



HEALTHCARE SAFETY
INVESTIGATION BRANCH

Procedure for escalating significant safety concerns arising from investigations

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Healthcare Safety Investigation Branch has made every effort to ensure this policy does not have the effect of unlawful discrimination on the grounds of the protected characteristics of: age, disability, gender reassignment, race, religion/belief, gender, sexual orientation, marriage/civil partnership, pregnancy/maternity. The Branch will not tolerate unfair discrimination on the basis of spent criminal convictions, Trade Union membership or non-membership. In addition, the Branch will have due regard to advancing equality of opportunity between people from different groups and foster good relations between people from different groups. This policy applies to all individuals working at all levels and grades for the Branch, including senior managers, directors, employees (whether permanent, fixed- term or temporary), consultants, contractors, trainees, seconded staff, homeworkers, casual workers and agency staff, volunteers, interns, agents or any other person associated with the Branch.

All Branch policies can be provided in alternative formats

1. Introduction

- 1.1 All staff, regulators and national bodies working in the health and social care system have a duty to ensure that services promote the safety and well-being of people using services and to protect them from harm. HSIB have a duty to share significant safety concerns with the relevant persons or authority where disclosure is required to protect people.
- 1.2 Safety concerns regarding individuals or organisations may arise during HSIB's activity (e.g. interviews, observations, referral management or intelligence gathering).

2. Purpose

- 2.1 The purpose of this document is to support HSIB staff in **escalating serious and significant safety concerns that lie outside individual investigation scope or require action before the completion of investigation**. It further supports staff and managers in deciding when these concerns should be shared with external regulatory bodies or other authorities. These decisions must take into account HSIB's duty to promote safety, its duty to carry out investigations that are not seen to apportion blame, and to apply the 'safe space' principle in accordance with the 2016 Directions of the Secretary of State (in relation to national investigations).
- 2.2 HSIB staff may need to escalate concerns in relation to a range of topics including, but not limited to:
 - Criminal activity (please refer to appendix B)
 - Coronial processes (see section 9.3)
 - Safeguarding children or adults at risk (please refer to HSIB Safeguarding [policy](#))
 - Patient safety concerns; at an individual or organisational level (this procedure)
 - Information governance (Please refer to HSIB Incident Management and Reporting [Procedure](#))
 - Serious issues relating to registered professionals (this procedure)

- 2.4 All HSIB staff have a duty to raise these concerns as soon as is practicably possible. The HSIB Medical Director and registered health professionals may have additional duties and should refer to their professional codes of conduct.

3. Scope

- 3.1 This guidance applies to all staff, subject matter advisors, contractors, voluntary agencies and volunteers who work for, in conjunction with, or on behalf of HSIB, including those staff, observers and visitors who may not come into direct contact with the patients, families or healthcare staff involved in HSIB investigations.

4. Objectives

- 4.1. To ensure that all HSIB employees, contractors and visitors are aware of the process to raise concerns that require escalation.

5. Responsibilities

HSIB's Executive Team

- 5.1 To ensure that systems and structures are in place for HSIB employees to raise concerns or issues that require escalation.
- 5.2 To familiarise themselves with this procedure and all other relevant policies and procedures that should be read in conjunction with this procedure.
- 5.3 To escalate concerns to relevant persons when deemed necessary and record actions taken.

Associate Director of Maternity Investigation Programme/Principal National Investigator

- 5.4 To familiarise themselves with this procedure and all other relevant policies that should be read in conjunction with this procedure.
- 5.5 To ensure operational implementation and adherence to this procedure by HSIB employees.
- 5.6 To escalate concerns to the HSIB Executive Team when deemed necessary and record actions taken.

HSIB Employees

- 5.7 To familiarise themselves with this procedure and policies that should be read in conjunction with this procedure.
- 5.8 To adhere to this procedure by escalating concerns both within normal working hours and through an on-call system out of hours and record actions taken.

On-call Staff

- 5.9 To familiarise themselves with this procedure and all other relevant policies and procedures that should be read in conjunction with this procedure.
- 5.10 Where necessary to escalate concerns in line with this procedure and record actions taken.

6 Raising Concerns (see appendices for flow charts)

- 6.1 Raising of concerns should be proportionate to the risk to patient/public safety and the immediacy of that risk. In general, organisations should be given the opportunity to resolve concerns raised by HSIB staff. **There may be circumstances where urgent escalation is required and some of the steps in escalation flowchart may be bypassed.**

The attached flowcharts may also be employed where repeated but individually less serious concerns arise; leading to serious concerns about the overall safety of a team, department or organisation.

The timescales in the flowcharts are indicative of reasonable timescales for response from organisations. The speed of escalation should be adjusted according to the level of concern and likelihood of repeated harm to patients.

7 Managing concerns about continuing risk to patients

- 7.1 In cases where investigation teams have concerns about continued on-going risk to patients, they should, in the first instance discuss the concerns with their line manager. A decision can then be made about how to proceed with the information following the attached flowcharts. Less serious concerns can be raised with Trusts and stakeholders during HSIBs regular communications without resorting to formal escalation.

8 Making disclosures to the police

- 8.1 HSIB will share legitimate information with the police in a justifiable way which upholds staff and patients' right to confidentiality and releases sufficient, appropriate information to assist the police with their enquiries. HSIB's Information Governance team, with oversight from the Chief Investigator, will manage all disclosures to the police, no individual staff member should disclose information outside of the process described in appendix C, unless there is an immediate risk to patients or the public.
- 8.2 Confidential patient information can be disclosed in the public interest where that information can be used to prevent, detect, or prosecute, a serious crime.
- 8.3 Theft, fraud or damage to property where loss or damage is not substantial are less likely to constitute a serious crime and as such may not warrant breach of confidential information, though proportionality is important. It may, for example, be possible to disclose some information about an individual's involvement in crime without disclosing any clinical information.

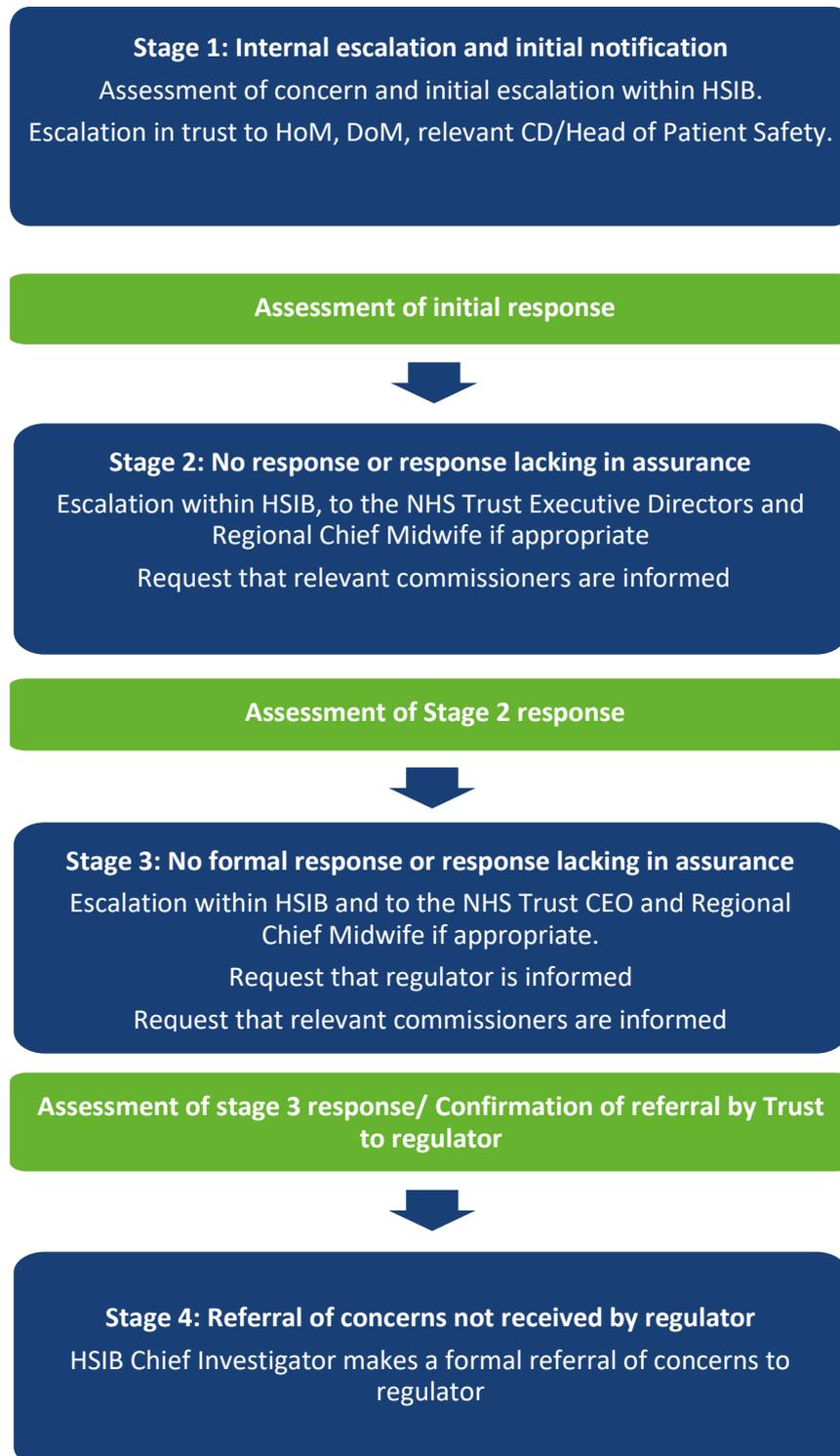
9 Specific disclosures required by law

- 9.1 The public interest defence is separate from, and additional to, specific statutory requirements for disclosure in relation to crime. Legislation provides for the obligatory disclosure of information, under particular circumstances. Examples include the Criminal Appeal Act 1995, Terrorism Prevention and Investigation Measures Act 2011, Public Health (Control of Disease) Act 1984 and the Road Traffic Act 1988.
- 9.2 Under the NHS Act 2006, investigations into fraud in the NHS may require access to confidential information. NHS counter fraud investigators have the power to require the disclosure of the relevant information including patient information, should they believe that this is important to the investigation.
- 9.3 The Notification of Death Regulations 2019 puts a duty on registered medical practitioners to notify the coroner of a death. If HSIB identify during an investigation cases that meet the criteria set out in the regulation, where a disclosure has not already been made to a coroner, HSIB must ensure the coroner is informed of this new information.

10 Monitoring and Governance

- 10.1 Adherence to this guidance will be monitored by the Operational Management Team to provide assurance that the Branch has robust escalation arrangements.

Urgent and emerging concerns requiring escalation flow chart



Urgent and emerging concerns requiring escalation: standard operating procedure

At any stage if there are ongoing, immediate risks to patient/public safety HSIB will directly inform the trust, the relevant regulator or authority and bypass the stages set out in this policy.

Concerns that do not reach the level of formal escalation (see stage 1 below for assessment of concerns) will be shared with trusts at quarterly review meetings (QRM), within maternity investigation updates (MIU) and during routine updates to trusts involved in national investigations.

The concern may relate to an organisation, individual, process or system.

Sources of urgent and emerging concerns include:-

- Intelligence gathering
- Incident referrals from trusts, public and staff
- Staff interviews
- Family feedback and interviews
- Site visits/workplace observations
- Number of repeated recommendations
- Investigator contact with trust teams
- Feedback at QRMs and trust meetings
- Trust response to information requests
- Trust response to factual accuracy; comments received; sharing of reports with staff
- Implementation of safety recommendations / changes to practice
- Number of cases/referrals of a similar type
- Trust response to maternity or national investigation updates
- Number of recommendations per report

For every letter of concern sent, consideration should be given to whether it is suitable to inform the family of the escalation. This decision will be made at the urgent and emerging concerns panel or by the principal national investigator (PNI) in discussion with the investigation team.

All steps and actions will be documented in the HIMS database.

Stage 1: Internal escalation and notification

HSIB maternity investigator (MI) to share internally with HSIB team leader (TL) and HSIB regional lead for maternity investigations (RL).

National investigators (NI) should share concerns with the principal national investigator (PNI) responsible for the investigation.

Consider rapid internal escalation to HSIB director of investigations (DOI), associate director of maternity investigations (ADMI) and the clinical director of maternity investigations (CDMI) if there is significant on-going risk to patients.

If RL agrees to proceed TL to organise urgent/emerging concerns panel by contacting CI admin. CIAdmin@hsib.org.uk

In national programme PNI to organise urgent/emerging concerns panel with investigation team and DOI.

Urgent/emerging concerns proforma completed by MI and TL. Link to [escalating urgent/emerging concerns TOR & proforma](#)

The urgent/emerging concerns panel will consider the significance and seriousness of the concerns raised and the urgency with which escalation should occur.

If outcome of urgent/emerging concerns panel is to proceed with escalation, then a letter detailing concerns is sent via email to the head of midwifery (HoM) or director of midwifery (DoM) and relevant clinical director (CD), and/or head of patient safety at the NHS trust.

The urgent/emerging concerns panel will decide if anyone else from the NHS trust should be copied into the escalation letter. Trust executives (medical director and chief nurse/DoM) copied into all escalation letters. Initial letters of escalation will be sent by RL/PNI unless panel consider otherwise.

Prior to letter of concern being sent TL/NI to share concerns verbally with the relevant lead at the NHS trust concerned. This may include the HoM, DoM and relevant CD and/or head of patient safety(national investigations).

Template for letter 1 (maternity investigations) [Letter 1](#) detailing concerns sent via email to NHS trust concerned.

PNI to construct bespoke letter in national investigations

RL & TL (maternity) and PNI (national) to be copied into email.

Assessment of initial response (Stage 1):

Initial email acknowledgment required within 24 hours. Response detailing immediate actions to be received within 2 working days for urgent concerns and 5 working days for emerging concerns.

Response from trust assessed by urgent/emerging concerns panel (in correspondence). The response should:

1. Acknowledge the safety concern raised by HSIB.
2. Articulate specific actions that the investigation team consider sufficient and reasonable to address the safety concern.
3. Specify the time frame for completion of the above actions.

If response indicates the above then the investigation continues and monitor for further concerns.

Trust will be informed that HSIB is continuing the investigation and HSIB will share any other urgent concerns identified.

The HoM/DoM/CD and board level safety champions will also be updated monthly by maternity investigations update.

If no response or inadequate response continue to stage 2.

Stage 2: No response, or response lacking in assurance

TL/PNI to arrange a second urgent/emerging concerns panel (ideally with the same people as the first panel for continuity)

If agreement that there is significant on-going risk a second letter is sent via email

to NHS trust executives (medical director and chief nurse/DoM) copied to the head of midwifery (HoM)) and relevant clinical director (CD), and or head of patient safety at the NHS trust, and also copied to RCM (maternity investigations).

Stage 2 escalation letters to be sent from HOMI, ADMI or CDMI (maternity), or DoI (national).

- Letter 2a – no response received from trust [Letter 2a](#)
- Letter 2b - response received but lacking in assurance [Letter 2b](#)

HSIB executive team made aware of escalation of concerns.

Assessment of stage 2 response:

Initial email acknowledgement of the letter required within 24 hours. The formal response should be received within 2 working days for urgent concerns and 5 working days for emerging themes.

The formal response should evidence that HSIB's safety concerns have been shared within the trust's internal governance system, and should detail what actions they are taking, where this is being shared/discussed, and what has been internally escalated and shared with clinical commissioning groups (CCGs), integrated care systems (ICSs) and the care quality commission (CQC).

If resolution of concerns agreed by ADMI and the CDMI (maternity), or DOI (national), in discussion with urgent/emerging concerns panel, continue with investigation and monitor concerns.

Trust to be informed that we are continuing the investigation and HSIB will share any other urgent concerns identified. The HoM/DoM will also be updated monthly by maternity investigations update.

No response or inadequate response inform HSIB Executive and continue to stage 3.

Stage 3: No formal response or formal response lacking in assurance:

Response will differ depending on whether concerns relate to the organisation or an individual.

Organisational concerns:

Formal letter sent by HSIB DOI to the trust CEO detailing concerns and requesting that the trust share HSIB concerns with the CQC, commissioners and RCM where appropriate.

Individual health professional concerns:

Formal letter sent by HSIB medical director to the trust MD or CN/DoN (as appropriate), requesting that the trust addresses HSIB's concerns and if necessary escalates to the GMC or relevant professional regulator.

Confirmation of referral to regulator:

HSIB DoI or MD contacts CQC or relevant regulator within 5 working days to confirm that the Trust has referred the concerns raised.

Stage 4: Referral of concerns not received by regulator

HSIB chief investigator makes formal referral of concerns to CQC chief inspector of hospitals or referral to relevant professional regulator.

Appendix B

Raising concerns of potential criminal activity

If you identify potential criminal activity during your employment, HSIB staff must escalate these concerns to the appropriate agency at the earliest opportunity.

Agencies HSIB may escalate concerns of potential criminal activity to include, but are not limited to, the Police, NHS Counter Fraud Services, Local Safeguarding Teams and Coroners. Unless there is an immediate threat to life all staff should escalate concerns through their line-management structure to ensure the external escalation of concerns is proportionate, to the appropriate agency and that there is a legal basis for data sharing. The line manager, in discussion with any other appropriate staff, will then forward any concerns of criminal activity to

CIOffice@HSIB.org.uk.



Raising a concern of potential criminal activity

If you are asked by the police to share information or you have any concerns of potential criminal activity during your employment at HSIB you must follow the below process.

Any concerns must be escalated at the earliest possible opportunity.

If the police approach you for information regarding an ongoing criminal investigations or you identify any possible criminal activity, please send to CIOffice@HSIB.org.uk

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CI acknowledges receipt of concern

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CI Office manager forwards the information request or concern to NHSE I Legal

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NHSE I Legal to liaise with NHSE I patient Safety Lead and the Chief People Officer. Any decision to disclose information to be communicated to the Chief investigator. Any decision to disclose concern NHSE I share with the police authority

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Information Governance liaise with the police to manage the data sharing.