



HEALTHCARE SAFETY
INVESTIGATION BRANCH

WWW.HSIB.ORG.UK

The Healthcare Safety Investigation Branch

Trust & Staff Information Pack

Version 1.0

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1 About HSIB

We conduct 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 the potential for harm to patients. The safety recommendations we make aim to improve healthcare systems and processes, to reduce risk and improve safety.

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

Our investigations

Our investigators and analysts have diverse experience of 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

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 all incidents in NHS maternity services across England that meet:

- the criteria of the Royal College of Obstetricians and Gynaecologists' Each Baby Counts programme, or
- our HSIB defined criteria for maternal 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. In addition, we identify and examine recurring themes that arise from trust-level investigations in order to make safety recommendations to local and national organisations for system-level improvements in maternity services.

For full information on our national and maternity investigations please **visit our website**.



2 More details about 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 HSIB 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.



3 What happens next in national investigations

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:

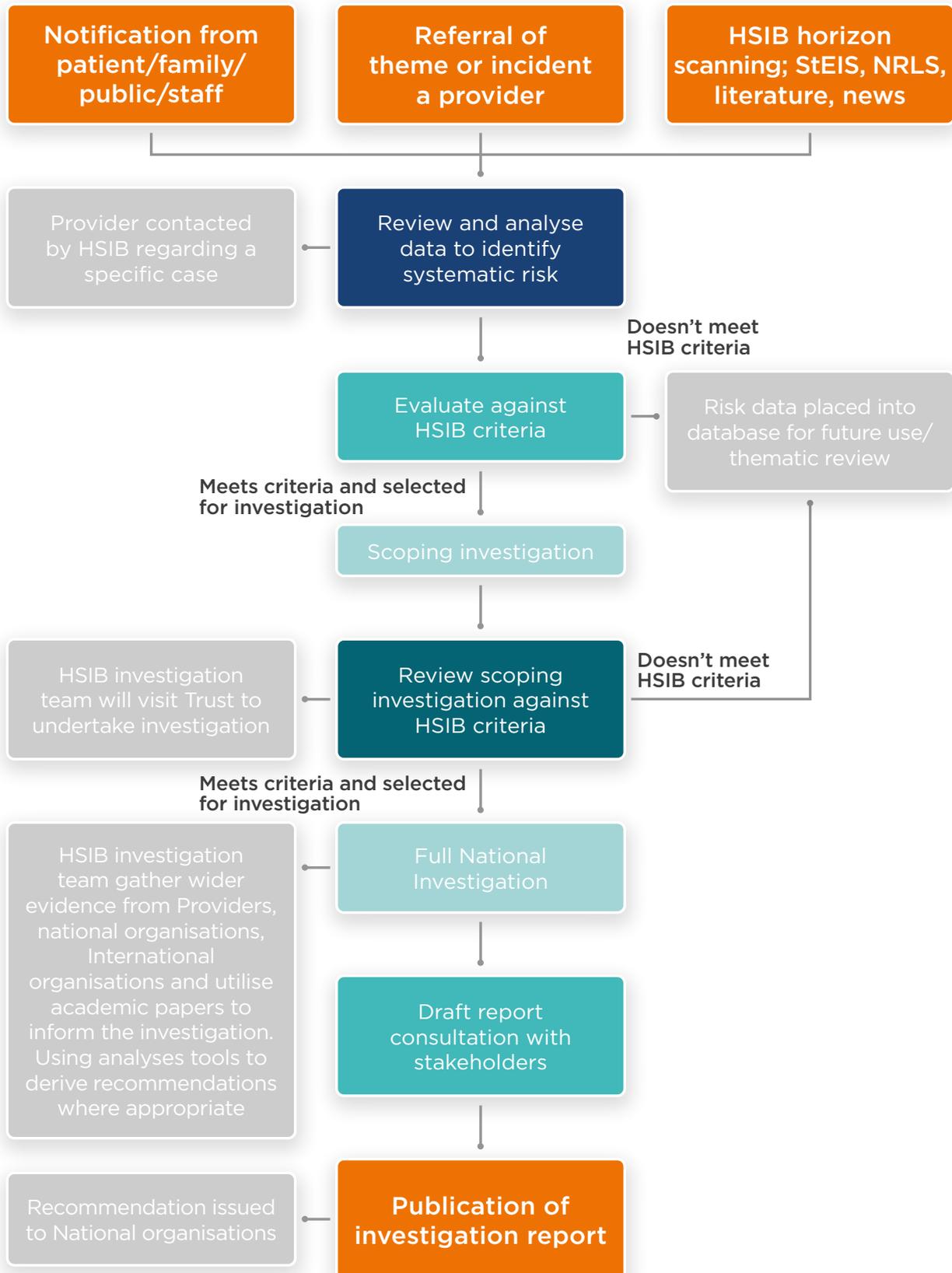
- patient notes, including radiology, pathology, observations etc.
- equipment memory downloads, printouts from all equipment where possible.
- consent forms
- staff rotas
- local policies relevant to event
- documents related to any SI investigation.

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.



4 How the national investigation process works



5 More details about HSIB maternity safety investigations

Why is HSIB carrying out maternity investigations?

We were instructed by parliament to carry out maternity investigations as part of a national strategy to improve maternity safety.

What is the criteria for a maternity investigation?

All maternity investigations need to be reported as a Serious Incident (SI).

Our directions instruct HSIB to investigate all term babies (at least 37+0 completed weeks of gestation) born following labour who have one of the below outcomes:

Intrapartum stillbirth: where the baby was thought to be alive at the start of labour but was born with no signs of life.

Early neonatal death: when the baby died within the first week of life (0-6 days) of any cause.

Severe brain injury diagnosed in the first seven days of life, when the baby:

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

During the COVID -19 pandemic a decision was made that HSIB would not investigate cases when there was no evidence of apparent neurological injury. Where there are trust or family concerns, we still investigate.

In line with our directions we do not investigate neonatal cases where the mother has not laboured. For example, a caesarean section which was performed before the mother had started contracting or ruptured her membranes.

Maternal deaths: We investigate direct or indirect maternal deaths of women while pregnant or within 42 days of the end of pregnancy.

Direct deaths include those resulting from obstetric complications of the pregnant state (pregnancy, labour and postpartum), from interventions, omissions, incorrect treatment or from a chain of events resulting from any of the above.

Indirect deaths include those from previous existing disease or disease that developed during pregnancy and which was not the result of direct obstetric causes, but which was aggravated by the physiological effects of pregnancy in the perinatal period (during or within 42 days of the end of pregnancy).



We may investigate some maternal deaths which do not entirely fit within the two above categories. For example, coincidental may be investigated following discussion with MBRRACE.

Our directions exclude the investigation of cases where suicide or homicide was the cause of death.

Host organisations should continue to investigate SI maternity events outside the specified criteria.

Further detail about our criteria can be found on our **website**.

What's the purpose of the investigation?

The purpose of the investigation is to establish the facts surrounding the case we are investigating.

This means we may need to interview you if you were involved in providing care, or witnessed anything that could be relevant to the case. This applies to both clinical and non-clinical staff.

We work closely with organisations, staff and families involved. Sharing learning from these investigations will be crucial, and we will use our position as an independent organisation to draw out wider themes for the system.

How are maternity incident referrals made to HSIB?

Referrals from all NHS trusts are made via the HSIB Investigation Management System (HIMS) the details and instructions for the use of this system will be provided by HSIB. It is recommended that three members of staff are registered to use this portal.

How is a maternity investigation undertaken?

The investigators work in partnership with the host trust to understand the clinical environment, explore staff perception of events by conducting interviews, reviewing patient notes and by considering all other relevant evidence. Our investigators will conduct thorough, independent and impartial investigations. We also work with clinical advisors and subject matter advisors within particular specialisms as required to make sure we produce a factual and accurate investigation. We aim to complete the investigations within a reasonable timeframe not exceeding six months in accordance with our directions.



How families are involved in HSIB investigations?

We involve the family throughout the investigation. Once a referral has been made, the trust will provide the family with some initial information explaining who we are and what will happen next. HSIB investigators will contact the family to discuss with them how they want to be involved.

Are individual staff required to engage with HSIB investigation?

Yes, individual staff are obliged, as per their professional code of conduct, to engage in an investigation. Staff interviews help establish the facts about the incident. Supporting staff is a priority. We make sure staff are fully informed of their legal obligations, the legal environment in which HSIB operates, and how this aligns with their professional responsibilities within an investigation. (Further information in interview section)

What information will you need from me?

The investigating team will ask you about your recollections of the incident. You may also be asked about how particular

systems and processes work within their maternity services. 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?

The information you give us will be used to inform the final report.

Who will the information be shared with?

The final reports are anonymised and shared with you, your Trust, families and other relevant organisations. In addition, key areas of learning will be published on our website.

Does this replace the Trust's internal Serious Incident investigation process?

Yes, this does replace the Trust's Serious Incident investigation process for cases within our criteria.

Who has ownership of recommendations?

Safety recommendations made in HSIB reports are discussed and agreed with



those responsible for implementing them, prior to being placed in the final report. The report will also contain HSIB findings that relate to issues identified within the investigation but were not on the causal pathway. Our reports will also reflect immediate actions taken to provide safer care and highlight where innovative and proactive approaches have led to improvements in maternity services.

How wider learning is shared?

HSIB analyse the findings and safety recommendations to identify any recurring themes. We may then use our national teams to investigate these themes further. We share the recommendations with regulators who can monitor implementation as part of their regulatory inspections.

Can we comment on the final report before it's published?

We will send a draft copy of the investigation report to the trust, to be shared with the staff involved so they can comment on the factual accuracy of the report. We will ask the trust to coordinate the comments from themselves. We will then share the working draft report with the family for comment.

Who sees the final report?

The final report are anonymised and shared with you, the staff involved, the family and other relevant organisations.

Do providers still complete the Perinatal Mortality Review Tool (PMRT), if the incident is referred to HSIB?

Yes. The Perinatal Mortality Review Tool (PMRT) remains the responsibility of the trust, who register the baby on the system at the time of the incident, however it will be completed jointly with HSIB on completion of the investigation.

Trusts will retain their mandatory and regulatory reporting responsibilities for example MBBRACE and StEIS.



6 What happens next in maternity investigations

Before the investigation starts the HSIB maternity team leader will contact the trust to provide names of the investigators assigned to each case. Each investigator will wear a badge to confirm their identity if they need to visit the trust.

The following is a suggested list to guide trusts on what you might need to collect for the investigation:

- Patient notes (electronic or scanned)
- Equipment memory downloads, printouts from all equipment where possible, for example delivery suite, theatres, recovery room
- CTG printouts
- Consent forms
- Staff rotas

In addition the investigators may request:

- To take photographs (delivery suite/ theatre layout, equipment screens, equipment switch positions). Any photos taken by HSIB will be agreed with the Trust
- CCTV recordings (ward, theatres, recovery rooms, drug cupboard videos, etc)
- ID access records
- Switchboard records

Timing

All information should be collected by the trust as soon as possible after the incident is identified as meeting the HSIB criteria.



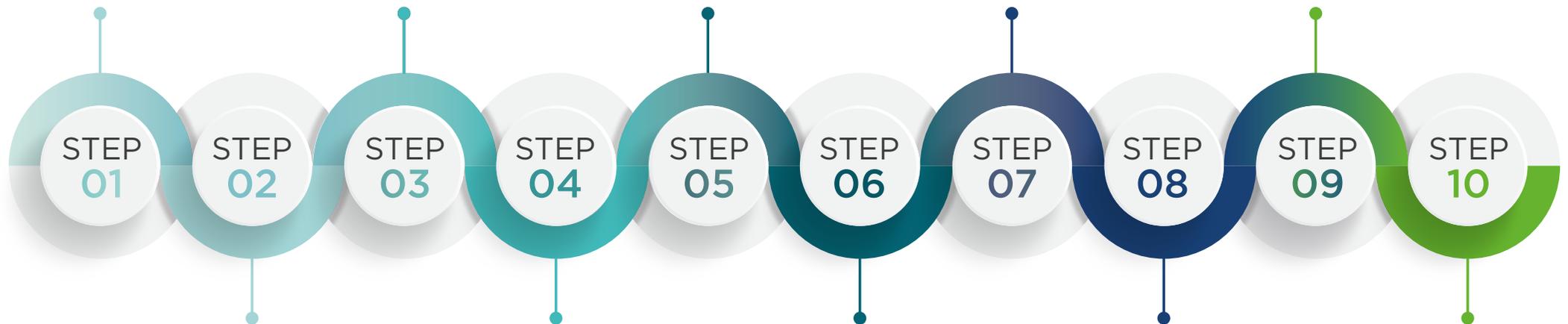
HSIB Maternity Investigation Process

A Ten Step Overview for Trust Staff

HSIB undertake maternity investigations which meet the Each Baby counts criteria and also investigate direct or indirect maternal deaths in the perinatal period.

HSIB investigations are intended to identify learning and do not apportion blame.

- The Trust makes a referral to HSIB as required by the Department of Health and Social Care.
- The Trust informs the family about HSIB and asks for their agreement to be contacted by HSIB investigators.
- Family interviews are arranged to understand their recollection of events.
- Medical records are reviewed and a chronology of events is written.
- Investigator seek clinical advice and agree terms of reference.
- The terms of reference of the investigation are discussed with the family and trust.
- HSIB investigators will ask about your recollections of the incident. You may also be asked about how systems and processes work within your maternity services.
- We may ask you to clarify certain points to ensure we fully understand.
- Your information will be used to inform the investigation report. You will not be personally identified.
- We can signpost you to support services if you would find this helpful.
- Investigators will seek clinical advice and analyse findings.
- The draft report is shared with the Trust to check it for factual accuracy. The Trust can share the report with you.
- Any feedback is considered and where necessary discussed further with the Trust.
- The draft report is then shared with the family to check for factual accuracy.



- HSIB appoints a lead investigator to the referral, who contacts the Trust to clarify any further details required.
- The lead investigator seeks the family's agreement to participate in the investigation, and give their consent for HSIB to access their medical records.
- If the family agrees for access to medical records, the investigation commences. The HSIB investigation replaces the Trust's serious incident process.

- Investigators will contact key members of staff to request an interview.
- You will be given an information sheet regarding the interview process and be asked for your consent to the interview being recorded.
- You can be accompanied to the interview. The person you bring is there in a supportive role only and cannot be a family member or friend.
- You will be given further information about this and how your interview data is handled.

- After your interview you can request a copy of the audio recording and further information will be given to you about how to do this.
- You will be asked to complete a feedback survey about your experience of the HSIB interview.

- A draft report is prepared detailing what happened and stating any findings or recommendations.
- This draft report is subject to a comprehensive quality assurance process.

- The final report is anonymised and shared with the family.
- The Trust also receive the final report as do any other relevant organisations.
- Key areas of learning will be published on our website.



7 The interview process

What should I expect from the interview?

- Interviews with staff are confidential; two HSIB investigators will be present during the interview.
- Interviews must take place in a private location, with out interruption.
- The aim of the interview is to understand what happened, the circumstances surrounding the event and to gain an understanding of how systems and processes work within your trust.
- 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.
- 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.
- Interviews may take place face to face or virtually.

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 trust or 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.

Who else will you interview?

We may interview other Trust staff involved in the incident and clinicians from other organisations who have been involved in the care. We will also interview family members.



What happens if I'm on annual leave or sick leave?

We can arrange a date to interview you on your return. In the case of long term absences we will request the trust to arrange an occupational health review to assess if you are well enough to be interviewed.

How can I contact you?

You will be provided with the contact details for the investigators, and you can access them from Monday to Friday, 9am-5pm throughout the course of the investigation.



8 Further information for maternity investigations

Information sharing fact sheet

Personal data is information that can identify you either by itself or in combination with other information and this may come in many formats. It can be electronic, paper, given verbally, photographic, video. If you would like to learn more about how HSIB hold your personal data please follow the link to our [helpful fact sheet](#).

Information protection and security

Personal data is information that can identify you either by itself or in combination with other information and this may come in many formats. It can be electronic, paper, given verbally, photographic, video. If you would like to learn more about how HSIB hold your personal data please follow the link to our [helpful fact sheet](#).

Providing feedback and comment on HSIB reports

At the Healthcare Safety Investigation Branch (HSIB) we welcome feedback on our investigation reports. The best way to share your views and comments is to email us at enquiries@hsib.org.uk or complete our online feedback form at www.hsib.org.uk/tell-us-what-you-think.

We aim to provide a response to all correspondence within five working days.

The trust and staff information pack is available as a hard copy on request.



