Health Services Safety Investigations Body

Investigation report

Investigation report: HSIB's local investigation pilot: shared learning for local healthcare systems

Date Published:
12/10/2022

Theme:
Analysis, Emergency care

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A note of acknowledgement

We would like to thank the patients, their families and the frontline clinical staff whose experiences contributed to the investigations undertaken as part of HSIB's local investigation pilot. We would also like to thank the healthcare organisations and the many other stakeholders who contributed to the evaluation of the pilot.

At the time of publication, HSIB had started its transition to becoming the Health Services Safety Investigations Body (HSSIB) and the Maternity and Newborn Safety Investigations Special Health Authority (MNSI). The findings of this pilot will be used to inform the transition, and will help develop future processes. In the meantime, this report provides learning for local healthcare systems.

Terms used in this report

- ‘Local healthcare organisation’ – healthcare organisations that deliver care directly to patients. In the pilot these were hospital and ambulance trusts, and a care home.
- ‘Local healthcare system’ – a group of ‘local healthcare organisations’ that provide care to patients across a geographical area or region and the organisations that commission services; this may be considered the Integrated Care System.
- ‘Multiagency safety events’ – incidents in which a patient was harmed, or had the potential to be harmed, through their care and in which multiple healthcare organisations were involved.
- ‘Pilot’ – abbreviation for ‘HSIB’s local investigation pilot;’ this refers to the implementation of an investigation approach on a small scale to test it.

Executive Summary

This report summarises how the HSIB local investigation pilot was undertaken and shares the findings that apply to local healthcare systems, including healthcare organisations and Integrated Care Systems. Further supplementary materials provide a fuller overview of the pilot’s evaluation. This overview will be considered when developing future processes when HSIB transitions to becoming the Health Services Safety Investigations Body (HSSIB) and the Maternity and Newborn Safety Investigations Special Health Authority (MNSI).

Since 2018 HSIB’s maternity investigation programme has investigated single events affecting babies and mothers that have occurred in healthcare organisations, with safety recommendations made directly to those organisations. In contrast, HSIB’s national investigation programme does not make safety recommendations to individual healthcare organisations, rather to national bodies.

In April 2022 HSIB completed a pilot combining the investigation approaches undertaken by the national and maternity investigation programmes. These were termed ‘local investigations’ and sought to investigate specific, single non-maternity events with safety recommendations made directly to the healthcare organisations where the events occurred.

HSIB's local investigation pilot published three investigation reports and an extensive evaluation which is summarised in the supplementary materials that accompany this report. Each of the investigations made safety recommendations directly to the healthcare organisations involved.

This report makes four safety observations from the findings of the evaluation of the pilot that may support local healthcare systems in developing their future processes. The safety observations also provide reflections on where regional and national bodies can offer future support to local healthcare organisations.

HSIB makes the following safety observations

Safety observation O/2021/193:

It may be beneficial if local healthcare systems consider how best to support the investigation of cross-organisation safety events as they implement the Patient Safety Incident Response Framework.

Safety observation O/2021/194:

It may be beneficial if national and regional bodies consider how healthcare organisations can be supported to develop effective systems-based solutions to identified patient safety risks.

Safety observation O/2021/195:

It may be beneficial if healthcare organisations develop processes to identify safety improvement themes from patient safety investigation reports.

Safety observation O/2021/196:

It may be beneficial if providers of NHS care consider low-harm and no-harm safety events as sources of learning in local patient safety incident response plans.

1 Background and context

1.1 The local investigation pilot

1.1.1 In early 2021 HSIB formed plans to explore the value of investigating specific, single non-maternity patient safety events that had occurred in healthcare organisations, with safety recommendations made directly to those organisations (referred to as ‘local investigations’). These plans were driven by:

- HSIB’s Directions (the legislation under which it operates), which include improving the quality of local investigations (NHS Trust Development Authority, 2016)
- HSIB’s recognition of its need to learn and evolve investigation processes to support ongoing, impactful improvements in patient safety
- requests from healthcare organisations (such as hospital and ambulance trusts) for HSIB to publish outputs directly applicable to them
- the need to consider and plan for future HSIB investigations at a time when supporting legislation and resources had not been confirmed.

1.1.2 HSIB’s plans became the local investigation pilot (referred to in this report as ‘the pilot’). The pilot integrated the HSIB’s national and maternity investigation programmes to undertake a limited number of investigations to test a different approach to investigation.

1.2 Aim

1.2.1 The aim of the pilot was for HSIB to develop and evaluate an approach for local investigations that was of value to local healthcare organisations, and provided national learning.

1.2.2 Value in this context referred to making care safer for patients. It was defined to include the identification of new learning in relation to patient safety risks, and the development of impactful safety recommendations and safety observations.

Objectives

1.2.3 The main objectives of the pilot were to:

- develop an efficient and effective investigatory approach for HSIB’s local investigations
- evaluate the outputs of the approach to see if they provided additional learning and impactful safety recommendations when compared with investigations undertaken by healthcare organisations

- determine whether HSIB's local investigations could also provide outputs that added value for the wider healthcare system.

1.2.4 Other objectives of the pilot were to:

- identify safety events, risks and situations where an HSIB local investigation would support improvements in patient safety
- consider how to support healthcare organisations and individuals to refer safety events to HSIB for local investigation.

2 Methods – undertaking the pilot

This section provides an overview of how the pilot was conducted. The **supplementary materials** provide a fuller overview and summary of the evaluation plan. The pilot was undertaken between April 2021 and April 2022.

2.1 Set-up of the pilot

2.1.1 An HSIB pilot steering group was formed with external representation from NHS England's Patient Safety Team. The group also received input from HSIB's Citizens' Partnership and the HSIB Advisory Panel. The group was tasked with managing the pilot and its evaluation.

2.1.2 The pilot steering group identified 'multiagency safety events' as a focus for the local investigations. Multiagency safety events were defined as incidents in which a patient was harmed, or had the potential to be harmed, through their care and in which multiple healthcare organisations were involved. The focus on multiagency events was chosen because:

- HSIB had received several previous referrals of safety events where multiple healthcare organisations were involved, and
- national recognition that these events are difficult to investigate because of the need to collaborate across multiple organisations.

2.1.3 HSIB's intelligence suggested that focusing on transfers of care between hospital and ambulance trusts would provide opportunities to identify safety events for investigation. The steering group engaged with four hospital trusts and three ambulance trusts to support the pilot.

2.2 Investigation operations

Referral of safety events

2.2.1 Criteria were created and pilot trusts were asked to refer (via an electronic form) safety events that met the criteria. A safety event had to have:

- affected a single or multiple patients
- occurred in NHS-funded care in England
- involved multiple healthcare organisations (multiagency)
- occurred within 2 weeks of the referral.

2.2.2 A 2-week timeframe was selected to support rapid launch of investigations. This was to help minimise the time following an event to help more accurate staff recall. The timeframe was later updated to ‘within 6 weeks’ as trusts sometimes found that they were not aware of events until after 2 weeks.

Investigations

2.2.3 Four investigations were planned and undertaken in line with HSIB’s National Directions (NHS Trust Development Authority, 2016). Investigations were allocated two investigators, one from each of HSIB’s national and maternity investigation programmes. The investigation process ensured that **patient/family, staff** and stakeholder engagement met the expectations of any HSIB investigation. Organisations were told that HSIB’s investigations did not replace their own.

2.2.4 The investigations used the Systems Engineering Initiative for Patient Safety (SEIPS) (Carayon et al, 2014) to support the analysis of collected evidence. The investigations also considered other safety concepts such as ‘controls’ (Chartered Institute for Ergonomics and Human Factors, 2016; National Patient Safety Foundation, 2015; The National Institute for Occupational Safety and Health, 2015) and the ‘varieties of human work’ (Shorrock, 2016). These are described further in the **supplementary materials**.

Safety recommendations and safety observations

2.2.5 The pilot investigations made safety recommendations to the local healthcare organisations. The aim of the safety recommendations was to highlight issues identified during the investigations that if addressed would reduce the risk of future, similar events occurring. It was not intended for safety recommendations to offer specific solutions. Investigations were also able to make safety observations where something had been identified that may be of benefit for an organisation to address.

Launching national investigations

2.2.6 Pilot investigations were restricted to making local safety recommendations only. This resulted in the development of pathways to share learning of national interest through HSIB's established intelligence process.

2.2.7 Investigation teams met every 2 weeks to discuss findings to date and common learning themes. Where these were felt to represent national safety risks, the investigation teams referred the risks into HSIB's intelligence process where they were considered for potential national investigation or to support the development of a national learning report.

2.3 Developments as the pilot progressed

2.3.1 As the pilot progressed there were two significant developments:

- On 26 January 2022 it was announced that HSIB's maternity programme would transition to the Maternity and Newborn Safety Investigations Special Health Authority (MNSI) in April 2023 (UK Parliament, 2022).
- On 28 April 2022 the Health and Care Bill became an Act of Parliament (Health and Care Act (2022)). This established the Health Services Safety Investigations Body (HSSIB) as a non-departmental public body. HSIB will transition to HSSIB during 2022/23.

2.3.2 The above developments provided clarity on the future of HSIB's national and maternity programmes. The developments led the pilot to consider how the findings of the evaluation could support development of future HSSIB and MNSI investigation processes.

3 Results – outputs and evaluation of the pilot

This section provides a summary of the reports published as part of the pilot and a brief overview of the evaluation findings. The supplementary materials provide a fuller summary of the evaluation.

3.1 Referrals and investigations

3.1.1 HSIB received 10 referrals for the pilot and launched 4 investigations. Three investigations progressed to final publication. The fourth investigation was stopped due to not having the patient's consent to investigate.

3.1.2 A summary of the events of each published investigation is available in table 1. The full, published reports are available via the links given within the table.

Table 1 Summary of events in the three published local investigations

Investigation/link	Event summary
Investigation 1 – incorrect patient identification	The Patient, a woman aged 75 years, was taken to an emergency department (ED) by ambulance following a 999 call. During the 999 call the wrong NHS number was used for the Patient. At the ED, the Patient was booked in under the wrong NHS number which belonged to a different patient. The wrong NHS number continued to be used during the Patient's time in hospital. Following a pharmacy review, the Patient's medications were changed to those taken by the other patient. The Patient declined to take these and the incorrect patient details were identified by a pharmacist the following day.
Investigation 2 – incorrect patient details on handover	The Patient, a woman aged 93 years, had dementia and was taken by ambulance to an ED after a fall in her nursing home. Incorrect patient details (date of birth and spelling of surname) were used to try to book the Patient into the ED. ED staff were unable to find the Patient's details on their digital system and so a new patient record was created with the incorrect details. The next day, after another fall, the Patient was again taken to the same ED. She was booked in under the patient record created the previous day, with the incorrect patient details. An X-ray showed a broken hip and she was admitted for surgery. During surgery the pathology department identified a problem with the Patient's identification.
Investigation 3 – transfer of a patient who had suffered a stroke to emergency care	The Patient, a man aged 75 years, woke at 01:30 hours feeling unwell. The paramedics who attended the Patient recognised the symptoms of a stroke and before setting off for the hospital, phoned the ED at Trust A. Trust A could not accept the Patient as its stroke service was not open between 23:00 and 08:00 hours. The paramedics therefore called Trust B and were told that it could not accept the Patient as he was outside the timeframe for immediate stroke treatment. Ultimately the paramedics took the Patient to Trust B after a further discussion with Trust A. When the ambulance arrived, the Patient was held in the ambulance for 40 minutes because the ED was very busy. He had a CT scan which confirmed a stroke caused by a blood clot in the brain.

Investigation themes and national risks

3.1.3 The pilot investigations identified two potential national safety risks:

- The NHS number, which is the unique patient identifier for people living in England (and Wales) (National Patient Safety Agency, 2009), is not consistently used. This puts patients at risk of harm if they are incorrectly identified and receive treatment and care that is not meant for them.
- There are delays to the handover of patients from ambulance to emergency departments, putting patients at risk of harm due to delays in care.

3.1.4 A thematic analysis of the three published investigations was undertaken to identify similarities in the factors that contributed to the events. This was structured against HSIB's Safety Intelligence ResearCH framework (SIRch, see appendix). The themes identified using this process are shared in section 4.1.

3.2 Summary of the evaluation

An efficient and effective approach for HSIB's local investigations

3.2.1 HSIB's local investigation approach was developed from the process used for HSIB's national investigations. The pilot launched four investigations, each within 5 working days of referral. The evaluation suggested that HSIB's approach identified contributory factors to incidents in a timely way, and balanced depth of investigation and early sharing of findings with organisations.

3.2.2 The final investigation approach is available in the **supplementary materials** with the learning from the pilot that influenced its development. The approach ensured investigators understood the 'work as done' – that is, how tasks were actually carried out rather than how they were set out in procedures or perceptions of how they were done – by visiting the location of safety events and observing local practice first hand.

Outputs supporting local learning and providing national value

3.2.3 No individual healthcare organisation undertook its own in-depth, formal investigation of the individual events investigated by the pilot. The evaluation was told this was for various reasons including that the event had not caused harm, had been referred to other organisations, or would have been considered as part of a thematic review. HSIB's local investigations highlighted that significant learning could be taken from individual safety events that had not caused harm. These types of events have historically not always contributed to safety learning in local organisations.

3.2.4 Twelve safety recommendations and seven safety observations were made. Safety recommendations often aimed to support standardisation of processes. In response, recipient organisations shared their action plans. While there was evidence of plans for stronger actions such as redesign of care pathways, the actions commonly involved awareness building, training and procedure creation. These types of actions are unlikely to always prevent future safety events, but the evaluation was told that developing effective actions locally is sometimes challenging because of limited capability and capacity. This further supports the role of HSIB to make safety recommendations to national bodies which local healthcare organisations have limited ability to do.

3.2.5 Healthcare organisations described further perceived benefits of the local investigations such as: motivating organisations to act due to the external lens on local safety; HSIB's no-blame approach helping staff to "open up"; and the multiagency focus supporting closer working between providers.

3.2.6 From a family perspective, the evaluation was told that the investigations gave families a voice and it was thought that they would help "eliminate safety risks".

3.2.7 Regarding national value of the pilot investigations, each pilot identified learning of national relevance (see 3.1.3) and potential national safety risks. The pilot investigations contributed to the launch of the following:

- HSIB national investigation **'Harm caused by delays in transferring patients to the right place of care**.'
- HSIB national learning report '**Positive patient identification**.'

3.2.8 National and regional bodies/groups described their support for HSIB's local investigations. They perceived benefits such as: improving investigation skills through working with organisations and showing methodologies used; challenging traditional safety beliefs that are holding back improvements; identifying research opportunities; and improving sharing across organisations. Integrated Care Systems described keenness to support safety improvements in their areas through work with local healthcare organisations.

Focus areas and referrals

3.2.9 Stakeholders described the importance of HSIB local investigations focusing on safety events where local healthcare organisations could not (based on local capability and ability to influence change) or should not (based on the need for independence) investigate the events themselves. HSIB's independence and no-blame approach was felt to be its unique offer to the healthcare system.

3.2.10 While the pilot focused on investigations where multiple healthcare organisations were involved, organisations commonly described these as difficult to investigate. Challenges related to the need for independence, difficulties co-ordinating multiple organisations, and not knowing who would be best to lead such investigations.

3.2.11 The pilot's referral criteria did not include the need for safety events to have resulted in harm. The four events referred were all locally classified as low-harm or no-harm. This approach was challenged by some stakeholders who questioned whether the absence of harm meant that the events provided fewer opportunities for learning. However, the evaluation disputed this with evidence that effective learning was achieved through the investigation of events where no harm was caused.

4 Discussion – learning themes for local systems

HSIB's local investigation pilot offers learning to HSIB to support the development of its future investigation approaches as it transitions to the Health Services Safety Investigations Body (HSSIB) and the Maternity and Newborn Safety Investigations Special Health Authority (MNSI). However, the pilot also provides valuable insights into patient safety risks and the design and delivery of effective investigation and improvement processes that may be of interest and use to local healthcare systems (healthcare organisations and Integrated Care Systems).

These insights are shared in the following sections:

4.1 Patient safety risks

4.1.1 The findings of the three final, published local investigations were combined using a qualitative, thematic analysis approach. This involved repeated coding and grouping of the findings from each of the investigations to identify factors that contributed to the safety events occurring.

4.1.2 The following themes were identified across all three investigations across four hospitals, three ambulance trusts and a care home. They are shared to highlight potential local safety risks in healthcare organisations:

- Delivery of safety-critical tasks, such as patient identification and handover of information, varied depending on who was carrying out the tasks.
- The variation in tasks more commonly occurred where processes had not been formally defined locally.
- Variation also occurred where the demands placed on staff meant thoroughness of tasks was reduced.

- Local digital systems were not always configured to provide controls that would prevent staff from completing tasks not as intended.

4.1.3 Two of the investigations identified a potential emerging theme around whether NHS systems and processes are able to provide for the variation within the English population. This variation occurs because of factors such as individuals' ability to mentally process information or people's ethnicity – for example, certain ethnic communities have different naming and date of birth conventions (**Healthcare Safety Investigation Branch, 2021**).

4.2 Investigation and improvement processes

4.2.1 In 2022 NHS England launched the Patient Safety Incident Response Framework (PSIRF), a new approach to responding to patient safety incidents for the NHS (NHS England, 2022a). The following insights from the pilot may support local healthcare systems in developing future processes within the PSIRF. In support, HSIB has made four safety observations.

Multiagency collaboration

4.2.2 The pilot focused its investigations on cross-organisation (multiagency) events. During the evaluation it was repeatedly heard that these types of investigations are challenging for healthcare organisations to undertake because of difficulties co-ordinating organisations, concerns around independence and reluctance for any one organisation to take the lead.

4.2.3 With healthcare delivery often relying on integrated processes across multiple organisations, safety investigations need to understand factors that contribute to events along care processes. This has been recognised in previous HSIB reports (**Healthcare Safety Investigation Branch, 2022**) and is considered in the PSIRF (NHS England, 2022a).

4.2.4 During the pilot the evaluation met with representatives of Integrated Care Systems (ICSs) who described the potential for ICSs to have a role in supporting safety learning across their local healthcare systems. Because of their role in co-ordinating care to improve population health within a geographical area, ICSs may be appropriately positioned to co-ordinate multiagency investigations and support learning from patient safety incidents (NHS England, 2022b).

HSIB makes the following safety observation

Safety observation O/2021/193:

It may be beneficial if local healthcare systems consider how best to support the investigation of cross-organisation safety events as they implement the Patient Safety Incident Response Framework.

Implementing effective actions

4.2.5 The local investigations made safety recommendations to local healthcare organisations. The aim of these safety recommendations was not to offer solutions; it was intended that the recipients, who best understand the local systems, would develop appropriate actions. However, the evaluation heard mixed perspectives on the ability of healthcare organisations to develop and implement actions that will bring about sustained improvements in safety. Capability and capacity concerns were described, with some organisations asking for external support with identifying actions.

4.2.6 As the scrutiny on patient safety has increased in the NHS, the focus has moved from reporting of safety events to ensuring that learning is taken from those events to support meaningful actions for improvement (Macrae, 2016; Peerally et al, 2017). The feedback on the safety recommendations made by HSIB as part of the pilot demonstrate a need to support healthcare organisations with the development of effective actions to those recommendations. A safety recommendation may be made with the potential for strong and long-lasting change, but the ability of organisations to take effective actions may be limited. Safety action generation is considered in the latest PSIRF (NHS England, 2022c).

4.2.7 During meetings with ICSs the evaluation heard of their keenness to support healthcare organisations to effect change to improve safety. ICSs may therefore have a future role in supporting safety actions.

HSIB makes the following safety observation

Safety observation O/2021/194:

It may be beneficial if national and regional bodies consider how healthcare organisations can be supported to develop effective systems-based solutions to identified patient safety risks.

Learning from the combining of findings

4.2.8 Healthcare safety investigations identify learning within the context of the specific events analysed. This may mean that the generalisation of findings is limited when investigations are considered in isolation.

4.2.9 The pilot demonstrated the benefits of combining the findings of multiple investigations to understand recurrent factors that may represent safety risks across an organisation. Section 4.1 described the recurrent factors across the organisations in the pilot; HSIB has similarly combined the findings from several investigations into similar event types to make national safety recommendations. Examples of HSIB investigations that have used themes drawn from several investigations include **Never events: analysis of HSIB's national investigations, Maternal death: learning from maternal death investigations during the first wave of the COVID-19 pandemic**, and the planned **Positive patient identification**.

4.2.10 To combine learning requires a structured and consistent approach to ensure valid conclusions are drawn and those extracting the learning do so in a reliable way. HSIB uses it's Safety Intelligence ResearCH framework (SIRch) to do this (see appendix). SIRch provides a framework against which investigation findings can be classified. PSIRF also encourages the use of the Systems Engineering Initiative for Patient Safety to help explore the work system (NHS England, 2022d) and provides 'top tips' around thematic reviewing (NHS England, 2022e).

4.2.11 The combining of learning offers opportunities to identify themes for future safety improvements in organisations and across local healthcare systems, again with support from ICSs.

HSIB makes the following safety observation

Safety observation O/2021/195:

It may be beneficial if healthcare organisations develop processes to identify safety improvement themes from patient safety investigation reports.

Learning from safety events regardless of severity

4.2.12 Safety event investigations have traditionally focused on events where harm has occurred. More recently, views on safety have suggested that learning can and should also be taken from events that have caused limited or no harm (Braithwaite et al, 2015). These events may offer new insights and alternative perspectives. However, as the pilot demonstrated, views on the value of investigating low-harm/no-harm events vary and they are often not investigated.

4.2.13 The pilot clearly demonstrated that significant learning can be taken from investigation of events that did not cause harm. This is learning that would otherwise have been lost and may contribute to actions that will prevent future harm. It is acknowledged that this requires resource, but with the implementation of PSIRF, healthcare organisations will have the flexibility to seek to learn from all types of safety events.

HSIB makes the following safety observation

Safety observation O/2021/196:

It may be beneficial if providers of NHS care consider low-harm and no-harm safety events as sources of learning in local patient safety incident response plans.

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6 Appendix

6.1 Summary of HSIB's Safety Intelligence ResearCH framework

HSIB's Safety Intelligence ResearCH (SIRch) framework is a systematic method of extracting safety intelligence from healthcare investigations. SIRch is used to identify how the design of work systems can impact on the safety of patients. Patient safety incidents can arise from conflicting, incomplete, or suboptimal systems of care, which patients are a part of, and interact with. SIRch identifies the problems within the systems and processes that determine how healthcare is delivered.

SIRch codifies and combines the internationally recognised Systems Engineering Initiative for Patient Safety (SEIPS) method (Carayon et al, 2014; Carayon et al, 2020) with the incident categories used by NHS England's Learn from Patient Safety Events (LfPSE) service (NHS England, n.d.).

Systems Engineering Initiative for Patient Safety (SEIPS)

SEIPS describes how components of the work system produce work processes which result in different outcomes. Healthcare investigations are coded using the following components of the work system:

- tasks: undertaken by people which may vary in complexity or variety
- tools and technology: used to undertake the tasks which may vary in usability and functionality
- internal environment: the physical space around people, for example layout, noise and temperature
- organisation: conditions that support the performance of tasks, for example, how information is communicated, the resources available and procedures developed
- external environment: factors outside of the healthcare setting that might include policy, societal or economic factors.

Learn from Patient Safety Events (LfPSE) service

Healthcare investigations are also coded by identifying stages of the patient's journey through the healthcare system. For example:

- the process of accessing healthcare or initial assessment of whether healthcare is needed
- assessing the patient/service user's condition in order to make or review a diagnosis or identify care needs
- identifying what actions to take, or care to provide, to treat or support the patient/service user
- delivering care, treatment or support to the patient/service user
- monitoring the impact, progress or effectiveness of the care, treatment or support
- communicating with the patient/service user (or their carers) about their care and its progress
- referral, escalation, handover, or moving care to a different service or team
- discharge planning, discharge, or ending a type of care.

Providing feedback and comment on reports

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