



HEALTHCARE SAFETY
INVESTIGATION BRANCH

WWW.HSIB.ORG.UK

ABOUT THE HEALTHCARE SAFETY INVESTIGATION BRANCH

Trust Introduction Pack

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The Healthcare Safety Investigation Branch (HSIB) conducts independent investigations of patient safety concerns in NHS-funded care across England. Most harm in healthcare results from problems within the systems and processes that determine how care is delivered. Our investigations identify the contributory factors that have led to harm or have the potential to harm patients. The recommendations we make aim to improve healthcare systems and processes in order to reduce risk and improve safety. Our organisation values independence, transparency, objectivity, expertise and learning for improvement. We work closely with patients, families and healthcare staff affected by patient safety incidents, and we never attribute blame or liability to individuals.

OUR INVESTIGATIONS

Our team of investigators and analysts have diverse experience working in healthcare and other safety critical industries and are trained in human factors and safety science. We consult widely in England and internationally to ensure that our work is informed by appropriate clinical and other relevant expertise.

We undertake patient safety investigations through two programmes:

NATIONAL INVESTIGATIONS

Our national investigations can encompass any patient safety concern that occurred within NHS-funded care in England after 1 April 2017. We identify the need to investigate potential incidents or issues based on wide sources of information including that provided by healthcare organisations, the public and our own research and analysis of NHS patient safety systems.

We decide what to investigate based on the scale of risk and harm, the impact on individuals involved and on public confidence in the healthcare system, as well as the potential for learning to prevent future harm. We welcome information about patient safety concerns from the public, but we do not replace local investigations and do not investigate on behalf of families, staff, organisations or regulators.

Our investigation reports identify opportunities for relevant organisations with power to make appropriate improvements though:

- safety recommendations made with the specific intention of preventing future, similar events; and
- safety observations with suggested actions for wider learning and improvement.

Our reports also identify actions required during an investigation to immediately improve patient safety. Organisations subject to our safety recommendations must respond to us within three months, these responses will be published on our **website**

More information about our national investigations, including detailed explanations of our criteria, how we investigate, and how to refer a patient safety concern is available on our website.

MATERNITY INVESTIGATIONS

From 1 April 2018, we became responsible for all patient safety investigations of maternity incidents occurring within NHS Trusts in England which meet criteria for the Each Baby Counts programme (Royal College of Obstetrics and Gynaecologists, 2015). The purpose of this programme is to achieve rapid learning and improvement in maternity services, and to identify common themes that offer opportunity for system-wide change. For these incidents HSIB's investigation replaces the local investigation, although the Trust remains responsible for Duty of Candour and for referring the incident to us. We work closely with parents and families, healthcare staff and organisations during an investigation. Our reports are provided directly to the families involved and to the Trust. The Trust is responsible for actioning any safety recommendations we make as a result of these investigations.

We are now operating in all NHS trusts across England. Our longer-term aim is to make safety recommendations to national organisations for system-level improvements in maternity services. These will be based on common themes arising from our investigations in trusts. More information is available on our **website**

OUR INDEPENDENCE

We are funded by the Department of Health and Social Care and sponsored by NHS Improvement, but we operate independently. A Bill for establishing the Health Service Safety Investigations Body (HSSIB) is currently being drafted based on recommendations from a parliamentary select committee, and we expect it to be introduced by parliament near future. The Bill will establish our full statutory independence and enshrine our right to conduct national investigations under protected disclosure. This provision, commonly known as 'safe space', enables staff to share their experience of a patient safety

incident without fear of reprisal. It does not prevent us from sharing important details with families, regulators or organisations about an incident or to address immediate risks to patient safety. The Health Service Safety Investigations Bill will also establish our responsibility for NHS maternity investigations that meet specific criteria. Full information about the draft Bill is available on the Department of Health and Social Care [website](#)

More information about HSIB is available at www.hsib.org.uk

THE PROCESS OF HSIB NATIONAL SAFETY INVESTIGATIONS

Why have we asked your organisation to participate in a national safety investigation?

We have identified an opportunity to develop systemic learning to improve healthcare safety by investigating an incident that has occurred within your services. The incident may have been directly referred to HSIB by the Trust, a healthcare employee, or a patient or family member. We also identify a Trust with a suitable reference event for an investigation through our analysis of NHS patient safety data.

Is your organisation required to participate in a national safety investigation?

The Healthcare Safety Investigation Branch is deemed a Supervisory Body for the purposes of conditions and requirements set in the NHS Standard Contract 2019/20. In practice, this requires providers of NHS services to comply with all reasonable requests made by HSIB for information.

How long does a national safety investigation take?

The timescales vary depending on the complexity of the investigation, however, we aim to complete an investigation in 12 months.

How do we decide to carry out a national safety investigation?

There are three key stages:

- 1 Scoping investigation:** This stage is to establish the facts and circumstances surrounding the reference event we are investigating. This helps us to understand whether it fully meets the criteria to progress to a national investigation. We work in partnership with the Provider to understand the clinical environment, get staff perspectives on what happened via interviews, review patient notes and consider any other relevant evidence.
- 2 Full national investigation:** Once we have decided to go forward with the investigation, we broaden out to look at the systemic factors that are contributing to the patient safety risks that we identified through the reference event. We identify areas for improvement through analysis of our findings, as well as working with Subject Matter Advisors to provide insight and specialist knowledge.

3 Developing recommendations and report publication: We work closely with the bodies and organisations that we propose to make recommendations to. We write the report detailing the reference event, analysis, findings, the wider investigation and setting out the safety actions, safety observations and safety recommendations as required.

Does a HSIB national safety investigation replace the local processes or the NHS serious incident investigation?

A HSIB national safety investigation does not replace any local processes and the Provider should continue with any mandated investigation. Our investigation team will work to make sure, where possible, duplication is avoided and the burden on the organisation is reduced.

What communication will HSIB release about the investigation?

- Once progressed to a full investigation, a notification will be published on the HSIB website.
- When we have more information to share about the investigation, an interim bulletin may be published. Prior to publication this will be shared with the Provider and other stakeholders for comment.
- Both the notification bulletin and the full investigation report will not include any details of where the reference event occurred.
- It would be beneficial for the Provider to assign a point of contact for HSIB investigators to communicate any deadlines for comment or the anticipated dates of publication.

Are staff required to engage with a national safety investigation?

Staff are expected to attend interviews, in accordance with their professional code of conduct. Staff interviews help establish the facts about the event and the context in which it occurred. Feedback we have received from staff involved in our investigations to date has been very positive.

HSIB investigations never attribute blame or liability to individuals and our processes are designed to uphold this principle.

Which staff will be interviewed?

All members of the Provider's staff involved in the reference event, alongside others who may be identified during the investigation, may be asked to give evidence through interview.

How are families involved in HSIB national safety investigations?

We involve patients and families throughout our investigations. Once a scoping investigation has started HSIB will ask the Provider to provide the patient and family with information explaining who we are and what will happen next. HSIB investigators will contact the patient or family to determine how they want to be involved, seek their written consent to participate in the investigation (including being interviewed) and obtain copies of their medical records.

Is there an opportunity to comment on the final report before it is published?

We will send a copy of the draft investigation report to all staff, organisations and patient(s) / family involved in the investigation for comment on factual accuracy. Four weeks will be given to review the report. The final investigation reports are anonymised and published on our website and the links shared across our social media channels. We also send copies to a list of subscribers who have signed up to receive updates on our investigations,

Who is responsible for implementing national safety recommendations made by HSIB?

Each recommendation is made to a national organisation to implement. The recommendations and responses from the organisations that have received them are published on our website.

WHAT HAPPENS NEXT

Timeliness is a critical factor in determining causal and contributory factors in a patient safety investigation. We aim to gather information as soon as possible and welcome the Provider's support and assistance in helping us with this.

The HSIB investigation team will conduct a site visit, working with the Provider to make sure this is done as smoothly as possible. We aim to be on site for between 3-5 days depending on availability of staff and scope of the investigation. It is helpful for our investigators to have access to a suitable working space that is private and allows for staff to be interviewed in confidence.

Before we visit the Provider, the Lead Investigator will provide the names of the investigators. Each investigator will wear a badge to confirm identity when attending the Provider's premises.

From our experience to date, there are particular senior members of the organisation for whom it is helpful to be aware at the outset about our investigation. These people are central to our work and facilitate our engagement with various staff responsible for the purposes of governance and reporting, providing access and information, liaising with the family, and supporting staff. The list is not prescriptive, and we welcome the opportunity to meet with any staff that the organisation would like to involve in the investigation:

- Chief Executive
- Medical Director
- Director of Nursing
- Staff directly involved in the incident
- Head of Patient Safety

There are types of information which we frequently seek to support our work. The investigation team may ask you to collect it prior to or in preparation for the investigation team visiting your Trust, this evidence may include:

- patient notes, including radiology, pathology, observations etc.
- equipment memory downloads, printouts from all equipment where possible.
- consent forms
- staff rotas
- local policies relevant to event
- documents related to any SI investigation.

In addition, the investigators may request other types of materials or evidence to support their analysis:

- to take photographs (environment, layout, equipment etc)
- CCTV recordings
- ID access records
- switchboard records
- training packages and records
- audit results.

THE INTERVIEW PROCESS

What should I expect from the interview?

- Interviews with staff are confidential; two HSIB investigators should be present during the interview.
- The aim of the interview is to understand what happened and the circumstances surrounding the event.
- We recognise staff can feel anxious about being interviewed. We make every effort to put staff at ease and make the interview a positive and supportive experience.
- Information provided at interview is treated as confidential but may be disclosed in certain, judicial or legal circumstances. The investigators understand that staff can often feel worried about how their information will be used and can explain in more detail about our remit for preventing disclosure of your information, as well as to talk through any concerns you have about this process.
- We ask to record interviews. This allows us to focus on listening to what staff are telling us. It also gives us an exact record of what has been said. If the interview has been recorded you can request a copy of the interview. Details on how to do this will be made available during your interview.
- If interviewees would prefer information not to be recorded, investigators will take notes. The interviewee's preference will be discussed with them at the start of the interview along with any other queries or concerns they may have.
- The only people that have access to the audio recordings are the investigation team who are directly working on that investigation.
- Prior to any recording staff are given an information sheet relating to how we will use the information and the opportunity to ask any questions.

Can I bring someone to the interview with me?

You are more than welcome to bring along someone to support you during our discussion. This must be someone who is bound by confidentiality agreements within your Provider and who you are happy to talk freely in front of. They are not able to speak on your behalf or contribute to the interview. If you would like a translator, please let us know in advance so we have enough time to arrange this.

How long will the interview take?

The interviews vary in length, we suggest you allow two hours.

What information will you need from me?

The investigation team will ask you about your recollections of the event and the circumstances surrounding what happened. Investigators may ask you to clarify certain points to ensure full understanding. Feel free to ask any questions.

What will happen to the information I give you?

Your information will be treated as confidential; the information you provide on the reference event is crucial and is a key part of our evidence gathering. The analysis we do informs the wider investigation and the recommendations made in the final report.

What if I remember something later which I think is important?

You are welcome to add more information after the original interview. This can be done either face to face via another interview, over the telephone or via email whichever works best for you.

Will you need to interview me again?

We will aim to get all the information we need in one interview. However, the investigators may need to return if the progressing investigation raises further questions or if they need more clarity over a particular issue. If this is the case, we'll let you know as soon as we can.

What happens if I'm not at work?

We can arrange a convenient date to interview you on your return. In the case of long-term absences, we may ask your organisation to arrange an occupational health review to assess if you are well enough to be interviewed.

How can the investigation team be contacted?

The investigation team will contact you before the interview and you can ask any questions you have at this point. The investigators will explain how they can be contacted throughout the duration of the investigation.

HOW WE WORK: THE INVESTIGATION PROCESS



