect deterioration in COVID-19 inpatients*
I2020/004	Neonatal collapse alongside skin to skin contact
I2020/014	Personal protective equipment (PPE): care workers delivering homecare during COVID-19 response*
I2020/007	Giving families a voice: HSIB's approach to patient and family engagement during investigations
I2018/019	The role of clinical pharmacy services in helping to identify and reduce high-risk prescribing errors in hospital
I2018/023	Management of venous thromboembolism risk in patients following thrombolysis for an acute stroke
I2019/008	Unplanned delayed removal of ureteric stents
I2020/018	COVID-19 transmission in hospitals: Management of the risk - a prospective safety investigation*
I2020/020	Nightingale hospitals review report (submitted to NHSE/I)*
I2019/020	Delays to intrapartum intervention once fetal compromise is suspected
I2019/009	Procurement, usability and adoption of 'smart' infusion pumps
I2019/006	Placement of nasogastric tubes
I2020/015	Support for staff following patient safety incidents
I2020/006	Never Events: analysis of HSIB's national investigations

Investigation number	HSIB report title
I2020/005	Severe brain injury, early neonatal death and intrapartum stillbirth associated with larger babies and shoulder dystocia
I2020/017	Maternal death: learning from maternal death investigations during the first wave of the COVID-19 pandemic*
I2019/013	Residual drugs in intravenous cannulae and extension lines
I2019/012	Emergency response to heart attack

* Investigations commenced in response to COVID-19

Ongoing national investigations commenced but not completed during 2020/21

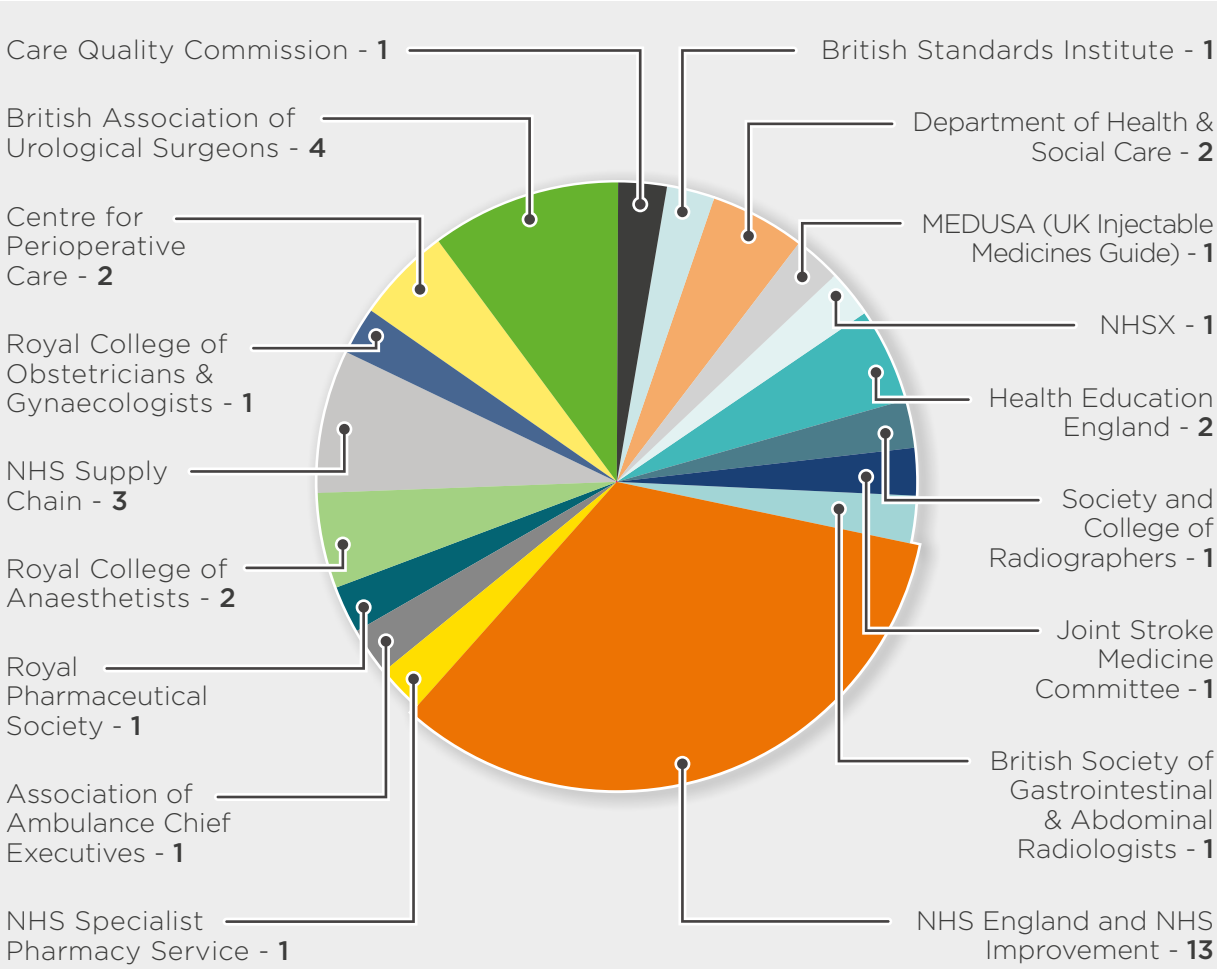
Investigation number	Investigation title
I2019/017	Wrong site surgery - wrong tooth extraction
I2019/011	Outpatient appointments intended but not booked after inpatient stays
I2019/010	Management of chronic asthma in children aged 16 years and under
NI-003748	HSIB maternity programme year in review 2020/21
I2019/018	Wrong site surgery – wrong patient: invasive procedures in outpatient settings
I2019/019	Suitability of equipment and technology used for continuous fetal heart rate monitoring
I2019/015	Timely detection and treatment of spinal nerve compression (cauda equina syndrome) in patients with back pain
I2020/022	Oxygen issues during the COVID-19 pandemic*

Investigation number	Investigation title
I2020/024	Intrapartum stillbirth: learning from maternity safety investigations that occurred during the COVID-19 pandemic 1 April to 30 June 2020*
I2019/007	Prescribing and administering insulin from a pen device
I2020/016	A thematic analysis of HSIB's first 22 national investigations
I2018/024	Recognition of the acutely ill infant
I2020/028	Response of NHS 111 to the COVID-19 pandemic*
I2019/004	Medicine omissions in learning disability secure units
I2019/016	Timely recognition and treatment of suspected pulmonary embolism
I2020/025	The assessment of venous thromboembolism risks associated with pregnancy
I2020/026	Weight-based medication errors in children
NI-000818	Maternity pre-arrival instructions by 999 call handlers
I2020/113	Surgical care of NHS patients in independent hospitals*
NI-003087	Treating COVID-19 patients using Continuous Postive Airway Pressure (CPAP)*

* Investigations commenced in response to COVID-19

National Report Safety Recommendations to different organisations in 20/21:

We made 39 safety recommendations to the below 18 organisations and these are listed in detail at the annex of this Annual Review with further details at **www.hsib.org.uk**.



Highlights of improvements being implemented from the above organisations to our National Report Safety Recommendations:

Patients suffering severe sight loss as a result of delayed glaucoma follow-up appointments
(report published January 2020)

Each month 22 people suffer severe or permanent sight loss as a result of delays in treatment, according to research. In our glaucoma report we featured the case of a woman aged 34 who lost her sight after continual delays in her follow-up appointments.

The woman saw seven different ophthalmologists, and the time between her being referred to hospital eye services and receiving laser eye surgery was 11 months. By this time her sight had deteriorated so badly she was registered as severely sight impaired. Improvements include:

- The Royal College of Ophthalmologists and stakeholders agreed criteria for the risk stratification of patients with glaucoma so that practice can be standardised across NHS hospital eye services.

- From April 2020 NHSE/I required commissioners to ensure compliance with Eye Health and Care follow-up performance standards. When this is not being met, providers must demonstrate how they are risk assessing patients, so those at greatest risk of sight loss are prioritised.

- The International Glaucoma Association has agreed to fund further research into the development and evaluation of an automated, predictive risk stratification tool.

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

Failures to communicate unexpected and significant X-ray findings to clinicians and families can have a life-threatening impact on patients.

In our radiological findings report a woman aged 76 years had had a chest X-ray showing possible cancer in her lung. This was not followed up properly and ended up in a delayed diagnosis. She died two months later. Improvements include:

- The Royal College of Radiologists (RCR) has standardised the coding of alerts and conditions for which a significant alert should be triggered to help ensure serious unexpected findings are acted upon. The RCR is working with relevant partners and industry to help enact our safety recommendations.

- NHSX, a joint DHSC and NHSE/I unit driving digital transformation of care, is exploring with radiologists a potential system to digitally inform patients of diagnostic test results. NHSX agreed 'that a method should be developed to digitally notif patients of unexpected significant radiological findings after an agreed timeframe'.

Technology and equipment investigations

Placement of nasogastric tubes

A nasogastric (NG) tube is a tube that is passed through a patient's nose and down into their stomach. NG tubes being placed incorrectly, going undetected and delivering food, liquid or medication into the lungs is a well-recognised Never Event in the NHS. Despite safety alerts and various safety initiatives, our investigation identified that this type of Never Event continues to happen and that there are no strong 'systemic' barriers to prevent NG tubes being accidentally placed into the lungs.

Between April and September 2020 there were 14 incidents of misplaced NG tubes.

Our investigation looked at the placement and confirmation of NG tubes which is done either via pH testing or an X-ray, and found that misinterpretation in both contributed to placement errors. The overall national investigation also considered the perception of safety culture related to placing NG tubes, the timeline for new technological solutions as well as reporting, regulation and procurement.

The report concluded with five safety recommendations focusing on agreeing standards and specifications relating to procurement and design of devices, researching new technologies and standardising competency-based training for national implementation.

Procurement, usability and adoption of 'smart' infusion pumps

Smart infusion pumps are the latest generation of programmable devices that administer medication. They are seen as a way of improving safety as the smart functionality aims to prevent underdoses or overdoses and has alerts or alarms to help detect problems.

Our investigation was launched after one NHS trust recorded three incidents where a smart infusion pump delivered an overdose of fentanyl, a powerful pain medication.

Our investigation focused on the barriers to implementing the technology effectively across the NHS, rather than on the technology itself. We examined these barriers through a '10 key considerations' framework' which looked at what is needed at each stage to ensure successful implementation. The framework covers everything from clarifying why the change is needed to constant evaluation once the system is in place.

The investigation made safety recommendations regarding the sharing of event log data, and validating national drug libraries.

Emergency response to heart attack

We started this investigation after a patient told us about his ambulance being delayed after he suffered a heart attack. Our investigation looked at the emergency response to heart attacks across the NHS in England.

There are different types of heart attack and this investigation looked into the most serious type – ST segment elevation myocardial infarction (STEMI). STEMI is what most people think of when they hear the term 'heart attack'.

A person suffering from a heart attack (STEMI) requires a swift response to ensure they receive the most appropriate medical intervention.

STEMI occurs when a clot forms in the blood vessel which serves a person's heart with oxygenated blood. The preferred treatment is where a stent (a wire mesh tube) is inserted into a blocked blood vessel in the heart, opening it up and re-establishing and maintaining blood flow.

If the clot is not removed or by-passed there is potential for further damage to the heart muscle or the patient having another heart attack.

Any delay in responding to a patient, or in transporting them to hospital, increases the risk of suffering additional harm.

The report made safety recommendations to NHSE/I and to the Association of Ambulance Chief Executives regarding the use of pre-hospital thrombolysis (treatment to dissolve blood clots) by paramedics and improving effective ambulance response.

Management of venous thromboembolism risk in patients following thrombolysis for an acute stroke

Every year in the UK over 100,000 people have a stroke. Patients who are admitted to hospital are assessed for their risk of developing blood clots.

Our investigation looked at the management of venous thromboembolism (VTE) risk (the risk of blood clots forming) for patients that have suffered an acute stroke and received thrombolysis. Thrombolysis is a treatment for some types of stroke with 'clot-busting' medicines.

This investigation focused on the management of VTE risk in inpatients following thrombolysis for an acute stroke and the detection of medical problems (that impact on VTE risk) occurring in inpatients following thrombolysis.

We made one safety recommendation to the Joint Stroke Medicine Committee and NHSE/I to develop a stroke specific VTE assessment tool and system for ordering treatment for patients who have suffered a stroke.

Investigations relating to the COVID-19 pandemic

COVID-19 transmission in hospitals: management of the risk (report published October 2020)

During the coronavirus pandemic in 2020 we investigated how the NHS could reduce the likelihood of a patient catching COVID-19 while in hospital, which is termed clinically as nosocomial infection. Improvements include:

- NHSE/I adapted its risk management strategies to deal with COVID-19.
- The NHSE/I Health Technical Memoranda was updated in relation to ventilation air changes, infection, prevention and control and cleaning advice.
- Funding was made immediately available for regional infection, prevention and control expertise to be delivered to NHS organisations reporting increased nosocomial infections.
- DHSC have been working with public health and NHS bodies to develop an improved process for infection, prevention and control guidance production and better clarify the roles and responsibilities for COVID-19 nosocomial guidance.
- Following the investigation NHSE/I published a suite of products to support excellence in **infection prevention and control measures**.

Oxygen issues during the COVID-19 pandemic

We were asked to support an NHSE/I-led rapid review of oxygen delivery to patients at an acute trust.

Patients suffering from COVID-19 need more oxygen to help them cope with the disease.

However, some hospitals found that their medical pipeline gas systems were beginning to freeze because of the cooling effect of more gas flowing through the pipes, with the freezing impacting oxygen supply to patients.

The aim of the rapid investigation was to understand options to improve oxygen flow to patients after increased usage.

The observations made by HSIB provided a practical solution to the issue and enabled trusts to develop plans to help ease the problem.

Since this rapid review was undertaken, we began a further investigation into oxygen systems, **Oxygen issues during the COVID-19 pandemic**.

The role of clinical pharmacy services in helping to identify and reduce high-risk prescribing errors in hospital

Research suggests that up to 237 million medication errors [b] may occur in England each year. When errors occur in prescribing high-risk medications for older patients with multiple medical problems, there is a significant risk of serious harm. High-risk medicines are those which risk significant patient harm or death when used in error, such as warfarin, which thins the blood.

To inform our investigation we used as a case study a hospital inpatient who was given repeated doses of warfarin in error and suffered significant harm. The error was detected 6 days later.

Our investigation focused on systems and processes which underpin the identification, prescribing and administration of warfarin, and other high-risk medicines, for older inpatients. We also considered the patient safety defences that act to protect people from medication errors with high-risk medicines.

In our safety recommendations we asked that work was carried out to define the role, organisation and prioritisation of hospital pharmacy services. (treatment to dissolve blood clots) by paramedics and improving effective ambulance response.

Unplanned delayed removal of ureteric stents

This investigation related to patients with kidney stones who had a ureteric stent inserted and where the stent was left in longer than planned.

A ureteric stent is a thin plastic tube that is inserted into the ureter (the tube that connects the kidney to the bladder). Stents keep the ureter open and enable urine to flow from the kidney into the bladder, as well as helping stone fragments drain away after treatment.

Ureteric stents are usually left in place for between a few days and 3 months, depending on why it has been inserted. The stents can become encrusted over time with the same deposits that form kidney stones.

This investigation looked at how ureteric stents were tracked following insertion, examined patient communication strategies that were being used at the time, and explored the reasons for delays in stent removal.

The report made safety recommendations to the British Association of Urological Surgeons. These centred on developing national standards for stent tracking, and providing advice and guidance to staff and patients about stent management.

Maternity investigations

Our maternity investigation programme is part of a national action plan to make maternity care safer. When the COVID-19 pandemic was declared in March 2020 we made amendments to our programme. Trusts 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. This adjustment reduced our overall caseload by 15% during 2020/21. During the year we completed a total of 1,024 reports.

Criteria for maternity investigations

Incidents that are eligible for investigation include those that involve term babies (at least 37 completed weeks of gestation) who experience one of the following outcomes.

Intrapartum stillbirth

Where the baby was thought to be alive at the start of labour but was born with no signs of life.

Early neonatal death

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

Severe brain injury

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

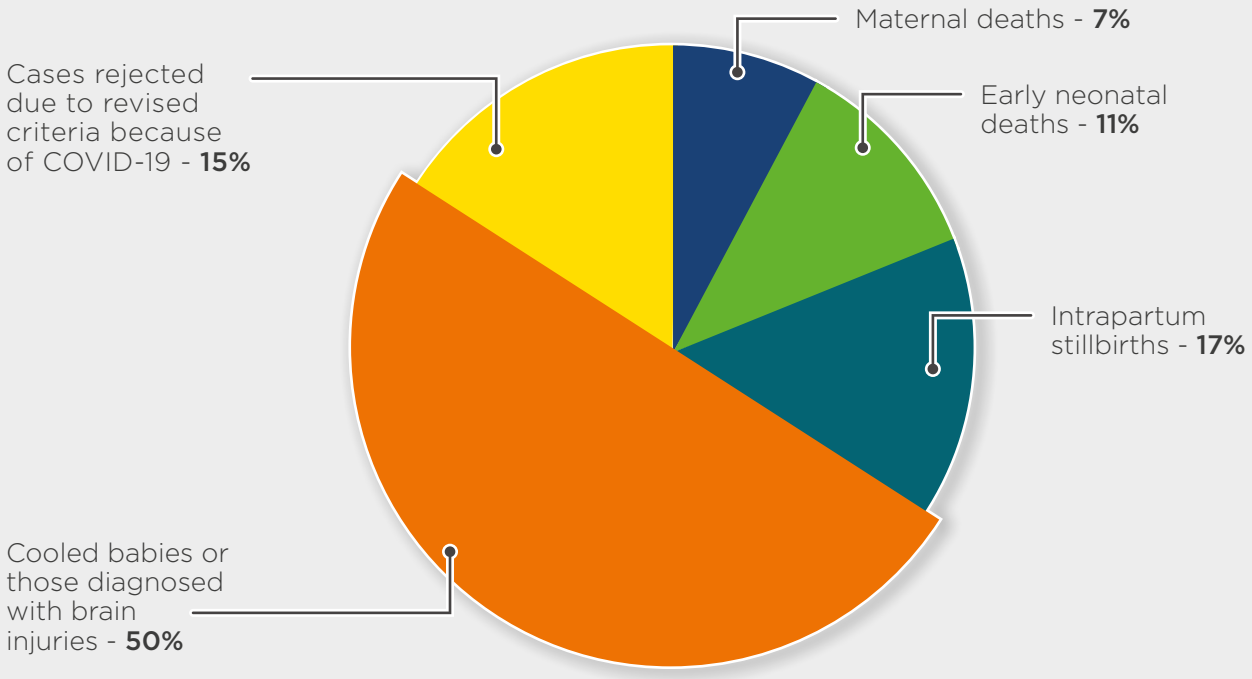
- diagnosed with grade III HIE, or
- therapeutically cooled (active cooling only), or
- had decreased central tone (described in layman's terms as 'floppy') and was comatose and had seizures of any kind.

Incidents involving babies whose outcome was the result of congenital anomalies (conditions present at birth) are excluded. We do not investigate neonatal cases where the mother has not gone into labour, for example, a caesarean section which was performed before the mother had started having contractions.

Maternal deaths

We investigate cases of women who die while pregnant or within 42 days of the end of pregnancy from any cause related to, or aggravated by, the pregnancy or its management, but not from accidental or incidental causes. We do not investigate cases where suicide is the cause of the mother's death.

Referrals by criteria



Maternity Investigations

1,024 investigation reports were completed during 2020/21, with all the reports and safety recommendations being shared with both the family and the trust. If a report makes safety recommendations, it is the hospital's responsibility to make improvements.

Below are some improvements implemented across maternity services as a result of our safety report recommendations.

Neonatal collapse alongside skin-to-skin contact
(report published August 2020)

When a baby is first born it is often laid directly on the mother's bare chest – this is called skin-to-skin contact.

When we did a thematic review of our maternity investigation reports we noted there had been 12 cases of sudden unexpected postnatal collapse (a rare but potentially fatal collapse in babies who otherwise appear healthy). In six of these cases the way the baby had been positioned during skin-to-skin contact may have contributed to the collapse.

We worked with UNICEF-UK, which support mothers to undertake skin-to-skin contact nationally and worldwide. UNICEF-UK supported us to ensure our report became a key learning document for midwives. As a direct result of the report safety recommendations one hospital told us it had developed a care bundle of measures aimed at promoting good initial care, particularly in the first hours of life post-delivery. We have now shared this bundle information with all maternity units across England.

The bundle includes:

- initial assessment of babies with respiratory distress (problems with breathing or getting enough oxygen) after birth
- first-hour care pathway (skin-to-skin, feed within the first hour, temperature monitoring and risk assessment)
- a modified British Association of Perinatal Medicine's Newborn Early Warning Trigger and Track (NEWTT) observations chart
- feeding chart for parents
- a QR code (a square barcode label read by a device) that links to a parent information leaflet
- an observation chart for first skin-to-skin contact.

Fetal monitoring

Between April 2019 and November 2020, a Trust reported 26 incidents to us. We completed 14 maternity investigation reports in a 4-month timeframe which enabled a thematic review by our HSIB team to identify three main themes in relation to safety recommendations and findings. These were around:

- fetal monitoring using a cardiotocograph to record the fetal (unborn baby's) heartbeat
- spontaneous rupture of membranes – also known as waters breaking – and induction of labour
- decision to deliver during the intrapartum period.

In response the Trust did a more detailed piece of work and identified that many of these themes occurred due to staffing, education and processes for induction of labour.

The Trust shared its findings with its staff as well as HSIB and secured an initial investment of £1.2m for staffing and education. This enabled teams to focus more closely on fetal monitoring and baby wellbeing. A review of cases of mothers with ruptured membranes and a lengthy induction of labour led to mothers being given the next available induction of labour slot, or 24 hours of prostaglandin (a treatment to induce labour). The Trust also instigated new ward rounds and used mobile computers during ward rounds to ensure SBAR communication was recorded efficiently and real time documentation captured. SBAR (Situation, Background, Assessment, Recommendation) is a technique used to explain information to different clinical colleagues accurately and effectively.

Since November 2020, the Trust has not had any further incidents that meet our criteria up to and including the end of March 2021.

Neonatal early warning score tool

A maternity report into care at one hospital recommended the Trust should implement the Newborn Early Warning Trigger and Track (NEWTT) chart for every baby, regardless of the clinical location. This was after the health of a term baby receiving care in the low dependency area of a neonatal unit unexpectedly deteriorated and was subsequently diagnosed with necrotising enterocolitis (NEC). NEC is a serious illness in which tissues in the gut become inflamed and start to die. This can lead to a hole developing, which allows the contents of the intestine to leak into the abdomen, potentially causing a dangerous infection.

The NEWTT chart is widely used on postnatal wards, but its use on neonatal units is less common. In this case there had been some signs including temperature instability earlier in the day and it was unclear whether this had been escalated to the senior clinical team. There was no early warning score tool used, which may have assisted staff in recognising the deteriorating clinical picture.

Following our HSIB report the Trust successfully implemented the use of early warning score charts for all babies receiving special care on its neonatal unit and these were adapted for gestational age. Since then, there has been positive feedback from staff regarding the early warning score charts and no adverse incidents associated with their use have been reported. This information has been shared with all maternity units in England.

Neonatal emergency call

A baby requiring resuscitation on the postnatal ward was the central incident for one of our maternity reports. During the incident several phone calls were made to contact neonatal team members. After this incident we recommended the Trust should ensure staff are aware of the 2222 emergency number for any neonatal resuscitation on the postnatal ward.

The Trust immediately placed laminated signs onto the resuscitaire reminding staff to ring 2222 if a baby required resuscitation. Staff were additionally trained with skills drills scenarios based on this case. The Trust reminded all staff and ward clerks to ring 2222 and ask for the neonatal team, and an emergency buzzer has been placed next to the resuscitaire which alerts staff on the ward. This safety recommendation has been shared with all maternity wards across England.

Publication of thematic learning reports

We have produced thematic reports that draw together the overarching themes and learning from our investigations and during this year we published:

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

NHS Maternity Transformation Programme

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

Over the last year we have made more than 1,500 safety recommendations to trusts addressing a wide range of issues. The most frequently recurring themes are detailed in our report 'HSIB maternity programme year in review 2020/21' and include:

- effective escalation of safety concerns about mothers and babies
- clinical oversight
- clinical assessment and monitoring
- use of guidance
- boundaries across pathways of care.

Engagement with trusts and local maternity systems

We share intelligence from our investigations with trusts on an ongoing basis to enable a rapid response to any safety concerns. Early awareness of new and recurring themes helps trusts communicate effectively with their frontline staff about risks and will enable them to help support learning from our work. We offer each trust a scheduled quarterly review meeting. We encourage the attendance of all clinicians involved in the provision of perinatal care to discuss the themes and possible solutions.

Collaboration with trusts and a continuous improvement approach are fundamental to our maternity programme's effectiveness. We undertook surveys of all acute and ambulance trusts in the maternity programme, and of NHS staff interviewed for maternity investigations. The results gave us valuable insight into the strengths of maternity programme. It also identified where we could do better – for example how we communicate with staff about investigations, the timeliness of our reports, and the factual accuracy checking processes for reports. The feedback was used to prioritise improvement work throughout the year.

NHS trust staff

We have conducted a significant number of NHS staff interviews during maternity investigations in the past year. Staff are now more aware of our processes and feel more confident about our approach and purpose of our investigations.

Feedback we have received from staff during 2020 includes:

"It was an open, non-pressured ... space to share what I really thought, with no judgement attached."

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

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

Feedback we have received from staff during 2020 includes:

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

"I feel very confident and comfortable to participate in HSIB investigations in the future if needed."

Health and Social Care Select Committee inquiry into safety of maternity services

We were invited to give evidence in January 2021 to the Health and Social Care Select Committee's inquiry into the safety of maternity services in England. We gave evidence detailing the benefit of the maternity programme and its contribution to the maternity safety environment and used the opportunity to provide reassurance to the committee of the programme's success and integration with both local and national improvement initiatives.

Response to the Ockenden report

The interim report of the Ockenden review, 'Emerging findings and recommendations from the independent review of maternity services at the Shrewsbury and Telford Hospital NHS Trust' was published in December 2020. This report contained seven immediate and essential actions to improve care and safety in maternity services.

Through our investigations we have developed a detailed understanding of where trusts have already undertaken considerable work to implement these actions, alongside trusts which require further support to achieve them.

We reinforced our support to trusts in a letter to assist their response to the interim Ockendon report. We highlighted where our work has already encouraged change in response to the recommendations.

Investigation education, learning and standards

One of our key priorities is to develop and exemplify best practice in patient safety investigation. To support this ambition, during the year we established an Investigation Education, Learning and Standards Team.

The department incorporates three core functions 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 have appointed an acting Head of Investigation Education, Learning and Standards and a team of senior Investigation Science Educators, who are developing standards, curriculum, competencies, and capabilities for the professional healthcare safety investigator.

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

During the year our team started to share its knowledge about how to conduct professional healthcare safety investigations with NHS colleagues. A number of pilot educational training courses ran through 2020/21 to develop and assess course content in preparation for wider scale NHS rollout during 2021/22.

In addition, the department began developing professional standards for healthcare investigators, and has been seeking the perspective of experts who have experience in investigating incidents from across the healthcare system to inform its work.

The curriculum's development derives from the experience we have gained in delivering training for our national and maternity investigators. It also accounts for the feedback we have received from NHS organisations and other stakeholders in response to our investigations.

It will provide opportunities for investigation science training in a variety of depths, from introductory courses designed for new patient safety investigators through to doctoral level modules to support the development of investigation science experts as set out below.

Investigation, education, learning and standards overview

HSIB Level 1 Award Safety Investigation Awareness	HSIB Level 2 Award Support Investigator	HSIB Level 3 Investigator	HSIB Level 4 Professional Investigator	HSIB Level 5 & 6 awards Senior Investigator		HSIB Level 7 Award Lead Investigator	HSIB Level 8 Award Expert Investigator
Recommended for anyone working in health/social care	Recommended for anyone supporting health/ social care investigations	Recommended for anyone who regularly conducts health/ social care investigations	Recommended for anyone who leads health/ social care investigations	Recommended for anyone who leads health/ social care investigations & wishes to lead a team of investigators	Recommended for anyone who regularly leads health/ social care investigations & wishes to lead a team of investigators	Recommended for anyone leading an investigation team in health/ social care	Someone who has made an original contribution to health/social care safety investigation knowledge through doctoral study, publication or extended experience in the field
Animated 30 minute video available on world wide web	12 hour virtual classroom or online with mentor to support work based project + self directed study	30 hour virtual classroom or online with mentor to support work based project + self directed study	60 hours virtual classroom or online with mentor to support work based project + self directed study	3 modules - 22 hours in a virtual classroom or online + self directed study	3 modules - 22 hours in a virtual classroom + self directed study	A single module – 600 hours work to produce a work based project in the field of healthcare safety investigation	
Assessment optional	Assessment	Assessment	Assessment	Assessment	Assessment	Assessment	

Supporting leadership teams

We aim to develop a range of further bespoke and short courses to assist in educating the NHS about investigation science at all levels. This will include:

- a bespoke course for senior NHS leaders to help promote and embed investigation science in senior decision making
- modules to support the NHS to address key learning needs, such as investigative interviewing and family engagement
- 'bite size' online learning resources to help promote the understanding of methods used in our published investigation reports.

We are contributing to the curriculum of training for the NHS Patient Safety Specialists to ensure they are appropriately knowledgeable and skilled in investigation science.

Patient and family engagement

Maternity/national investigations

Engagement with patients and families is embedded throughout our entire investigation process for both the national and maternity programmes. It provides an environment where family and patient insights can inform the investigation. Their questions are answered within the boundaries of the investigation, and they can be signposted to further support if required. Meaningful engagement with families during an investigation delivers better learning, higher-quality reports and an improved experience of the investigation for all involved.

Over the last year 89% of families engaged with us in our national investigations and 86% with our maternity investigations. All families are asked by the relevant trust if they agree for our investigators to contact them. The purpose of this contact is to ask for consent to access their medical records and to discuss how they would wish to be involved in any ongoing investigation. In our maternity programme, for example, 14% of families did not end up engaging in our investigations. Of these, 7% did not agree to be contacted by HSIB at all. The remaining 7% were involved in initial discussions but decided they did not wish to be involved further in the investigation.

Feedback continues to indicate that the way we approach and deal with families provides good learning and a better experience for both families and trusts when compared with what most trusts can offer through their local investigations.

Within our maternity investigations programme, families have described how our investigations have helped them to:

- fully understand the circumstances of their care
- trust that the knowledge generated has been fair, transparent and independent
- feel reassured that they have been an important part of the investigation.

Non-English-speaking families have also benefited from our inclusive approach. For example, we have produced our information resources in 19 languages other than English, used interpreters, and translated 57 investigation reports into the family's preferred language. In addition, we produce reports in other formats such as audio files, as requested, to support a family's needs.

Some of the feedback received over the last year:

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

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

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

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

Some of the feedback received over the last year:

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

‘Our investigator was phenomenal. Outstanding at supporting us and delving deep into the issues surrounding our boy’s birth. I am enormously grateful for all of the support and getting to the bottom of the circumstances surrounding the birth.’

Some of the feedback received over the last year:

‘We are very grateful this process exists to fill in the gaps and give us answers to such a shocking and traumatic event for us and our baby. I hope this continues to be made available to families that suffer major HIE events.’

Patient and Public Engagement

We are pleased to be in the process of establishing a Citizens' Partnership with the support of our initial Design and Delivery Group (DDG). The DDG is comprised of lay members from diverse backgrounds along with HSIB staff who have designed the terms of reference for HSIB first Citizens' Partnership. The Chair of the DDG is a member of the Advisory Panel.

The DDG has also been providing invaluable input into some investigations and other public facing components of our work.

- personal and sensitive information relating to individuals, such as patients and employees.

- Implemented an IT transformation strategy, and ensured we have an IT system which is futureproof and can support home working to a highly professional level.

We would like to thank the design and delivery group membership for their valuable work in helping us work towards a pointing our Citizens' Partnership.

Stakeholder engagement

Our relationships with NHS national bodies and other major healthcare organisations such as royal colleges and medical unions continued to grow and evolve during 2020/21.

Responding to COVID-19 pressures delayed much of the strategic engagement we undertake to promote the value of independent patient safety investigations in healthcare. However, the strength of our stakeholder relationships was born out in the high response rate to our safety recommendations within the standard 90-day window, demonstrating the value stakeholders recognise in our investigation reports for improving safety.

Our major policy contributions this year included written submissions to inquiries still underway by the Health and Social Care Select Committee for the safety of NHS maternity services in England (which included our maternity programme as an area of focus), and resilience and burnout of health and social care staff.

We responded to policy consultations by NHSE/I for establishing patient safety partners in the NHS, drawing on our extensive experience of family engagement and the work to develop our Citizens' Partnership, and we also contributed to the Care Quality Commission's strategy consultation.

We will continue to formalise our key stakeholder relationships with memoranda of understanding and these include:

Memoranda of Understanding
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

Equality, diversity and inclusion

Ensuring we are compliant with equality and human rights law is one of our highest priorities. Over the year we have taken great strides to develop a network of equality, diversity and inclusion (EDI) champions from among our staff who have been busy raising awareness and helping educate the organisation about EDI. The champions have been improving HR processes, taking part in recruitment, and ensuring the agenda is embedded effectively across HSIB.

We have finalised our EDI strategy and action plan which will be published during summer 2021.

We have continued to refresh our information and communication materials to make sure they are as clear as possible, and this work will be echoed across our redeveloped website where all our reports will be made fully accessible.

Upholding 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.

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

In the past year, we finalised our equality, diversity, and inclusion (EDI) strategy and action plan for the period 2021 to 2023. This is a high-level, iterative document which will be reviewed in 2022 against any transformational changes over its life cycle. It documents the commitments of different departments to embed EDI in their core business and actions, which they will then deliver over the course of the strategy. The strategy will be published in July 2021 on our website. Further work on revising equality objectives will take place in 2022 including an update report on actions undertaken.

The EDI strategy references actions already in progress or delivered by our equality workforce report for 2020/21, which is available on our website. These relate mainly to recruiting processes, workforce data and trend analysis

against protected characteristics using both the equality workforce report for 2018/19 and the one published for 2020/21. While there are improvements in the profile of the workforce for ethnicity, there remains more work to be undertaken around disability and ensuring all applicants and staff feel able to disclose protected characteristics.

The EDI Champions network has gained in strength and now comprises 20 EDI Champions, who are staff with knowledge and expertise around protected characteristics. Indeed, many have lived experience to contribute to the awareness and education of the whole organisation. They are focusing on a range of activities to ensure EDI is in the DNA of the organisation. These include:

- recruitment, from shortlisting to panel appointment
- reviewing operational documents to include EDI at different milestones
- improving HR processes such as including an EDI objective in appraisals
- consideration of positive action where team appointments are lacking in diversity.

The EDI Champions also share lived experience by participating in all staff awareness raising sessions for example by marking World Autism Day with a session on neurodiversity.

Collaboration with different departments around embedding EDI will be structured throughout 2021/22.

Since September 2020 we have been collecting additional data on the notifications of patient safety concerns coming via our web referral forms. This is so we can measure and evaluate the protected characteristics of the people reaching out to us to see if this reflects the community at large and whether we need to take any action to reach out to different groups.

Cultural intelligence training continues to be a focus for the organisation. To ensure maximum coverage, two members of staff enrolled on a facilitator development programme. This means they can become accredited cultural intelligence trainers and help to progress a programme of training throughout the organisation starting in 2021/22.

Our Staff

Professional development of staff

Over the next year we will continue to develop the new investigation science curriculum for our staff and elements of the new curriculum set out above have already been delivered internally to safety investigators in our maternity programme. We are launching the full curriculum of training during 2021/22 for staff to encompass the range of professional disciplines that form the basis of investigation science.

The new Investigation Education, Learning and Standards Team developed regular opportunities for both formal and informal learning to ensure the professional development of our investigation staff. Opportunities have included weekly education seminar series, quarterly debates, book clubs, and an investigation science support inbox. Leading international experts on safety science and healthcare services have participated and supported our internal knowledge which has fed into our overall education programme.

During the year we worked with staff to consider their development requirements and held eight virtual group training events across the organisation. These were on a variety of topics including incident reporting, cultural intelligence, post-traumatic stress disorder, and multiple maternity-specific subjects. In addition to these, we held two learning events for the maternity team and clinical advisors to ensure the latest clinical knowledge was shared widely. We also delivered our first version of the HSIB professional investigator award at level 4 to an intake of new safety investigators within our maternity programme. The course, which is built upon 10 distinct modules, covers the principles of investigation science and will be followed by a programme of mentoring and assessment during live investigations.

Mandatory and statutory training

We are delighted that by the end of the year we had an overall compliance rate of 95%. This was up 6% from the year before.

Staff Health and Wellbeing

During the year our former Staff Engagement Group broadened its remit and membership to become the Staff Health and Wellbeing Group. It set up workstreams around health and wellbeing, trauma incident management and peer support, charity and social activities.

COVID-19 prompted a greater focus on health and wellbeing resources and listening support for staff via a task and finish group whose work is now amalgamated into the Staff Health and Wellbeing Group. The geographical reach of our organisation and the total coverage of homeworking during the pandemic underlined the need for staff to feel greater connectivity with a range of ways to voice their concerns and support needs. The impact of homeworking on those with children heightened the need for support across teams. The Staff and Wellbeing group will continue to be vigilant about needs and concerns expressed via the membership as we move to a more normal way of working later in 2021.

Despite access difficulties, staff raised several hundred pounds for their annual chosen charity, Alzheimer's Research UK. Charity work will continue through innovative and inclusive opportunities during the rest of 2021. The Staff and Wellbeing Group benefits from the synergy of its members also being involved with Equality, Diversity and Inclusion Champions, the FTSU Guardians and the Staff Survey Group. Staff and Wellbeing Group members are active contributors to the actions being proposed and implemented to address areas of need arising from the 2020 staff survey.

Staff survey 2020/21

We completed our second annual staff engagement survey in September 2020. We achieved a response rate of 91%, which was 11% above the benchmark. The Staff Survey Group is now working with staff to formulate and suggest actions for improvement for the top areas highlighted. We have already implemented improvements for one of these areas by awarding permanent contracts for those staff who were previously fixed-term.

In January 2021 we appointed two Freedom to Speak Up (FTSU) Guardians to provide support to staff should they wish to raise a concern. Part of their role is to work with our executive leadership team to ensure staff concerns are heard and dealt with appropriately. This supports our work in confidence online platform for staff to share ideas or concerns that inform improvements.

Supporting staff by investing in the latest Information technology (IT)

During 2020/21 we have been undergoing significant IT transformation to support HSIB's evolving requirements. We had been running two distinct investigation management platforms that supported the two different investigation pathways: maternity investigations and national investigations. To ensure greater efficiency we required a secure, integrated and fit-for-purpose investigations management system to support staff over a wide geographic area, whether working from home or in a field location.

Governance

Responsibilities, accountability, and independence

We are accountable to the Secretary of State for Health and Social Care and our performance is scrutinised by the DHSC. Through this Annual Review we report every year to the Secretary of State for Health and Social Care on our performance and it is published 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 February 2021, the government published a White Paper setting out legislative proposals for a Health and Care Bill*, which will include legislation to create the Health Services Safety Investigations Body (HSSIB). The passage of this Bill through Parliament will continue throughout 2021 and if passed will support the HSSIB to establish a Board of non-executive and executive directors.

Risk Management

We implemented a new online self-service risk management system 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 secure arrangements by first assessing arrangements with robust risk assessments.

* At the time of publication of this Annual Review, the Bill has been introduced.

Financial Performance

During the year we kept within our funding allocation. Our net expenditure for the year was £18,224,000. The reduced expenditure was due to the decrease in business travel and training as a result of the pandemic.

	2020/21	2019/20
Target: Funding allocation	£19,800,000	£19,800,000
Performance: Net expenditure	£18,224,000	£19,287,000
Performance: Capital expenditure	456,000	91,000

Main categories of revenue expenditure

	2020/21	2019/20
Revenue	£(1,000)	-
Staff	£15,744,000	£14,904,000
Purchase of goods and services	£2,218,000	£4,086,000
Other operating expenditure	£263,000	297,000
Total	**£18,224,000**	**£19,287,000**

(as at time of publication above amounts are unaudited).

In addition to the expenditure above, £456,000 of information technology, software and a website under construction were capitalised in the year (2019/20: £91,000).

The largest area of spend is workforce costs, representing an increase to 86% of net expenditure in 2020/21 from 77% in 2019/20.

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 NHSE/I.

Conclusion

HSIB is a young organisation with just over 200 staff and a relatively small budget, yet our Annual Review documents how we continue to make a significant and positive impact on patient safety. The pandemic continued to globally challenge how we all live and work but none more than NHS staff.

We are proud to have supported and worked alongside the NHS in England with our investigation programmes and we will continue to build on this work to enable HSIB to become an integral part of the emerging new patient safety landscape as set out in the Health and Care Bill* 2021. Our work is testament to the extraordinary commitment of our staff and we conclude this Annual Review by sincerely thanking each and every one of our staff for their hard work, determination and drive to improve safety in the NHS.

* At the time of publication of this Annual Review, the Bill has been introduced.

Appendix

For the very latest information on our investigations, reports, safety recommendations and safety recommendation responses, please visit our website: **www.hsib.org.uk**

Published national reports and safety recommendations 2020/21

The role of clinical pharmacy services in helping to identify and reduce high-risk prescribing errors in hospital (September 2020)

R/2020/087 - It is recommended that **NHS England and NHS Improvement** carry out work to understand and further define the work of hospital clinical pharmacy teams, including the period between initial medicine reconciliation and discharge, in consultation with relevant stakeholders.

R/2020/088 - It is recommended that the **Royal Pharmaceutical Society**, supported by NHS England and NHS Improvement, should provide guidance on models of hospital clinical pharmacy provision. The guidance should provide information on the models' ability to enhance safety and healthcare resilience and include consideration of the appropriate skill mix and experience within the clinical pharmacy team.

R/2020/089 - It is recommended that the **NHS Specialist Pharmacy Service** should update its resource on the prioritisation of hospital clinical pharmacy services to facilitate the dissemination of developments in good practice and policy with respect to pharmacy prioritisation and the issues highlighted in this report.

Management of venous thromboembolism risk in patients following thrombolysis for an acute stroke (October 2020)

R/2020/090 - It is recommended that the Intercollegiate Stroke Working Party with support from the **Joint Stroke Medicine Committee** and **NHS England and NHS Improvement** develop a stroke specific venous thromboembolism (VTE) assessment tool and system for ordering the associated treatment for patients who have suffered a stroke. HSIB recommend that the Intercollegiate Stroke Working Party supports development of a tool that ensures that important information is recorded and reviewed at appropriate intervals. The following points should be considered in the development of this tool:

- The aetiology/type of stroke (ischaemic and haemorrhagic).
- A record of the individual risk factors for VTE that are identified.
- Contraindications for VTE treatment measures.
- The VTE preventative treatment recommendation.
- The record of administration of that treatment.
- The reason that treatment is not administered.
- Patient's level of mobility and activity (in relation to IPC administration).
- Frequency of IPC devices checking.
- Record of patient's consent and understanding of risk/benefits of intervention, including patient's decision.

Unplanned delayed removal of ureteric stents (October 2020)

R/2020/091 - It is recommended that the **British Association of Urological Surgeons**, in collaboration with other relevant specialties (such as the Royal College of Radiologists and British Transplant Society), develops national standards which support electronic and paperbased systems for stent logging/ tracking. These standards should include guidance on monitoring and human oversight.

R/2020/092 - It is recommended that the **British Association of Urological Surgeons** works with the Patient Information Forum to review its stent patient information leaflet. This should include accessibility and clinical considerations, especially with regards to side effects and complications, and advice on the action to take should concerns arise.

R/2020/093 - It is recommended that the **British Association of Urological Surgeons** provides guidance for staff working within the stone care pathway to promote consistent advice to patients as part of discharge planning.

R/2020/094 - It is recommended that the **British Association of Urological Surgeons** encourages members to include information in discharge letters and other communication sent to GPs and patients regarding patients' stent status, potential complications and the possibility of a retained stent.

COVID-19 transmission in hospitals: Management of the risk - a prospective safety investigation (October 2020)

R/2020/095 - It is recommended that the **Department of Health and Social Care**, working with NHS England and NHS Improvement, Public Health England, and other partners as appropriate, develops a transparent process to co-ordinate the development, dissemination and implementation of national guidance across the healthcare system to minimise the risk of nosocomial transmission of COVID-19.

R/2020/096 - It is recommended that **NHS England and NHS Improvement**:

- supports additional capacity for testing for NHS patients and staff (Pillar 1 testing)
- facilitates the accessibility of rapid testing for NHS trusts, as soon as an increase in rapid testing supplies becomes available.

R/2020/097 - It is recommended that **NHS England and NHS Improvement**:

- develops a national intensive infection prevention and control (IPC) safety support programme for COVID-19 which focuses on leadership, IPC technical support education, practice, guidance and assurance
- develops a national IPC strategy which focuses on developing IPC capacity, capability and sustainability across the NHS in England.

R/2020/098 - It is recommended that **NHS England and NHS Improvement** reviews the principles of the hierarchy of controls in its health building notes (HBN) and health technical memoranda (HTM) for the design of the built environment in existing and new hospital estate to reduce the risk of nosocomial transmission.

R/2020/099 - It is recommended that **NHS England and NHS Improvement** responds to emerging scientific evidence and shared learning when reviewing guidance for NHS trusts on the role of hospital ventilation systems in nosocomial transmission.

R/2020/100 - It is recommended that **NHS England and NHS Improvement** investigates and evaluates the risks associated with the potential impact of staff fatigue and emotional distress on nosocomial transmission of COVID-19.

R/2020/101 - It is recommended that the **Department of Health and Social Care** reviews and identifies the mechanisms which enabled regional and local organisations to adapt and respond with agility during the pandemic. This should inform the development of a strategic approach to national leadership models at times of crisis and under normal conditions.

R/2020/102 - It is recommended that **NHSX** considers how technology can assist in mitigating nosocomial transmission in the ward environment with regard to:

- the use of digital communication technologies in assisting with the deployment of staff and the dissemination and circulation of key information

- the increased use and availability of personal computing devices and electronic health record systems.

Delays to intrapartum intervention once fetal compromise is suspected (November 2020)

R/2020/103 - It is recommended that the **Care Quality Commission**, in collaboration with relevant stakeholders, includes assessment of relational aspects such as multidisciplinary teamwork and psychological safety in its regulation of maternity units.

Procurement, usability and adoption of 'smart' infusion pumps (December 2020)

R/2020/104 - It is recommended that **NHS Supply Chain** develops an agreed specification that defines an open standard format for the sharing of event log data, thus allowing dose error reduction systems (DERS) to be evaluated to establish patient safety benefits.

R/2020/105 - It is recommended that the **MEDUSA** (UK Injectable Medicines Guide) advisory board, in conjunction with other relevant multi-professional organisations, develops validated national drug libraries for smart infusion pumps.

Placement of nasogastric tubes (December 2020)

R/2020/106 - It is recommended that **Health Education England** develops and publishes a national standardised competency-based training programme for NG tube placement and confirmation by pH testing. The model may include simulation, observed practical assessment and ongoing competency assessment. The competency-based training programme would need to be defined, developed, and tested using a human factors approach prior to any widespread implementation. The competencybased training programme will lead to a recognised accreditation which will be transferable across the NHS care providers in England.

R/2020/107 - It is recommended that **NHS England and NHS Improvement** works with the Department of Health and Social Care and others, to identify the process by which the NHS can identify and commission necessary research to support improvements in patient safety. This would include research to confirm NG tube placement.

R/2020/108 - It is recommended that **NHS Supply Chain** and the **British Standards Institution** work together (engaging other system leaders as appropriate, such as the Medicines and Healthcare products Regulatory Agency and NHS England and NHS Improvement), to develop and publish an agreed standard to minimise the risks relating to human errors in the use of pH strips designed for testing human gastric aspirate at the bedside. The standard should consider product design, regulatory standards, procurement practices and human factors engineering to provide a consistent approach that can be embedded within NHS Supply Chain product specifications.

R/2020/109 - It is recommended that **NHS Supply Chain** develops essential specifications to support the clinically-led procurement of devices to include devices to confirm NG tube placement, for example, pH testing strips. The essential specifications should set out a range of factors critical to inform the selection by NHS Supply Chain of a product including, but not limited to: clinical output requirements; design and ergonomics; human factors and intended use; and limitations on use and usability. Critically, these specifications should ideally be established in partnership across the healthcare system with clinicians, healthcare professionals and safety leads, while maximising best practice.

R/2020/110 - It is recommended that the **British Society of Gastrointestinal and Abdominal Radiologists**, working with **Health Education England** and the **Society and College of Radiographers**, develops and publishes a national standardised competency-based training programme for X-ray interpretation to confirm NG tube placement. The competency-based training programme will include the referral process for X-ray to confirm NG tube position and the subsequent reviewing, recording and communication of the clinical evaluation of the X-ray findings prior to initiation of feed. The standards must meet the Ionising Radiation (Medical Exposure) Regulations IR(ME)R requirements. The competency-based training programme will lead to a recognised accreditation for those qualified to clinically evaluate and record their findings, for example doctors, radiographers and advanced care practitioners. The accreditation certificate will be transferable across NHS care providers in England.

Never Events: analysis of HSIB's national investigations (January 2021)

R/2021/111 - It is recommended that **NHS England and NHS Improvement** revises the Never Events list to remove events, such as those presented in this national learning report, that do not have strong and systemic safety barriers.

R/2021/112 - It is recommended that **NHS England and NHS Improvement** develops and commissions programmes of work to find strong and systemic safety barriers for specific incidents where barriers are felt to be possible but are not currently available.

R/2021/113 - It is recommended that the **Centre for Perioperative Care** reviews and revises the National Safety Standards for Invasive Procedures (NatSSIPs) policy to increase standardisation of safetycritical steps that are common across all procedures.

Severe brain injury, early neonatal death and intrapartum stillbirth associated with larger babies and shoulder dystocia (NLR) (February 2021)

R/2021/114 - It is recommended that the **Royal College of Obstetricians and Gynaecologists** (RCOG) takes into consideration the findings of this HSIB review when updating the RCOG Green Top shoulder dystocia guideline (No.42).

Residual drugs in intravenous cannulae and extension lines (March 2021)

R/2021/115 - HSIB recommends that the **Royal College of Anaesthetists** and **Centre for Perioperative Care** work with relevant stakeholders, such as the Association of Anaesthetists, College of Operating Department Practitioners, and Association for Perioperative Practice, to review, update and integrate new guidance on the surgical safety checklist 'Sign- Out' process. Specifically, the guidance should be updated in relation to the flushing of cannulae and extension lines by strengthening the current administrative barriers, considering the hierarchy of hazard control, and the issues identified by the HSIB investigation.

R/2021/116 - HSIB recommends that the **Royal College of Anaesthetists** reviews its 'Guidelines for the provision of anaesthetic services' regarding the planning and oversight of perianaesthetic care in non-theatre settings. This should include:

1 guidance to assist anaesthetic departments to consistently plan for short-notice or emergency cases which take place in the nontheatre setting

2 planning which considers and mitigates against unexpected changes in conditions.

Emergency response to heart attack
(March 2021)

R/2021/117 - HSIB recommends that **NHS England and NHS Improvement** revise the Ambulance Clinical Quality Indicator: Clinical Outcomes for ST-elevation myocardial infarction to reflect each element of the call to balloon response and review this indicator alongside the critical time standards workstream.

R/2021/118 - HSIB recommends that the **Association of Ambulance Chief Executives**, working with the College of Paramedics and cardiology specialists, produces a position statement on the use of pre-hospital thrombolysis by paramedics.

R/2021/119 - HSIB recommends that **NHS England and NHS Improvement** support the Joint Ambulance Improvement Programme to respond to emerging risks and research highlighting factors impacting on effective ambulance response.

Oxygen issues during the COVID-19 pandemic - interim bulletin (March 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.

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

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