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HEALTHCARE SAFETY INVESTIGATION BRANCH

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HSIB's local investigation pilot: supplementary materials from the pilot evaluation

Independent report by the
Healthcare Safety Investigation Branch NI-008601

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Providing feedback and comment on HSIB reports

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

Introduction to this supplementary report

These supplementary materials complement the report '**HSIB's local investigation pilot: shared learning for local healthcare systems.**' That report summarises how the HSIB local investigation pilot was undertaken and shares findings felt to be applicable to local healthcare systems including healthcare organisations and Integrated Care Systems. These supplementary materials provide the background to the pilot and a summary of the main evaluation findings.

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.

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1 Background and aim

These supplementary materials provide a summary of HSIB's local investigation pilot ('the pilot') and an overview of the findings from its evaluation. HSIB has published these materials to supplement its publication '**HSIB's local investigation pilot: shared learning for local healthcare systems**.'

1.1 Background

1.1.1 The pilot was commenced in April 2021 to explore the broadening of 'local investigations' beyond HSIB's maternity investigation programme. A 'local investigation' in this context is where investigators seek to understand the local system factors in a healthcare organisation(s) that contributed to a safety event. These factors include tasks, environments, technology and organisation of systems.

1.1.2 The drivers for the pilot were:

- 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.

1.1.3 As the pilot progressed there were two significant developments for HSIB which are acknowledged in the evaluation:

- On 26 January 2022 it was announced that HSIB's maternity investigation 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 establishes the Health Services Safety Investigations Body (HSSIB) as a non-departmental public body. HSIB will transition to HSSIB during 2022/23.

1.2 Aim and objectives of the pilot

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 for 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 of the pilot

1.2.3 The main objectives of the pilot were to:

A develop an efficient and effective investigatory approach for HSIB's local investigations

B 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

C 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:

D identify safety events, risks and situations where an HSIB local investigation would support improvements in patient safety

E consider how to support healthcare organisations and individuals to refer safety events to HSIB for local investigation.

2 Methodolgy

2.1 Delivery of the pilot

2.1.1 The pilot was undertaken between April 2021 and March 2022, with investigations completed between May 2021 and March 2022. Three investigation reports were published.

2.2 Governance

2.2.1 At the time of the pilot, HSIB was directed to undertake its national investigations via Directions originally published in 2016 (NHS Trust Development Authority, 2016). The pilot investigations were undertaken in line with these Directions.

2.2.2 A pilot steering group was formed internally 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. The group kept action, risk and challenge logs. The challenge log tracked issues raised during the pilot and logged solutions.

2.3 Pilot site engagement

2.3.1 The pilot steering group identified 'multiagency safety events' as a focus for the local investigations. This was informed by intelligence gathered by HSIB through its referral routes, and through proactive identification of where safety events were occurring.

2.3.2 'Multiagency' was defined as where a patient was harmed, or had the potential to be harmed, through their care, and where there were multiple healthcare organisations involved. Examples would include patients transferred or referred from one care organisation to another.

2.3.3 HSIB's intelligence suggested that the transfer of care between ambulance trusts and hospital trusts would provide opportunities to identify safety events for local investigation. The steering group engaged with four hospital trusts and three ambulance trusts who agreed to support the pilot and refer relevant safety events.

2.4 Investigation operations

Integrated approach

2.4.1 The pilot brought together all parts of HSIB. HSIB's Intelligence Unit supported the identification of events and review of referrals for the pilot. The maternity and national investigation programmes worked together with representation from each to undertake the investigations.

Referral of safety events

2.4.2 A set of referral criteria was created and the pilot trusts were asked to refer (via an electronic referral form) any 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.

2.4.3 A 2-week timeframe was selected to support rapid launch of investigations following the occurrence of a safety event. This was to help minimise the time following an event to help staff recall the events more accurately. It is known that with the passage of time, people's recall can become less accurate. The timeframe also allowed HSIB to review how it was able to respond quickly.

2.4.4 It was necessary to update the timeframe criteria to 'within 6 weeks' as patient safety teams in trusts sometimes found that they were not becoming aware of their local events until after 2 weeks.

Investigations

2.4.5 The intent of the pilot was for four investigations to be undertaken. Investigations were each allocated two investigators, one from each of HSIB's national and maternity programmes.

2.4.6 The investigation process ensured that patient/family, staff and stakeholder engagement met the expectations of any HSIB investigation. Trusts were also informed that HSIB's investigations did not replace their own investigations.

Analysis

2.4.7 The investigations used the Systems Engineering Initiative for Patient Safety (SEIPS) (Carayon et al, 2014) to support the analysis of collected evidence (see figure 1). This allowed investigators to form a clear understanding of the work systems (**paragraph 1.1.1**) involved and how they contributed to processes and outcomes.

2.4.8 The investigations also included other safety concepts as part of their analysis. These included the concepts of controls (**see figure 2**) (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 (**see figure 3**) (Shorrock, 2016).

Figure 1 The Systems Engineering Initiative for Patient Safety, adapted from Carayon et al (2014)

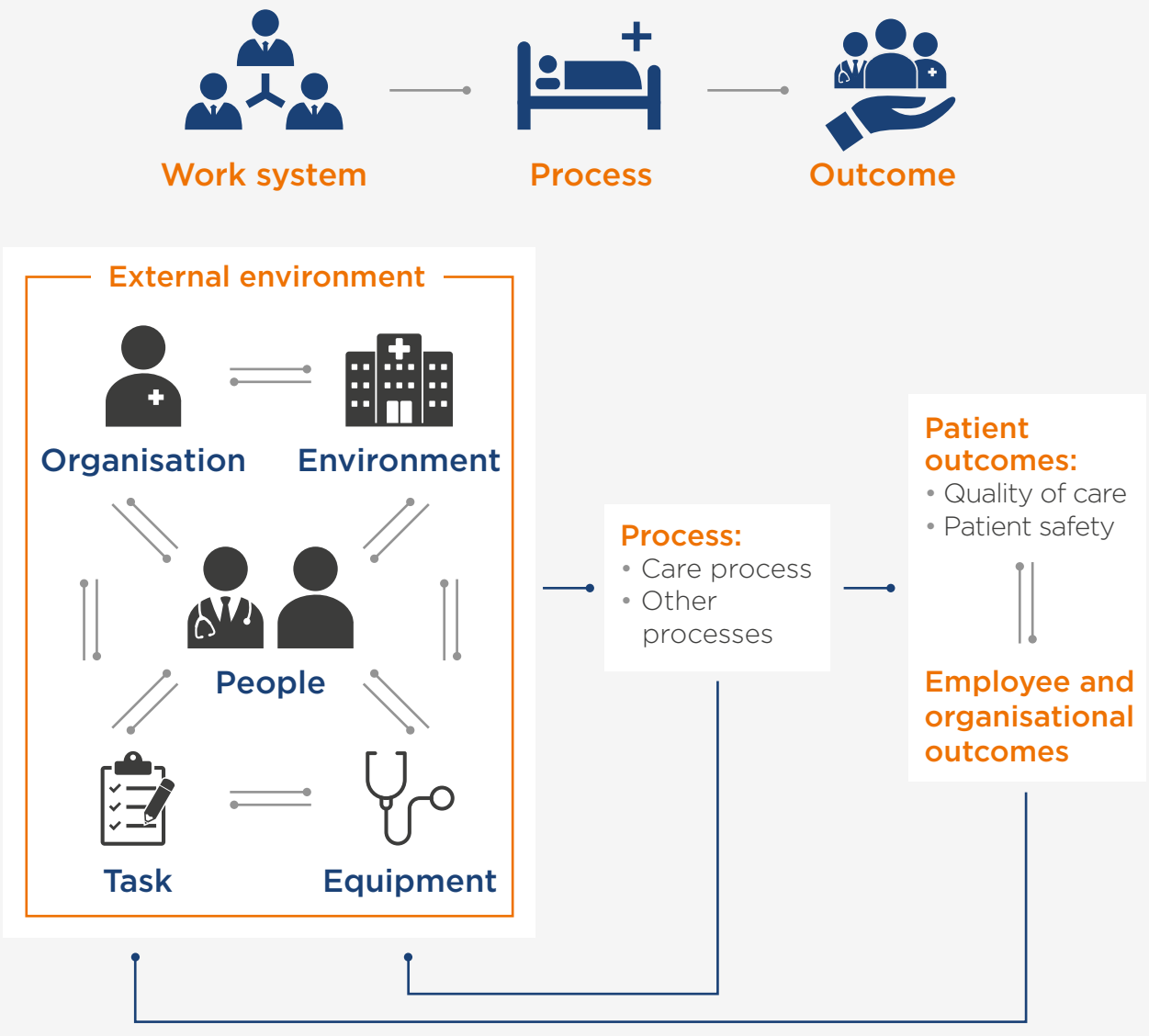


Figure 2 Hierarchy of controls, adapted from The National Institute for Occupational Safety and Health (2015)

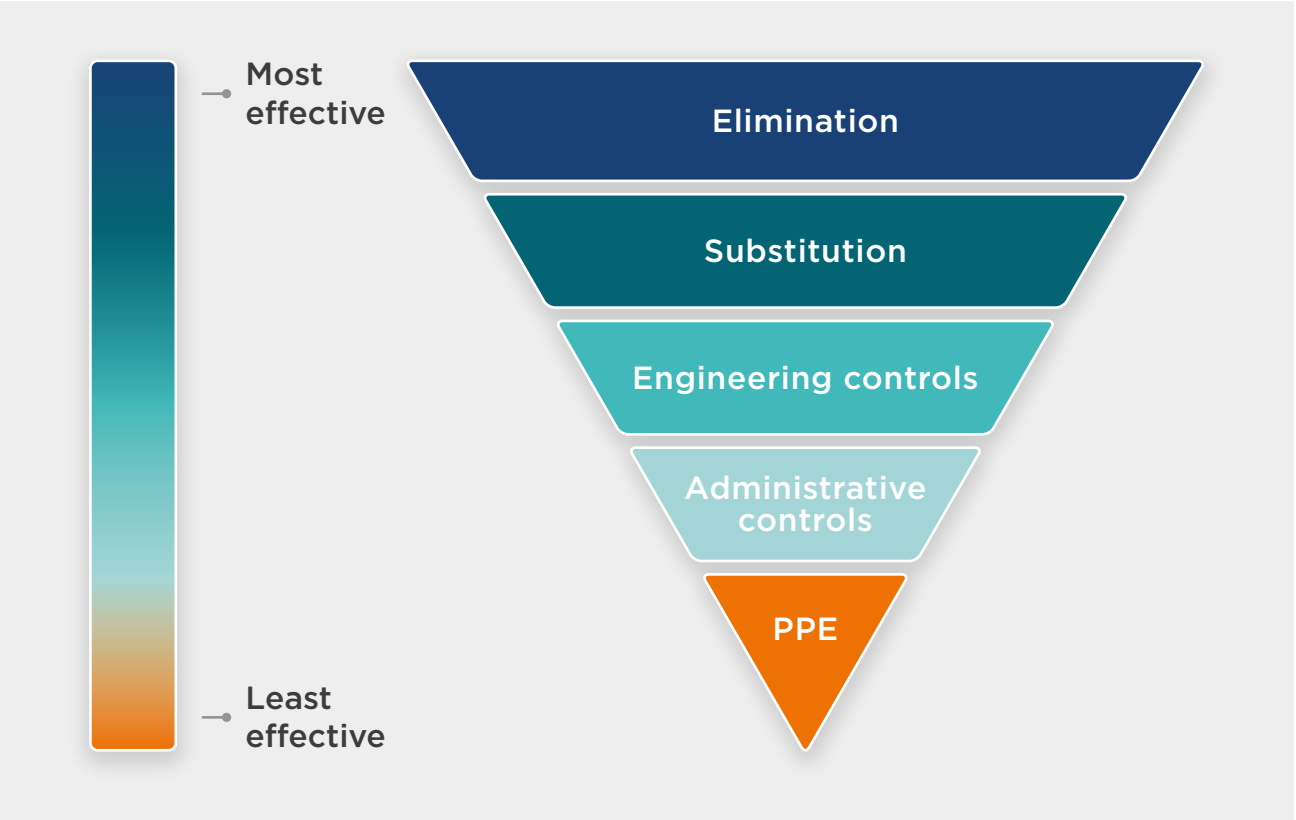
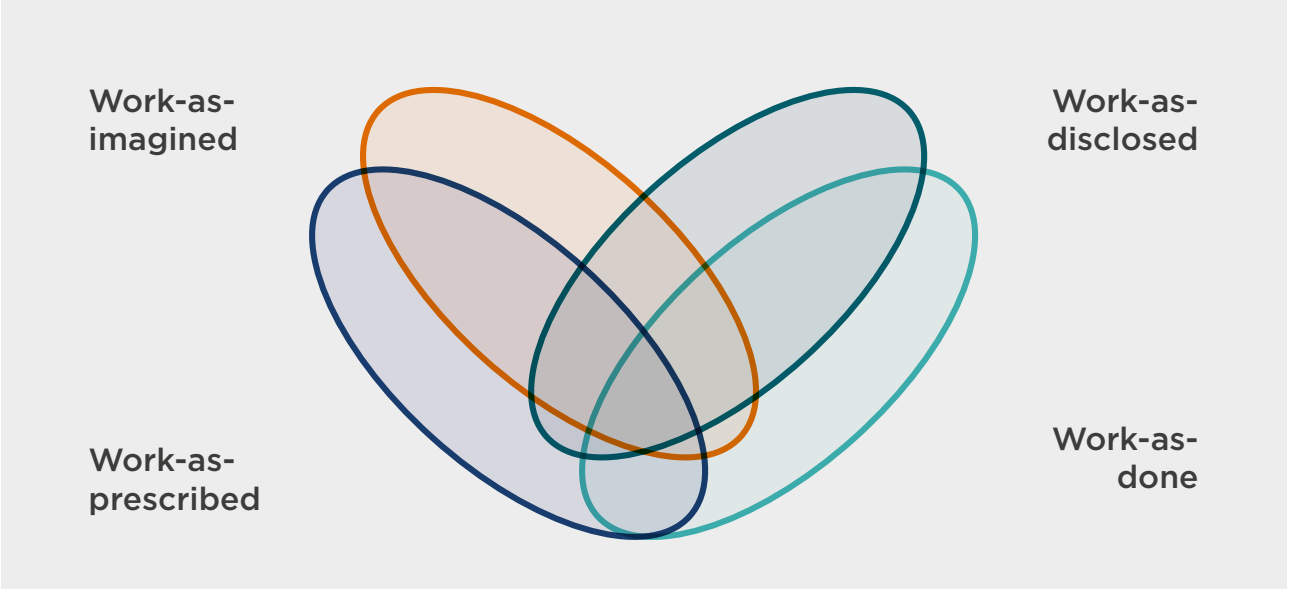


Figure 3 Varieties of human work, adapted from Shorrock (2016)



Launching national investigations

2.4.9 The steering group decided to restrict pilot investigations to only making safety recommendations to the trusts involved. This was because the evidence and analysis for each investigation was specific to the trusts where events took place. However, each investigation highlighted potential national learning; pathways were therefore developed to share learning of national interest.

2.4.10 Pilot investigation teams met every two 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 for potential future national investigations and learning reports.

2.5 Evaluation plan

2.5.1 The evaluation set out to analyse the outputs of the pilot against the objectives described in **section 1.2**. An evaluation plan was developed prior to the launch of the first investigation. Data for the evaluation was quantitative and qualitative (see table 1).

Table 1 Summary of the pilot's evaluation plan mapped against objectives

Evaluation plan/objectives*		A	B	C	D	E
Stakeholder feedback	Qualitative interviews, focus groups and surveys (see stakeholders in table 2)	X	X	X	X	X
Secondary intelligence	Qualitative analysis of intelligence from, for example, meeting minutes and investigation reviews	X	X	X	X	
Pilot challenge log	Qualitative live log of challenges and responses during the pilot	X	X			
Resource quantification	Quantitative approximation of investigation costs and time	X				
Performance indicators	Quantitative review of pilot progress against key indicators	X				
Investigation content review	Thematic analysis of reports using a standard approach (Braun and Clarke, 2006) and software (QSR International, n.d.)		X	X		
Safety recommendation and action review	Mixed methods analysis of safety recommendation strength and effectiveness of actions		X	X		
National learning	Launch of national learning reports and investigations			X		

*Letters refer to the objectives stated in paragraphs **1.2.3 and 1.2.4**

Qualitative data

2.5.2 Qualitative data was collected through interviews, focus groups and questionnaires from individuals and groups internal and external to HSIB (at local, regional and national levels, see table 2). Questions were developed by the steering group and tested with representative individuals. Qualitative data was supplemented with other evidence sources such as meeting minutes, debriefing minutes and policy documents (see table 2).

Table 2 Sources of qualitative data for the pilot's evaluation

Level	Type	Who
HSIB	Focus groups and interviews	Operational: Principal National Investigators, National Investigators, Maternity Investigators, Intelligence Unit, Investigation Education, and Pilot Investigators Corporate: Operations Management Team, Executive Team, Citizens' Partnership and Advisory Panel
	Documents	Steering group logs: action, challenge and risk Meeting minutes: steering group monthly and evaluation subgroup meetings; investigation progress reviews, milestone and debriefing meetings; corporate meetings following discussion of progress Pilot investigation: reports and their drafts
National	Focus groups and interviews	NHS England, Care Quality Commission, NHS Providers, and the Parliamentary and Health Service Ombudsman
	Documents	Strategies, policies and guidance
Regional	Interviews	Clinical Commissioning Groups/ Integrated Care Systems, and NHS England regional teams
	Questionnaires	Patient Safety Collaborative representatives and Patient Safety Specialists
	Documents	Strategies and guidance

Level	Type	Who
Local (trusts)	Interviews	Patient safety and executive teams
	Questionnaires	Healthcare staff who were involved with specific safety events Patients and families involved with specific safety events
Local	Documents	Policies, guidance and action plans

Quantitative data

2.5.3 Quantitative analysis was used to analyse investigation performance against milestones, and to review safety recommendations. Each safety recommendation and safety observation made in the pilot was reviewed by a group of three HSIB employees who were independent of the investigations. These were the pilot Chair/National Investigator, Head of the Intelligence Unit, and a maternity investigator supporting the evaluation.

2.5.4 Each safety recommendation and the actions taken in response were considered by each reviewer independently and then a group discussion held. The intent was to identify the part of the system the safety recommendation was aimed at (using SEIPS) and the strength of any actions undertaken. Strength of the actions was considered against the 'action hierarchy' (National Patient Safety Foundation, 2015) and the 'hierarchy of controls' (The National Institute for Occupational Safety and Health, 2015).

Rigour

2.5.5 Throughout the pilot the steering group attempted to ensure rigour in the evaluation, as follows:

- Credibility – the findings make sense: a wide range of data sources were used, with clarification of findings with participants. Those involved in the pilot were debriefed, and findings were triangulated with evidence from various sources.

- Dependability – undertaken in a dependable way: the evaluation plan was maintained and updated throughout the pilot. All evidence collected was stored and analysed in a consistent manner.

- Transferability – generalisation of findings: the pilot focused on local investigations, but provided insights into wider HSIB processes. This was because of the rich insights gained from participants.

- Confirmability – objectivity of researchers: the pilot identified assumptions and potential biases during its progress. These were logged and are addressed among the internal findings.

2.5.6 At all stages of the pilot the processes for investigation and evaluation were transparent and open to challenge by any stakeholder internally and externally to HSIB. A challenge log was developed and reviewed at each steering group meeting. Preliminary and final findings were shared internally prior to publication of any external reports.

3 Results

3.1.1 Ten referrals from the pilot sites were received: eight from ambulance trusts and two from hospital trusts. Seven of the ambulance referrals were from one trust and were all received on the same day after proactive work by HSIB to prompt referrals. Referrals related to:

- delays to handover of patients from ambulance to emergency departments
- positive patient identification at handover of care
- care of people under Section 136 of the Mental Health Act.

3.1.2 All referrals were reviewed and taken to HSIB's scrutiny panel within 5 working days of the referral. Three referrals did not meet the original criteria for the pilot as they were referred more than 2 weeks after the incidents; they did meet the updated timeframe criteria. One of the three did not relate to patient safety. Four investigations were launched and all referrers received feedback on the outcome of their referrals.

3.2 Investigations

3.2.1 Four pilot investigations were launched and three progressed to final publication. The pilot's original target was for an investigation to be completed within 140 working days (around 6 months) of referral. The six-month timeframe was chosen to include 3 months for investigation and 3 months for the necessary process to review and prepare HSIB reports for external publication.

3.2.2 The target for completion was later updated to within 140 working days of receiving consent from the patient/family. This was because HSIB was unable to start investigations without such consent. In one investigation, consent was obtained after 30 working days. In another, consent was obtained after 47 working days, but then withdrawn (this investigation was not published). All published investigations were completed within 140 working days.

Investigation summaries

Investigation 1 – incorrect patient identification

3.2.3 The Patient (Patient 1), a woman aged 75 years, was taken to an emergency department (ED) by ambulance. This followed a 999 call from Patient 1's Granddaughter to the emergency operations centre. The emergency operations centre used the wrong NHS number for Patient 1. They used the NHS number of another individual (Patient 2), who had the same date of birth as Patient 1 and a similar name.

3.2.4 At the ED, Patient 1 was booked in under Patient 2's NHS number. This NHS number continued to be used during Patient 1's time in hospital. Initially, Patient 1 received medication based on her own supply brought in by her family. Following a pharmacy review, the medications were changed to those taken by Patient 2. The Patient declined to take the incorrect medication and the incorrect patient details were identified by a pharmacist the following day.

3.2.5 The investigation was published in December 2021 and made four safety recommendations and four safety observations. Safety recommendations were made to the hospital and ambulance trusts.

Investigation 2 – incorrect patient details on handover

3.2.6 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. After having an X-ray the Patient was discharged the same day.

3.2.7 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 fractured neck of femur (broken hip) and she was admitted for surgery. During surgery the pathology department identified a problem with the Patient's identification.

3.2.8 The investigation was published in January 2022 and made five safety recommendations and two safety observations. Safety recommendations were made to the hospital trust, ambulance trust and a care home.

Investigation 3 – transfer of a patient who had suffered a stroke to emergency care

3.2.9 The Patient, a man aged 75 years, woke at 01:30 hours feeling unwell. The Patient's Wife rang NHS 111 and was transferred to the 999 service. The paramedics who responded immediately recognised symptoms consistent with 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.

3.2.10 When the ambulance arrived at Trust B, 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.

3.2.11 The investigation was published in March 2022 and made three safety recommendations and one safety observation. Safety recommendations were made to two hospital trusts and the ambulance trust.

Investigation themes and national risks

3.2.12 The three pilot investigations identified two potential national safety risks. These related to:

- The NHS number – 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.

3.2.13 A thematic analysis of the three published investigations was undertaken to identify similarities in the work system factors that contributed to the events. The coding was structured against HSIB's Safety Intelligence ResearCH framework (SIRch, **see main report**). The high-level themes (seen in all three reports) were:

- 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.

3.3 Stakeholder feedback

3.3.1 The evaluation undertook 50 interviews/focus groups before, during and after the publication of the pilot investigations. Those who took part included stakeholders from the individual healthcare organisations, HSIB and national safety bodies (**see table 2**).

3.3.2 Questionnaire feedback was sought from frontline staff involved in the investigations, the family of the patients involved, and those with an interest in patient safety across the **Patient Safety Collaboratives** (PSCs). Two family members, six staff, and eight PSC representatives provided responses.

3.3.3 Qualitative data was supplemented with around 120 further evidence sources, such as meeting minutes (**see table 2**). Qualitative data was analysed using the research software NVivo (QSR International, n.d.) with the creation of a coding matrix mapped to the pilot's objectives to identify themes from across the data.

3.3.4 The findings from the stakeholder feedback and other qualitative data sources are included within the analysis of the results in **section 4**.

4 Analysis and findings of the evaluation

This section provides a summary of the analysis and findings from the pilot's evaluation against the objectives outlined in **section 1.2**.

4.1 An efficient and effective approach

4.1.1 The pilot launched 4 investigations following 10 referrals. Each was launched within 5 working days of referral. Three investigations progressed to publication, each within 140 working days. From the perspective of the trusts involved, the investigations did not create a significant amount of extra work and reports provided meaningful learning promptly.

Developing the approach

4.1.2 The approach to local investigation evolved from HSIB's national investigation process. While this provided an initial template, it became apparent that a bespoke approach was needed to balance duration of the investigations, scope, depth and resource. The evaluation found that local healthcare organisations wanted prompt and early learning to mitigate any local risks.

4.1.3 The approach in place at completion of the final investigation is shown in the appendix. Two evaluation themes particularly influenced this final approach:

- Aim, objectives and scope of a local investigation: as the pilot progressed it was evident that there were different views on the role of an HSIB local investigation. These differed across HSIB and the national bodies engaged with. The views related to audience, focus, breadth and depth of the investigations. In response, the difference between the terms of reference of an HSIB national versus local investigation were clarified. The terms of reference for an HSIB local investigation are outlined in **figure 4**.

- Local investigations making national safety recommendations: the steering group agreed that HSIB local investigations should make safety recommendations to the local healthcare organisations. However, there were views that single local investigations could provide credible evidence for national safety recommendations. To ensure national learning was not lost, the steering group developed pathways for potentially relevant learning to be fed into HSIB's Intelligence Unit for future national investigations.

4.1.4 HSIB investigators described the importance of setting clear expectations from the outset to help shape the focus of the investigations and to help write the reports for the chosen audience. They also highlighted the importance of visiting the location of safety events and observing local practice first hand.

Figure 4 Terms of reference for an HSIB local investigation

Aim: to investigate a patient safety incident to identify and share learning with the goal of reducing the recurrence of incidents and/or harm to patients.

Objectives – to:

- investigate a specific healthcare incident identified through a process of referral and scrutiny
- investigate using a systems approach with identification of work system factors that contributed to the incident
- share learning around the work system factors that contributed
- where appropriate and based on findings, make safety recommendations to address limitations in local processes and systems to reduce the recurrence of incidents
- describe, if identified through the process of investigating, learning that may inform future HSIB national investigations or programmes of work
- demonstrate an approach to high-quality healthcare safety investigations undertaken by professional investigators.

Scope – the investigation should include:

- hearing from the patient and family about events with their agreement
- organisations and their staff involved in the care pathways and those that directly commission or manage them.

4.2 Outputs to support learning and improvement

4.2.1 The evaluation sought to understand whether the outputs of the pilot:

- provided local learning for local healthcare organisations and useful, impactful safety recommendations
- could add value to support safety learning across the wider healthcare system.

There was support from stakeholders for HSIB to include local investigations in its future processes as it transitions to the Health Services Safety Investigations Body (HSSIB).

Local learning and recommendations

4.2.2 The learning identified by the pilot investigations may not have been achieved if the investigations had not taken place. No individual healthcare organisation undertook its own in-depth, formal investigation of the individual events investigated by the pilot. This was for various reasons including that the events had not caused harm, had been referred to other organisations, or would have been considered as part of a thematic review.

4.2.3 The individual trusts involved in the pilot described that they would not have investigated the incidents in depth because they were low-harm or no-harm events. They also described challenges undertaking investigations that involve multiple healthcare organisations and that therefore learning is lost. By co-ordinating and undertaking these types of investigations, HSIB offered independence and value.

> '... feel extraordinarily helpful to have an external organisation working with [the ambulance service] and care home, as otherwise it would have been very difficult to sort for [the hospital]. HSIB can get better and quicker information and can get the bigger picture ... if external agency spots it, it has more kudos.'
> **External feedback on the pilot**

4.2.4 Pilot trusts described their perceived benefits of the pilot investigations:

- Improved local awareness of systems and processes.
- Staff support to "open up" about long-term challenges not previously raised.
- Improved relationships with other providers across which incidents had occurred.
- Increased attention to issues in their organisations and motivation to act.
- Increased awareness of cultural factors and diversity.

4.2.5 Having experienced the pilot, pilot trusts also described future benefits:

- Freeing up local capacity by HSIB taking on certain investigations.
- Capability building of staff through training, mentoring and the HSIB investigatory approach.
- Shaping of local investigatory approaches.

- Financial savings by reducing investigation demand and litigation.
- Embedding a just culture.

> 'I found all the staff I engaged with very approachable, honest and felt comfortable sharing information in an open and honest environment.'
> **Trust staff feedback on an investigation**

> 'It was professional and reassuringly systems focused. We have much to learn from this approach.'
> **Trust staff feedback on an investigation**

Local safety recommendations

4.2.6 The investigations made 12 safety recommendations to eight different healthcare organisations (ambulance trusts, hospital trusts and a care home), and seven safety observations. The safety recommendations commonly focused on reducing variability in local processes and practices, and so were organisational recommendations made with the hope that actions would support frontline staff and their work. The evaluation's reflections on the safety recommendations included:

- Some were difficult to read and understand in isolation without the support of the main body of text and clarifying statements.
- They were generally feasible, but risked weak implementation depending on local time, resource and capability.
- Wording was sometimes weak such as 'consider' and 'review.'
- Some asked for further analysis to identify solutions.
- The frameworks for considering the strength of actions, such as the hierarchy of controls, can only be applied to actions and not safety recommendations.
- Some of the safety recommendations could be considered to be offering solutions.

Local responses to safety recommendations

4.2.7 HSIB's safety recommendations aim to identify issues from an investigation of a safety event that, if addressed, would reduce the risk of future, similar events occurring. The safety recommendations do not aim to offer solutions and it is intended that a recipient would identify the solution/action based on their knowledge of the local system.

4.2.8 In response to the safety recommendations, trusts provided HSIB with an overview of their intended actions. While there was evidence of plans for stronger actions such as pathway redesign, the actions commonly involved awareness building, training and procedure creation. Trusts described that it is challenging to identify appropriate and effective actions in response to safety recommendations either because of local capability and capacity, or because actions are outside of their control.

4.2.9 Regarding capability and capacity, the trusts did not always feel that they had the internal knowledge, skill and resource to develop effective actions, monitor them and evaluate them. They did not necessarily know what the most appropriate action was and what other organisations had done to address a similar risk. The capacity of those implementing the actions was also limited; there was often a reliance on operational staff to address actions in addition to their core roles. This meant actions often took the form of 'reminders' or 'awareness building' as these were easier to introduce.

> 'HSIB's role is investigating and recommending – are we missing a trick as a wider NHS in supporting the 'how' to implement the recommendations?'
> **External feedback on an investigation**

4.2.10 As a result of the difficulties described, several trusts wanted HSIB to offer potential solutions to its safety recommendations, while recognising that these will be context specific. One trust did not want solutions to be offered by HSIB because it felt it was best placed to understand its local needs and systems.

> 'There is potential that multiple differing local solutions could have a detrimental effect on safety, especially given the overlapping interactions of different care homes and different ambulance, acute and mental health trusts.'
> **External feedback on an investigation**

4.2.11 Integrated Care Systems (ICSs) supported HSIB's local safety recommendations. They further identified that they could have a future role in supporting the implementation of actions in their regions, particularly those involving multiple agencies.

4.2.12 The above findings support the case for HSIB and the value it can provide to local healthcare organisations with appropriate support to implement local actions. Where actions are outside of the ability of healthcare organisations, HSIB has the ability to influence national change to benefit the wider healthcare system.

National learning

4.2.13 The national value of a local investigation programme has already been evidenced by HSIB's maternity investigation programme. This has shown value through the collation of learning from different reports and the publication of national learning reports. It has also informed national strategy and guidance.

4.2.14 Each of the pilot investigations identified national learning and potential national safety risks. The investigations did not make national safety recommendations, but this was controversial with challenge from within and outside of HSIB.

> '... we noted several opportunities throughout the report where potential 'national' recommendations/observations could be made ... it may be worthwhile considering explicitly noting these areas for improvement and any next steps HSIB plans to make ...'
> **External feedback on an investigation**

4.2.15 National bodies also described other potential benefits of HSIB's local investigations, including cross-NHS capability building in investigation skills, challenge of the status quo around safety, challenge of national metrics for risk and safety, potential research opportunities, and improved sharing of learning across organisations. There was a keenness for HSIB to undertake secondary analysis (collating findings from different investigations) to identify learning to share nationally; this was felt to be poorly done across the NHS.

Launch of national investigations and learning reports

4.2.16 Each pilot investigation identified learning of national relevance and highlighted potential national safety risks. The secondary analysis of reports through collation of findings using HSIB's SIRch framework (**see main report**) further identified cross-cutting safety themes as per **paragraph 3.2.13**.

4.2.17 The pilot contributed to the launch of a national investigation and national learning report:

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

4.2.18 The national outputs demonstrate how local investigations can stimulate a national focus, combining learning from several sources of intelligence.

Other stakeholder perspectives

4.2.19 The pilot was only able to receive limited feedback from families. Two investigations involved families who could be approached. One family (two responses) provided feedback which was fully supportive of HSIB's role and a future local investigation programme. They felt it would eliminate safety risks, clarify accountabilities, and give families a voice.

4.2.20 Beyond family feedback, the pilot sought feedback from the Citizens' Partnership. Again there was thought to be value in local investigations to patients and families. They would potentially help with 'closure' for families; this has been echoed in feedback from HSIB's maternity investigation programme.

4.2.21 The pilot also received feedback from staff involved with aspects of each of the investigations. Positive responses provided evidence for support of local investigations and HSIB's approach. There were perceptions that the approach would support improvements in patient safety and evidence was provided of where improvements had already been made. Staff also felt the process of investigation was supportive and professional.

'Engagement was better, it felt less like being 'done to'.'
Trust staff feedback on an investigation

4.2.22 From an HSIB perspective, the pilot broadened national and local awareness of HSIB's role in safety in the NHS. The pilot also supported HSIB to investigate in areas that it has not previously accessed which included a care home. HSIB's investigators described how the pilot had supported their own professional development in areas such as report writing and human factors.

Challenge to the local investigation approach

4.2.23 None of the feedback indicated complete opposition to HSIB undertaking local investigations in the future. Rather, any challenges heard related to how a local approach may undermine HSIB's ability to deliver against its current and future requirements. Concerns focused on resource and value.

4.2.24 Concerns around resource related to:

- overwhelming HSIB's resource at the time of the pilot with investigation teams already under pressure to deliver
- whether the resource allocated was excessive for low-harm/no-harm incidents

- whether any future local programme may be implemented without appropriate considerations or resource requirements.

  At the time of the pilot the future resource of the HSSIB was unknown.

4.2.25 Other, less commonly heard concerns included whether the pilot would distract from HSIB's other programmes of work such as education; whether the pilot was premature without knowing the future of HSSIB; and whether local investigations were outside of the original intentions for HSIB.

4.3 Focusing local investigations in the future

4.3.1 The pilot focused on events involving multiple healthcare organisations across boundaries of care. There was consistent support for this as a focus.

> '… cross-organisation investigations are difficult for an individual organisation to investigate – needs independent view.'
> **External feedback on the pilot**

4.3.2 It was heard that cross-boundary investigations are complex and challenging for individual organisations.

4.3.3 The evaluation identified three potential areas for a local approach. These all related to situations where local organisations could not or should not carry out investigations themselves:

- events outside the ability of local organisations to investigate or address (with focus on specific areas of risk, for example Never Events)
- events that require independence
- events through which local capability could be enhanced via HSIB support.

> '… we have recurring things happen, for example Never Events in surgery, things we can't get a grip on, intractable problems … it would be really great to get someone external to help and be completely objective and see things [we] don't see … recognition that if HSIB can't fix it, it might not be fixable and reduces blame from [national bodies].'
> **External feedback on the pilot**

Focus areas

4.3.4 It is likely that a 'focus area' approach would be most appropriate (making local safety recommendations) with the combining of learning from several local investigations to identify national risks and provide national safety recommendations. Cross-boundary and mental health focus areas were repeatedly suggested.

4.3.5 Choice of area will be influenced by future HSSIB resource. For example, the current HSIB national investigation programme is required to deliver 30 national investigations per year; two of these could be national learning reports based on six local investigations per report.

4.3.6 The evaluation noted that this was not the first time a 'focus approach' had been suggested to HSIB. In 2019/20 HSIB's Intelligence Unit introduced focus areas with limited success. It may be appropriate for HSIB to revisit the 'focus approach' with the backing of the evidence from this pilot.

4.3.7 Regarding the features of incidents to investigate, harm was most commonly considered. There was debate about whether low-harm/no-harm incidents should be included. Several stakeholders felt that seriousness alone should not be the trigger and that it may be beneficial to focus on higher frequency events. Lower-harm events may also be easier to investigate. However, not all agreed with the value of low-harm investigations; stakeholders questioned whether they were less motivating, caused unnecessary anxiety to the patient and family, and could stimulate a complaint.

> 'A focus on the low-level harm but high-frequency incidents again as a proactive approach.'
> **External feedback on the pilot**

Building capability

4.3.8 HSIB's primary role is to undertake independent safety investigations. A secondary role is to support the development of local patient safety investigation expertise. Through its primary role, HSIB can model best practice to contribute to its secondary role. This may be through publication of methodologies and analyses. There may also be a role for HSIB to support other organisations' investigations through the education strategy.

> 'Great opportunity to support development of organisational safety profile and training.'
> **External feedback on the pilot**

Independence

4.3.9 As the independent investigator, it was suggested that HSIB should also have a 'rapid response' ability for novel/emerging and imminent risks (such as undertaken with **Oxygen issues during the COVID-19 pandemic** and **COVID-19 transmission in hospitals: management of the risk** – a prospective safety investigation). This would require an 'on-call' response and a process for rapid sharing of learning to mitigate system-wide risks.

4.4 Supporting organisations and individuals to refer incidents

4.4.1 The evaluation heard views that HSIB is predominantly 'reactive,' meaning that some significant healthcare safety risks may be underrepresented in its investigations, such as in mental health and primary care. HSIB was encouraged to be more proactive by seeking and identifying qualifying events from national safety databases, local patient safety plans, Patient Safety Specialists, and ICSs. The health system needs to 'tell' HSIB where the risks are.

> 'Themes that appear in several organisations but don't appear as a top priority as low numbers in individual organisations (or occurring in different sectors) …'
> **External feedback on the pilot investigations**

4.4.2 Identification of events for a local approach will depend on focus areas. Criteria would require development and should be informed by stakeholders such as royal colleges.

4.4.3 The writing of focus area criteria needs to be clear, not subjective, and they should be written for those referring, ensuring equal access to HSIB for organisations, and patients and the public. Agreement of criteria (potentially through a scrutiny panel) and user testing should be undertaken before criteria are launched. Criteria would need to be specific enough to focus investigations on a theme, but broad enough to help referrers. Whether 'levels of harm' should be relevant was controversial.

4.4.4 Wider engagement highlighting HSIB's role is needed. Very few participants of the pilot were aware of HSIB's national investigation programme. This may limit future referrals.

4.5 Questions and considerations for the future

4.5.1 During the pilot, the evaluation identified several questions for HSIB that were outside of the scope of the pilot. These questions were commonly existential or related to HSIB policy and process.

4.5.2 Some operational questions related to consistency and consent. Consistency questions highlighted the need for common expectations of investigations across HSIB. Consent questions highlighted the challenges faced when gaining consent and the delays to, and therefore possible lost learning from, investigations; this was exemplified by investigation three which did not progress to publication.

5 Conclusions

5.1 Summary

5.1.1 The pilot provided insights into the opportunities and benefits of HSIB having a local investigation approach. It has raised questions for future consideration as HSIB transitions to the Health Services Safety Investigations Body and the Maternity and Newborn Safety Investigations Special Health Authority.

5.1.2 The findings suggest that HSIB would benefit from having a form of local investigation as part of its future portfolio. This is because it offers support to individual organisations in their pursuit of patient safety, builds HSIB's reputation, allows showcasing of high-quality investigations, and has national benefits through the launch of national learning reports and national investigations. The inclusion of several investigations across the country in a national learning report will provide an appropriate volume of evidence to produce credible national safety recommendations.

5.2 Limitations and reflections

5.2.1 The pilot's steering group wish to acknowledge several limitations of the pilot and reflections on the way it was carried out. These may have affected the available learning, but also offer learning for future task and finish groups.

- The resource allocated to the milestone meetings in the pilot was excessive and not realistic for a future model. This was because the pilot was undertaken under HSIB's Directions for national investigations and reports were published externally.

- Questionnaires were used to access harder-to-reach individuals. A significant limitation of surveys is engagement by participants with their completion. Limited survey feedback was received.

- The organisations chosen for the pilot were supportive. With no organisation undertaking their own investigation, they were also receiving 'free' learning from an independent and external organisation. This may have influenced perceptions of the value of the pilot.

- The referrals received were locally categorised as low-harm or no-harm events. However, each event had the potential to cause significant harm. The investigations showed that significant learning can and should be taken from these events. However, there were perceptions that these types of events may be less motivating for organisations to learn from.

6 References

Braun, V. and Clarke, V. (2006) Using thematic analysis in psychology, Qualitative Research in Psychology, 3(2), pp. 77–101. doi: 10.1191/1478088706qp063oa.

Carayon, P., Wetterneck, T.B. et al. (2014) Human factors systems approach to healthcare quality and patient safety, Applied Ergonomics, 45(1), pp. 14–25. doi: 10.1016/j.apergo.2013.04.023.

Chartered Institute for Ergonomics and Human Factors (2016) Human factors in barrier management. Available at **https://ergonomics.org.uk/resource/human-factors-in-barrier-management.html** (Accessed 1 August 2022).

Health and Care Act (2022) Available at **https://www.legislation.gov.uk/ukpga/2022/31/contents/enacted** (Accessed 6 July 2022).

National Patient Safety Agency (2009) Risk to patient safety of not using the NHS number as the national identifier for all patients. Available at **https://webarchive.nationalarchives.gov.uk/ukgwa/20171030130740/http://www.nrls.npsa.nhs.uk/resources/type/alerts/?entryid45=61913&p=2** (Accessed 6 July 2022).

National Patient Safety Foundation (2015) RCA2 Improving root cause analyses and actions to prevent harm. Available at **https://www.ashp.org/-/media/assets/policy-guidelines/docs/endorsed-documents/endorsed-documents-improving-root-cause-analyses-actions-prevent-harm.ashx** (Accessed 1 August 2022).

NHS Trust Development Authority (2016) The National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) Directions 2016: WITHDRAWN. Available at **https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1088077/Withdrawn_HSIB_directions.pdf** (Accessed 1 August 2022).

QSR International (n.d.) NVivo. Available at **https://www.qsrinternational.com/nvivo-qualitative-data-analysis-software/home** (Accessed 1 August 2022).

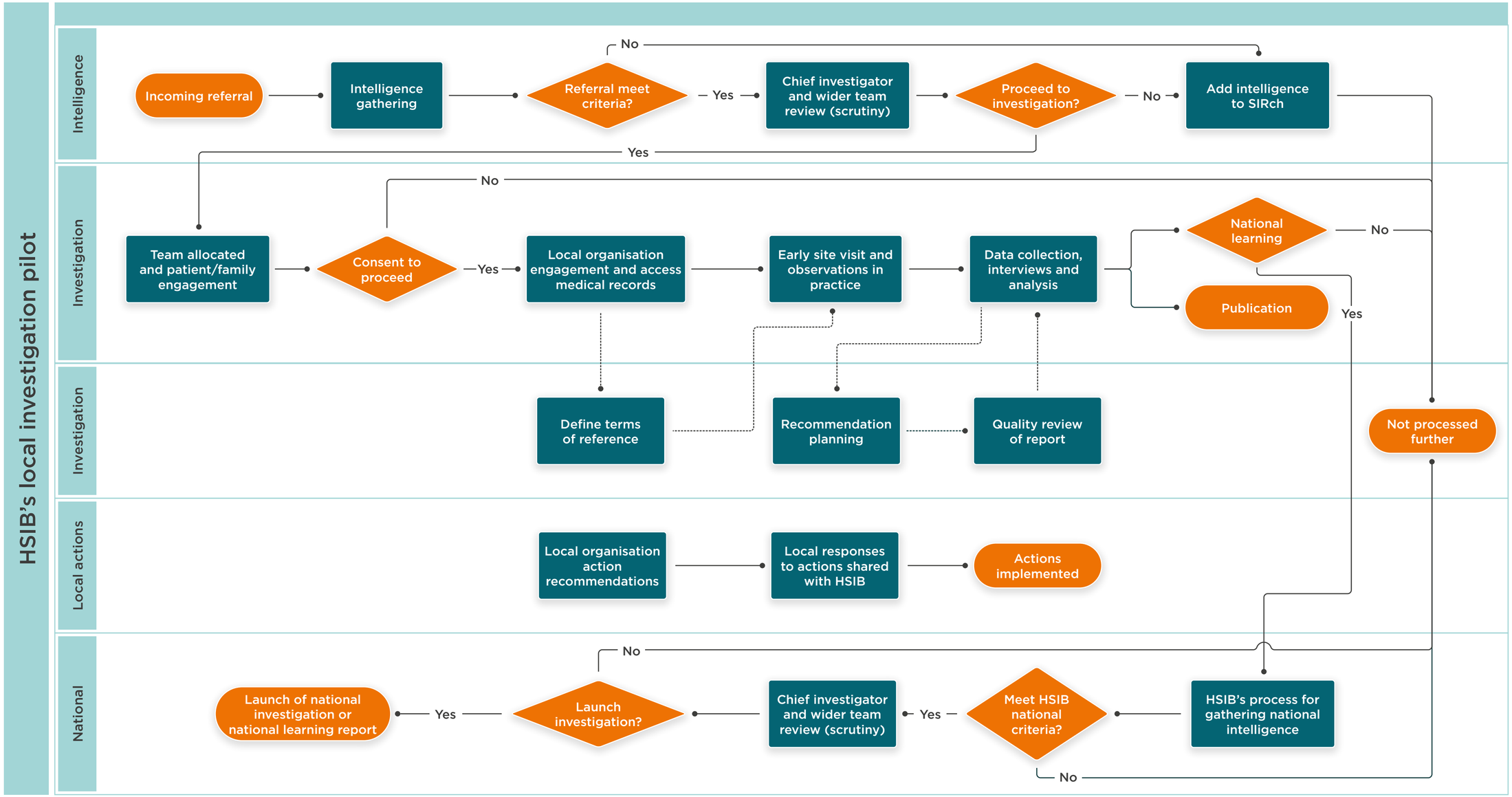
Shorrock, S. (2016) Humanistic Systems. The varieties of human work. 5 December. Available at **https://humanisticsystems.com/2016/12/05/the-varieties-of-human-work/** (Accessed 1 August 2022).

The National Institute for Occupational Safety and Health (2015) Hierarchy of controls. Available at **https://www.cdc.gov/niosh/topics/hierarchy/default.html** (Accessed 1 August 2022).

UK Parliament (2022) Special Health Authority for Independent Maternity Investigations: statement made on 26 January 2022. Available at **https://questions-statements.parliament.uk/written-statements/detail/2022-01-26/hcws560** (Accessed 6 July 2022).

7 Appendix

HSIB's local investigation approach



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