



HEALTHCARE SAFETY
INVESTIGATION BRANCH

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National Learning Report Never Events: analysis of HSIB's national investigations

Independent report by the
Healthcare Safety Investigation Branch I2020/006

January 2021



HEALTHCARE SAFETY
INVESTIGATION BRANCH



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About HSIB

The Healthcare Safety Investigation Branch (HSIB) conducts independent investigations of patient safety concerns in NHS-funded care across England. Most harm in healthcare results from problems within the systems and processes that determine how care is delivered. Our investigations identify the contributory factors that have led to harm or the potential for harm to patients. The

safety recommendations we make aim to improve healthcare systems and processes, to reduce risk and improve safety. Our organisation values independence, transparency, objectivity, expertise and learning for improvement. We work closely with patients, families and healthcare staff affected by patient safety incidents, and we never attribute blame or liability to individuals.

Considerations in light of coronavirus (COVID-19)

A number of national reports were in progress when the COVID-19 pandemic significantly affected the UK. Much of the work associated with developing reports necessarily ceased as HSIB's response was redirected. For this

national learning report, COVID-19 has created further conditions that may increase the risk of Never Events occurring. These conditions are acknowledged in this report and described further.

National learning reports

These reports offer insight and learning about recurrent patient safety risks in NHS healthcare that have been identified through HSIB investigations. The reports present a digest of relevant, previously investigated events, highlight recurring themes and, where appropriate, make

safety recommendations. National learning reports can be used by healthcare leaders, policymakers and the public to aid their knowledge of systemic patient safety risks and the underlying contributory factors, and to inform decision making to improve patient safety.

A note of acknowledgement

We would like to acknowledge the patients and families who have supported our investigations into Never Events. Their engagement

has helped to inform the output of HSIB investigations and therefore this national learning report.

Our investigations

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

We undertake patient safety investigations through two programmes:

National investigations

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

We decide what to investigate based on the scale of risk and harm, the impact on individuals involved and on public

confidence in the healthcare system, and the learning potential to prevent future harm. We welcome information about patient safety concerns from the public, but we do not replace local investigations and cannot investigate on behalf of families, staff, organisations or regulators.

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

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

Our reports also identify ‘safety actions’ taken during an investigation to immediately improve patient safety.

We ask organisations subject to our safety recommendations to respond to us within 90 days. These responses are published on our website.

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

Maternity investigations

From 1 April 2018, we have been responsible for all NHS patient safety investigations of maternity incidents which meet criteria for the **Each Baby Counts programme** (Royal College of Obstetricians and Gynaecologists, 2015) and also maternal deaths (excluding suicide). The purpose of this programme is to achieve learning and improvement in maternity services, and to identify common themes that offer opportunity for system-wide change. For these incidents HSIB's investigation replaces the local investigation, although the trust remains responsible for meeting the Duty of Candour and for referring the incident to us. We work closely with parents and families, healthcare

staff and organisations during an investigation. Our reports are provided directly back to the families and to the trust. Our safety recommendations are based on the information derived from the investigations and other sources such as audit and safety studies, made with the intention of preventing future, similar events. These are for actions to be taken directly by the trust, local maternity network and national bodies.

Our reports also identify good practice and actions taken by the Trust to immediately improve patient safety.

Since 1 April 2019 we have been operating in all NHS Trusts in England.

We aim to make safety recommendations to local and national organisations for system-level improvements in maternity services. These are based on common themes arising from our trust-level investigations and where appropriate these themes will be put forward for investigation in the National Programme. More information about our maternity investigations is available on our **website**.

Executive Summary

This national learning report analyses 10 investigations carried out by HSIB into Never Events. Never Events in the NHS are defined as ‘patient safety incidents that are wholly preventable where guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and have been implemented by healthcare providers’ (NHS Improvement, 2018a). A structured qualitative analysis was carried out using the Systems Engineering Initiative for Patient Safety (SEIPS) (Carayon et al, 2006). Seventeen themes contributing to the Never Events were identified, originating from across the work system. SEIPS was found to be an effective framework for analysis of the Never Events.

The analysis of the 10 Never Events included in this report found barriers that were neither strong nor systemic. These events are therefore not wholly preventable and do not fit the current definition of Never Events. This has led to two safety recommendations to NHS England and NHS Improvement. These are to review and revise the Never Events list, and to develop and commission programmes of work to find strong and systemic barriers for specific incidents where barriers are felt to be possible but are not currently available.

This report also highlights the variation that exists in the delivery of processes, where this contributed to the Never Events occurring. The

National Safety Standards for Invasive Procedures (NatSSIPs) were intended to address some of this variation and recommended individual organisations make their own Local Safety Standards for Invasive Procedures (LocSSIPs) (NHS England, 2015a). This report found that LocSSIPs allow variation in key safety-critical processes across the NHS. As a result, a further safety recommendation is made to the Centre for Perioperative Care to increase standardisation of specific safety-critical steps that are common across all procedures covered by the NatSSIPs policy.

This report also provides further intelligence to inform future HSIB investigations and analysis. It may not be possible to ensure the incidents investigated, currently termed as Never Events, never happen, but preventative actions should still be explored to mitigate the risk of them occurring in future.

Safety recommendations and safety observation

HSIB makes the following safety recommendations

Safety recommendation R/2021/111:

It is recommended that NHS England and NHS Improvement revises the Never Events list to remove events, such as those presented in this national learning report, that do not have strong and systemic safety barriers.

Safety recommendation R/2021/112:

It is recommended that NHS England and NHS Improvement develops and commissions programmes of work to find strong and systemic safety barriers for specific incidents where barriers are felt to be possible but are not currently available.

Safety recommendation R/2021/113:

It is recommended that the Centre for Perioperative Care reviews and revises the National Safety Standards for Invasive Procedures (NatSSIPs) policy to increase standardisation of safety-critical steps that are common across all procedures.

HSIB makes the following safety observation**Safety observation O/2021/093:**

It would be beneficial if significant safety events, such as those presented in this national learning report, continue to be reported and investigated by NHS organisations without apportioning blame or liability, using a recognised systems-based approach such as the Systems Engineering Initiative for Patient Safety (SEIPS) as used in this report.

When reading this report

HSIB has published this national learning report for a variety of audiences. These include healthcare staff, healthcare academics, patients and the general public. Further information on the Never Event investigations undertaken by HSIB are available via its website:

- **Implantation of wrong prostheses during joint replacement surgery (Healthcare Safety Investigation Branch, 2018a).**
- **Administering a wrong site nerve block (Healthcare Safety Investigation Branch, 2018b).**
- **Insertion of an incorrect intraocular lens (Healthcare Safety Investigation Branch, 2018c).**
- **Piped supply of medical air and oxygen (Healthcare Safety Investigation Branch, 2019a).**
- **Detection of retained vaginal swabs and tampons following childbirth (Healthcare Safety Investigation Branch, 2019b).**
- **Prescribing and administering insulin from a pen device in hospital (Healthcare Safety Investigation Branch, 2019c).**
- **Inadvertent administration of an oral liquid medicine into a vein (Healthcare Safety Investigation Branch, 2019d).**
- **Wrong site surgery - wrong patient (Healthcare Safety Investigation Branch, 2020a).**
- **Wrong site surgery - wrong tooth extraction (Healthcare Safety Investigation Branch, 2020b).**
- **Placement of nasogastric tubes (Healthcare Safety Investigation Branch, 2020c).**

The following sections of the report are recommended for different audiences:

- For people new to Never Events who seek to understand the background to Never Events and this report's key conclusions, HSIB recommends sections 1, 5 and 6.
- For people working in clinical or patient safety teams who are familiar with Never Events who seek to understand the themes from HSIB's Never Event investigations and this report's key conclusions, HSIB recommends sections 4, 5 and 6.

- For people with an interest in safety science, HSIB recommends reading the whole report, including section 3 and appendix 8.2 where information is provided on the SEIPS approach.

This report contains some medical terms related to investigation and Never Events. A glossary relating to concepts and methods is available in section 7. A description of each Never Event is provided in appendix 8.1.



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1 Introduction to Never Events

1.1 Never Events as safety-critical incidents

1.1.1 Definition

The definition of Never Events is set by the current version of the Never Events policy and framework. This states:

‘Never Events are patient safety incidents that are wholly preventable where guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and have been implemented by healthcare providers.’
(NHS Improvement, 2018a)

Barriers or controls are those parts of a system that prevent deviations from the expected processes occurring (Ruijter and Guldenmund, 2016). They are measures that are put into place to reduce the risk of things going wrong.

A Never Event is a safety-critical incident that has the potential to cause serious patient harm or death, although these do not always need to have happened for an incident to be categorised as a Never Event. Never Events are clearly defined in a list to facilitate their recognition (NHS Improvement, 2018b). Data about reported Never Events demonstrates that they continue

to occur and that the risk of them recurring remains (NHS England and NHS Improvement, n.d.).

1.1.2 Evolution of Never Events

The term ‘Never Event’ was first used in 2002 by the National Quality Forum, a patient advocacy group in the USA (Kizer and Stegum, 2005). Following the Institute of Medicine’s recommendation that healthcare errors should be reported more systematically (Kohn et al, 2000), the National Quality Forum selected 27 serious reportable events that they referred to as ‘Never Events’. These serious reportable events included examples that are now seen on the NHS Never Events list (NHS Improvement, 2018b), such as surgery performed on the wrong body part. Other events that are more akin to what NHS England and NHS Improvement has termed ‘Serious Incidents’ (NHS England, 2015b), such as death following a fall while in a healthcare facility, were also included.

The concept of serious reportable events was included in Lord Darzi’s NHS report, ‘High quality care for all’ (Department of Health, 2008). It recommended that a Never Events list be developed for the NHS. The first iteration of that list was published in 2009 and included eight types of event (National Patient Safety Agency, 2009a).

At the launch of NHS Never Events the associated framework importantly defined Never Events as ‘serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented by healthcare providers’ (National Patient Safety Agency, 2009a). This discordant language of a Never Event being ‘largely preventable’ was changed in the 2015 revision of the NHS Never Events framework (NHS England, 2015c) to the current wording, which describes Never Events as being ‘wholly preventable’ (NHS Improvement, 2018a).

The initial aim of the Never Events framework was to provide ‘**a lever for increasing transparency of organisations and the levels of reporting and learning around these very serious safety incidents**’ (Department of Health, 2010). There was subsequently a commitment ‘**to impose contractual penalties for an extended list of Never Events**’ (Department of Health, 2010), although this was later removed as it reinforced the perception of a blame culture (NHS Improvement, 2018a).

Subsequent to the publication of ‘A promise to learn – a commitment to act’ (National Advisory Group on the Safety of Patients in England, 2013) following the Mid-Staffordshire

NHS Foundation Trust inquiry, the purpose of the Never Events framework evolved to promote ‘**honesty, accountability and learning in response to a group of incidents that can be prevented if accepted practice (including available preventative measures) has been implemented**’ (NHS Improvement, 2018a).

1.1.3 Current Never Events

Table 1 lists the Never Events defined by the current framework (NHS Improvement, 2018a) in order of their reported frequency. Figure 1 shows the reported frequency of four of the top five common Never Events – wrong site surgery, wrong implant/prosthesis, retained foreign object post procedure and misplaced nasogastric tube – over an eight-year period along with the total number of Never Events per year during that time (NHS England and NHS Improvement, n.d.). Changes in the Never Events framework in 2015 and 2018 mean that making direct comparisons on reporting rates is not possible. However, the persistence in the reporting of Never Events over time is clear.

Table 1 The Never Events list 2018 to 2019

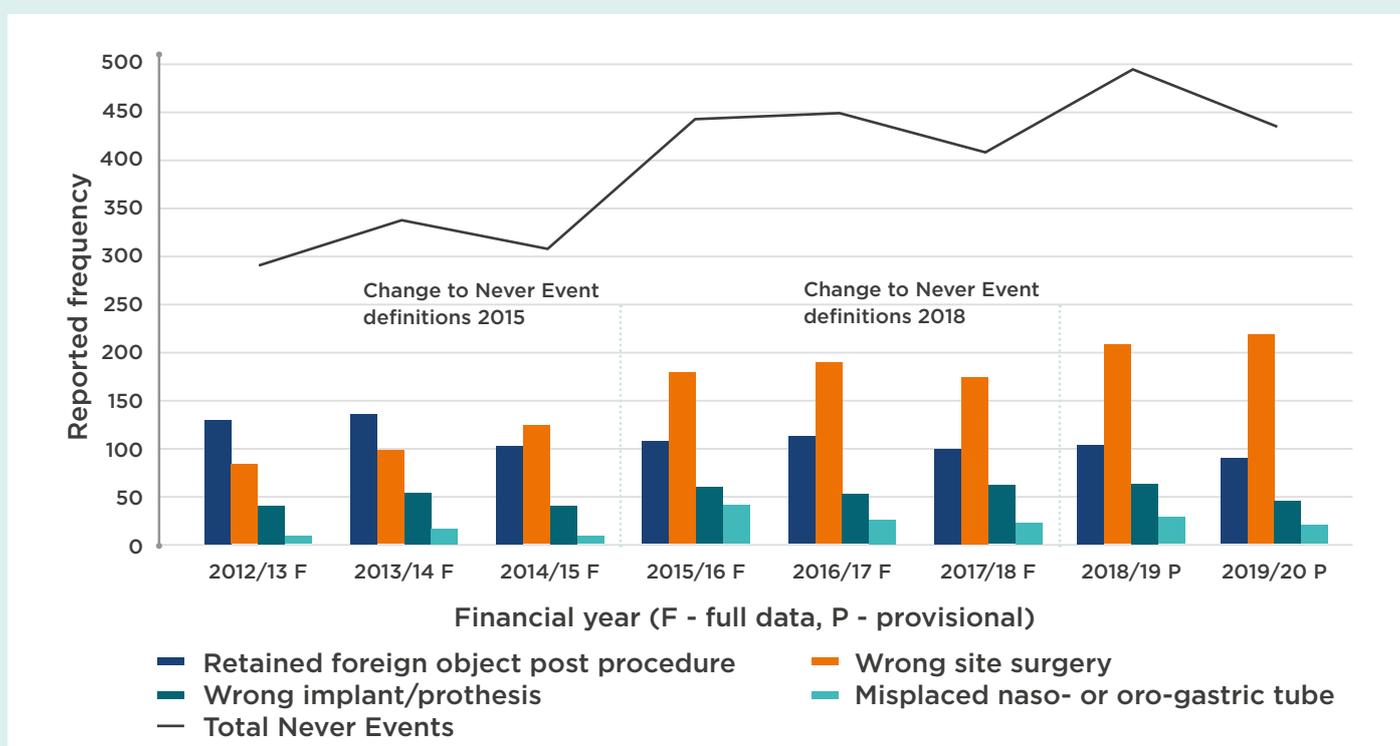
Never Event	Number reported 2018-2019 (provisional data published 29 April 2019)	Percentage of total Never Events reported 2018-2019	Investigated by HSIB (number of ticks represents number of investigations)
Wrong site surgery	207	41.7%	✓✓✓ (HSIB, 2018b; 2020a; 2020b)
Retained foreign object post procedure	104	21%	✓ (HSIB, 2019b)
Wrong implant/prosthesis	63	12.7%	✓✓ (HSIB, 2018a; 2018c)
Unintentional connection of a patient requiring oxygen to an air flowmeter	50	10.1%	✓ (HSIB, 2019a)
Misplaced naso- or oro-gastric tubes	29	5.8%	✓ (HSIB, 2020c)
Overdose of insulin due to abbreviations or incorrect device	14	2.8%	✓ (HSIB, 2019c)
Administration of medication by wrong route	10	2%	✓ (HSIB, 2019d)
Failure to install functional collapsible shower or curtain rails	7	1.4%	✗
Transfusion or transplantation of ABO-incompatible blood products or organs	4	0.8%	✗
Overdose of methotrexate for non-cancer treatment	3	0.6%	✗
Mis-selection of high strength midazolam during conscious sedation	3	0.6%	✗
Falls from poorly restricted windows	2	0.4%	✗

Note: The table shows the frequency of each incident, the percentage of the total number of Never Events and which Never

Events have been investigated by HSIB (NHS England and NHS Improvement, n.d.)

Never Event	Number reported 2018-2019 (provisional data published 29 April 2019)	Percentage of total Never Events reported 2018-2019	Investigated by HSIB (number of ticks represents number of investigations)
Mis-selection of a strong potassium solution	0	0%	✘
Chest or neck entrapment in bed rails	0	0%	✘
Scalding of patients	0	0%	✘

Fig 1 The reported frequency of four selected Never Event types from 1 April 2012 to 29 February 2020



Note: The data in this figure for 2012/13 to 2014/15 is available in the form of final data summaries in The National Archives (NHS England, n.d.). Data for 2016/17 to 2019/20 is available from NHS England and NHS Improvement (n.d.). At the time of writing,

data for 2018/19 and 2019/20 (up to 29 February 2020) was provisional. Due to the changes in definitions in 2015 and 2018, direct comparisons of reporting are difficult, but Never Events continue to occur.

1.2 Context and summary of relevant literature

Since the establishment of the Never Events framework in 2009 the aim was always to improve safety and reduce the number of these incidents. As the numbers of reported Never Events did not dramatically reduce, especially the so called ‘surgical’ Never Events (wrong site surgery, wrong implant or prosthesis, and retained foreign object post operation), a number of reports have been produced assessing the continued occurrence of Never Events.

In 2014 the NHS England Never Event Taskforce concluded that there needed to be greater standardisation of generic operating department practice; systemic education and training for operating theatre environments; and a harmonisation of activity to support a safer environment for patients (NHS England, 2014). Subsequently the National Safety Standards for Invasive Procedures (NatSSIPs) were published in 2015 with the aim of standardising processes that underpin patient safety (NHS England, 2015a). The NatSSIPs set out key steps to deliver safe care, but crucially individual institutions were asked to develop their own Local Safety Standards for Invasive Procedures (LocSSIPs). This national standardisation of only the key steps and the recommendation

for more detailed individualised LocSSIPs has meant that there is still potential variation in approaches to common procedures across the NHS.

A subsequent report of surgical Never Events in the NHS published in 2018 looked at how NatSSIPs and LocSSIPs had been implemented and their impact (NHS Improvement, 2018c). It identified that some challenges remained to prevent reoccurrence including:

- ‘reducing the risks and enhancing awareness of safety in situations where team members are unfamiliar with each other or with the environment, equipment or procedure’
- ‘developing the use of safety checks, so that they are done because all those participating realise their importance, not because they have been mandated.’

The report demonstrated that the desired outcome of standardisation, education and harmonisation had not been achieved, with Never Events continuing to be reported with a similar frequency, as shown in table 1 (NHS Improvement, 2018c).

In December 2018 the Care Quality Commission (CQC) published ‘Opening the door to change’, a report on the persistent occurrence of Never Events in the

NHS (Care Quality Commission, 2018). The CQC considered how a sample of trusts had responded to Never Events to gain insight into their safety culture. The CQC wrote that:

‘The occurrence of a Never Event is thought to tell us something important about the patient safety processes in the service where it happens. There is undoubtedly some truth in this, but as we have carried out this review it has become increasingly clear to us that our failure to reduce the toll of Never Events tells us something fundamental about the safety culture of our health care.’
(Care Quality Commission, 2018)

The CQC’s findings demonstrate that the harmonisation of activity to support patient safety in hospitals as recommended by

the NHS England Never Events Taskforce in 2014 had not occurred (NHS England, 2014).

The NHS Patient Safety Strategy states a goal of continuously improving patient safety based on a patient safety culture and a patient safety system (NHS England and NHS Improvement, 2019). This more cultural approach, allied with the Patient Safety Incident Response Framework (NHS England and NHS Improvement, 2020), does not concentrate on Never Events except to highlight that solutions to prevent them from occurring may be easier to engineer for some than for others.

2 Purpose of this report

2.1 Purpose

This national learning report analyses HSIB's national investigations into Never Events using a structured qualitative approach. The intention was to identify similar interacting elements, the work system factors, across the different investigations that contributed to the Never Events occurring.

By identifying the work system factors the aim was to explore the circumstances that contribute to the risk of a Never Event occurring. This may allow for more effective recommendations and approaches to help reduce the risk of unwanted outcomes and challenge the expectation that these incidents should never happen.

2.2 Scope

This report considers 10 specific Never Event investigations undertaken by HSIB as per appendix 8.1. Seven of these investigations have been published at the time of writing. The other three are ongoing. General findings to date in the ongoing investigations have been included in this report. The selection criteria for HSIB's investigations are available via its website (Healthcare Safety Investigation Branch, n.d.).

The Never Event investigations selected by HSIB to date have focused on the most common Never Events in England. The 10 investigations cover seven of the 15 listed Never Events. These seven Never Events accounted for more than 96% of the total Never Events recorded in 2018/19 (NHS England and NHS Improvement, n.d.).

3 Methods

The following sections provide an overview of the methods used to analyse HSIB's Never Event investigations. Appendix 8.2 provides further detail on the methods.

3.1 HSIB's Never Event investigations

The 10 HSIB Never Event investigations analysed included seven published reports and three currently unpublished investigations. The published investigation reports are available on the HSIB website (Healthcare Safety Investigation Branch, n.d.) and quotes from those reports are included in this national learning report. A short summary of each investigation is provided in appendix 8.1 with descriptions of the associated national safety requirements for prevention of each Never Event (NHS Improvement, 2018b; 2018d).

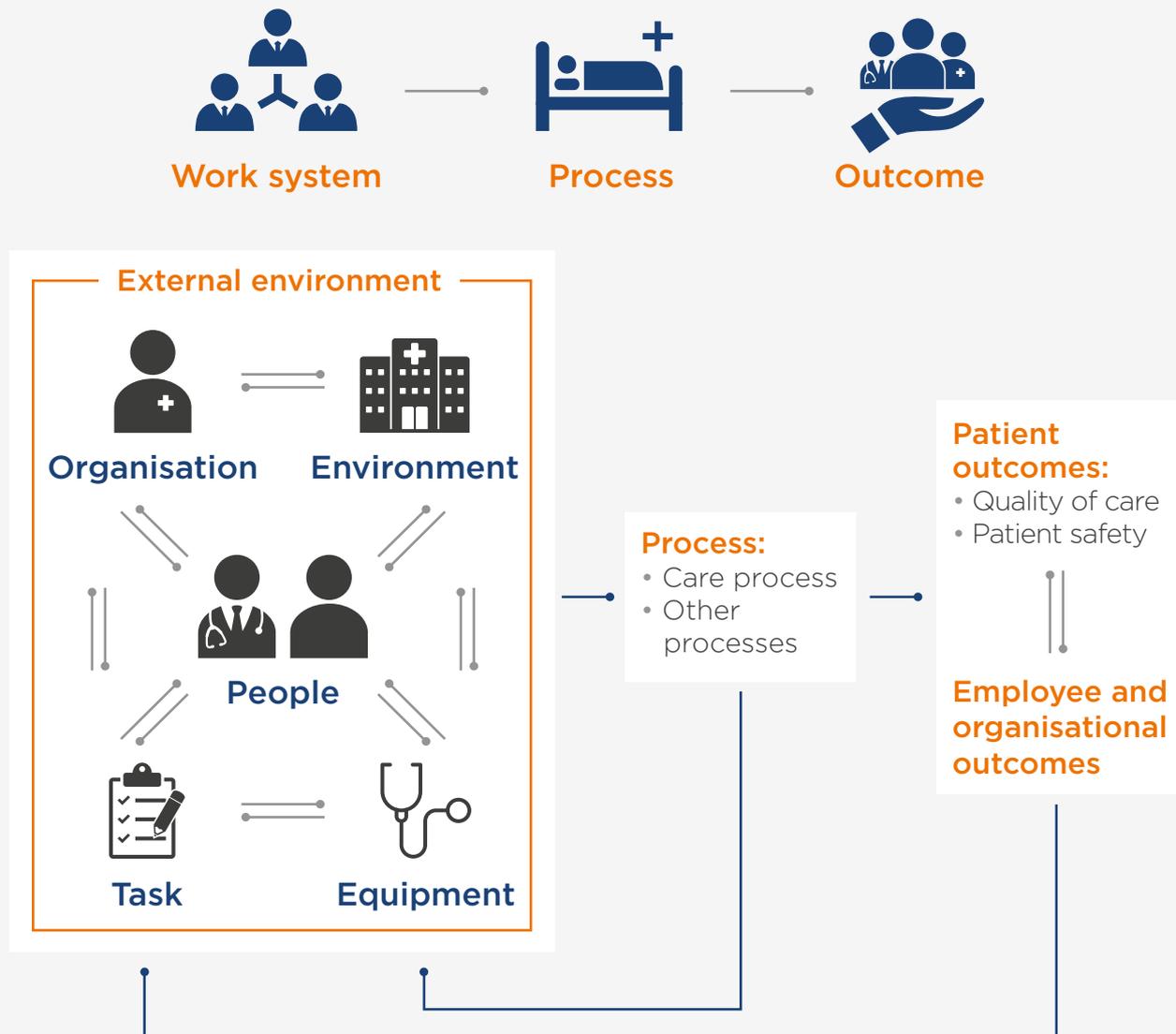
3.2 Analysis methods

A qualitative, thematic analysis approach was taken to identify the work system factors that contributed to the occurrence of the Never Events investigated by HSIB. Thematic analysis was undertaken using the Systems Engineering Initiative for Patient Safety (SEIPS) (Carayon et al, 2020; Holden et al, 2013; Carayon et al, 2006) as the framework, focusing on themes within the work system.

3.2.1 Introducing SEIPS

SEIPS was first described by Carayon et al (2006) as a framework for understanding the structures, processes and outcomes in healthcare and the relationships between them. It is a systems engineering approach with human factors principles embedded within it. Figure 2 provides a representation of SEIPS.

Fig 2 The Systems Engineering Initiative for Patient Safety (SEIPS) adapted from Holden et al (2013)



SEIPS describes how components of the work system produce work processes which result in different outcomes. Work system factors are described below (Holden et al, 2013; Carayon et al, 2006) and figure 3 provides a practical example from one of HSIB's investigations.

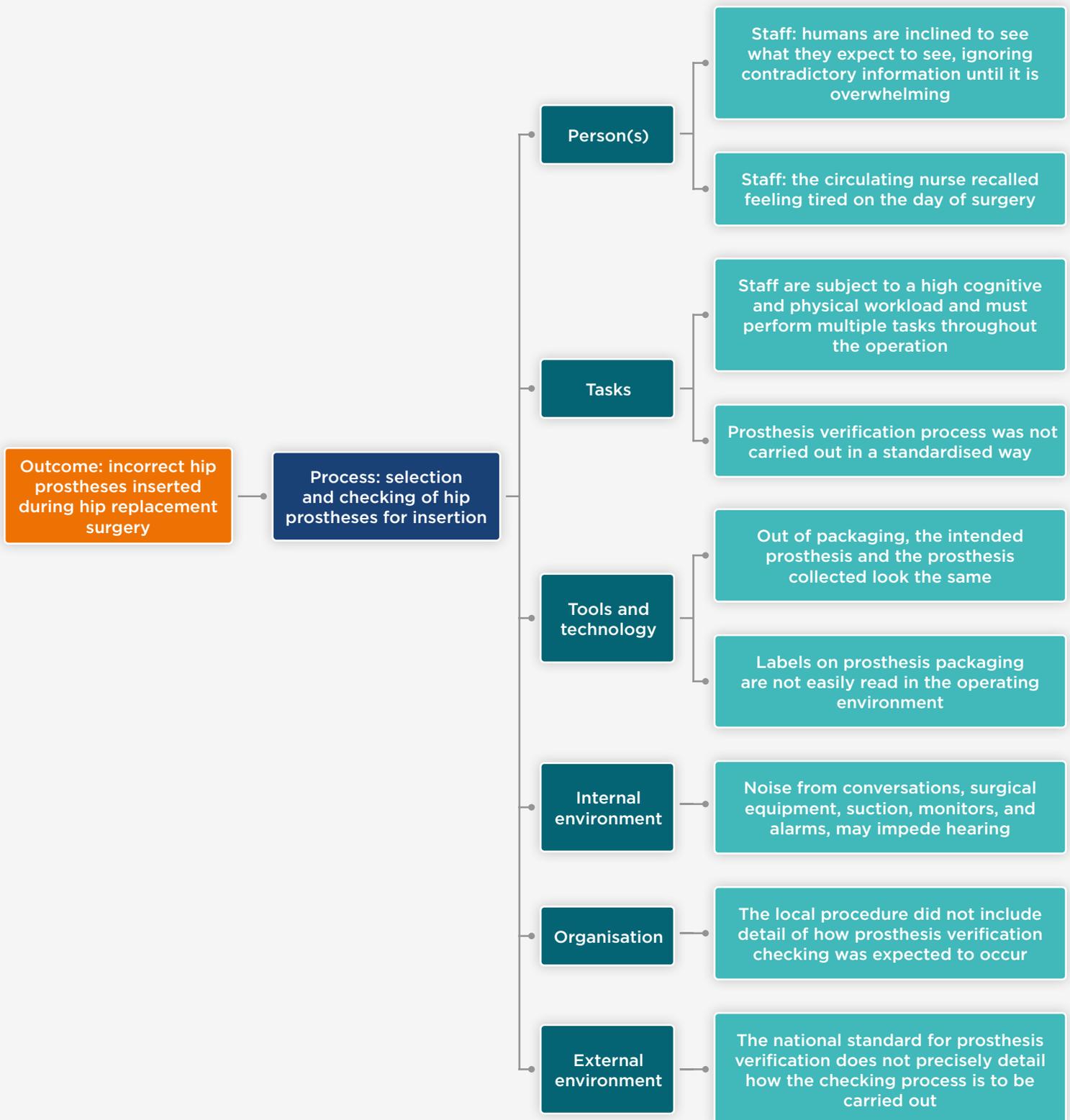
- person(s): the people working in the particular system and the patient
- tasks: undertaken by the persons which may vary in complexity or variety
- tools and technology: used to undertake the tasks which may vary in usability and functionality
- internal environment: the physical space around the persons, for example layout, noise and temperature

- organisation: conditions external to the persons to support the organisation of, for example, resources and activity
- external environment: factors outside of the healthcare institution that might include policy, societal or economic factors.

Processes can be physical, cognitive, or behavioural and lead to outcomes for the patients,

professionals or healthcare institutions. The interactions between the various components of the work system lead to different outcomes, both positive and negative. The framework includes feedback loops which represent the adjustments systems make over time.

Fig 3 Abbreviated example of SEIPS applied to HSIB’s investigation into the implantation of wrong prostheses during joint replacement surgery



3.2.2 Using SEIPS to explore Never Events

The analysis undertaken for this report focused on the processes and work system factors immediately preceding the Never Events occurring, for example, the check prior to final selection and insertion of a joint prosthesis. These processes are generally the points at which the barriers to the Never Events act. They are the processes that aim to prevent deviation and therefore unintended outcomes.

In this report:

- A 'common theme' is highlighted in green and describes a work system factor that was found across more than two-thirds of investigation reports in which it was relevant.
- A 'theme' is highlighted in orange and describes a work system factor that was found across more than one-third of investigation reports in which it was relevant.
- A 'safety note' is highlighted in blue. A safety note refers to a work system factor that was found in under a third of investigation reports (these are not referred to as themes).
- Work system factors found in single investigation reports are not described.

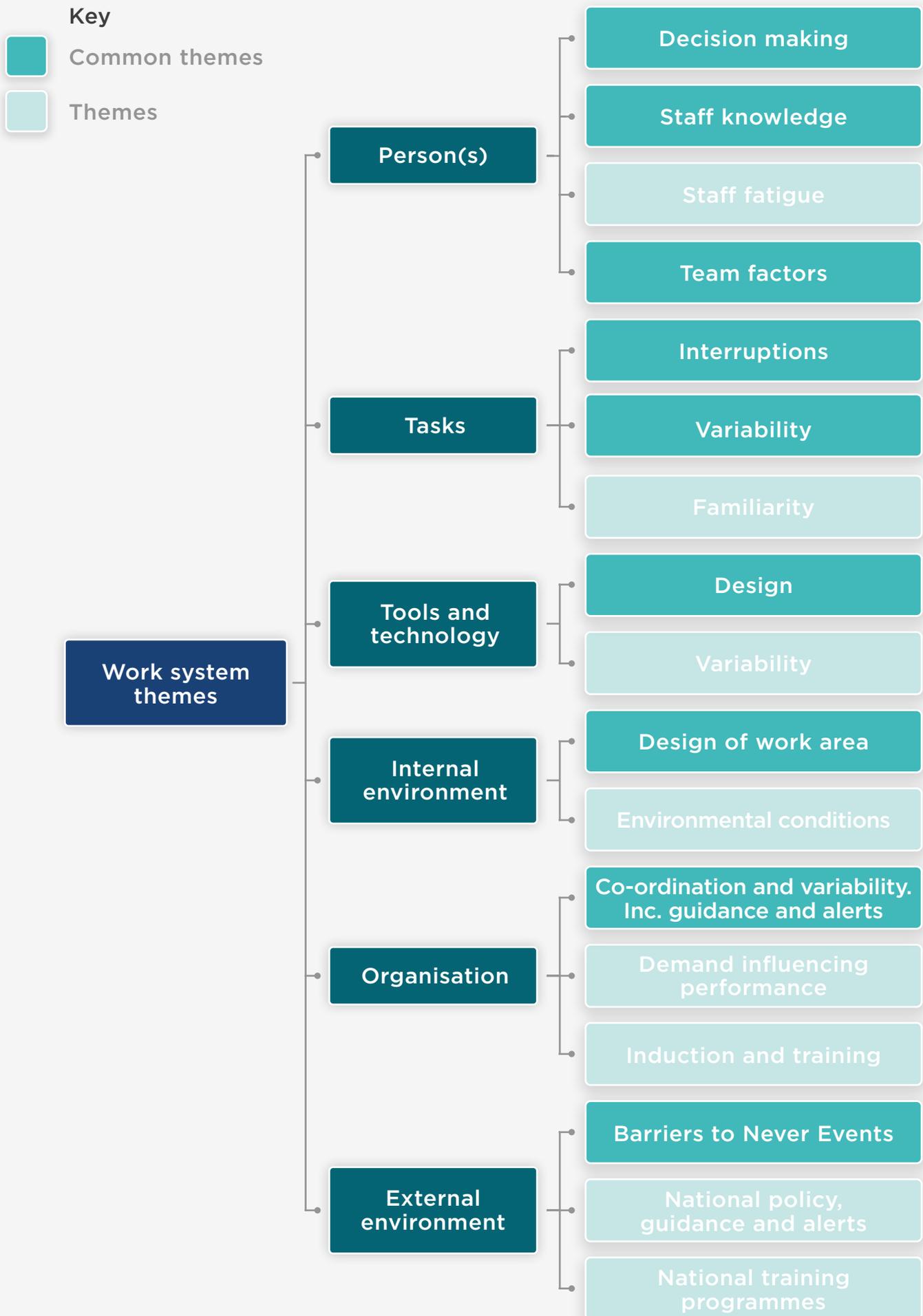
4 Themes from HSIB's investigations

The following section describes the work system factors identified as themes across HSIB's Never Event investigations. These are the factors that contributed to the process of interest for each Never Event. Appendix 8.3 describes each Never Event in this analysis in relation to its outcome versus goal, the process for which the work system factors were analysed, and the expected strong and systemic barriers for prevention of the Never Event.

This section is structured to explore the work system from the micro (person) to macro (external environment) level. This is as presented by the SEIPS literature and does not imply that any one category is more important than another. A summary of the themes is provided in figure 4.

There is overlap of certain themes across different parts of the work system with blurring of the boundaries between the parts. This demonstrates the complexity of the system and how different parts interact with each other. Quotes from published investigation reports are included.

Fig 4 Summary of work system themes found in HSIB's Never Event investigations



4.1 Person(s)

In the context of the HSIB investigations analysed for this report, 'persons' refers to the patient and their family, and those people working in the system. Factors individual to them, such as cognition and how they worked together as teams, were explored.

4.1.1 Staff factors

Decision making

Theme 1 (common): People used mental shortcuts in complex situations which were not always reliable

Across the investigations the complexity and time-pressured nature of the healthcare systems resulted in reliance on unconscious mental shortcuts during decision making. These mental shortcuts, called heuristics, are used in everyday decision making to help achieve a desired outcome. Heuristics are often used when the necessary information or cue to support the appropriate decision is not clearly or easily available. However, when the outcome of the decision is not the intended one, the heuristic may be judged as a bias (Tversky and Kahneman, 1974). There are many different types of bias (Benson, 2016) with the most common in healthcare including (Whelehan et al, 2020):

- availability bias: the tendency to think that examples of things that come readily to mind are more representative than is actually the case
- anchoring bias: the tendency to rely too heavily on a specific piece of information without considering other information with equal value
- confirmation bias: the tendency to process information by looking for or interpreting information that is consistent with one's existing belief.

Within the investigation reports, search satisfaction bias and inattentive blindness were also seen. Search satisfaction bias is the tendency to stop looking for information as soon as it is believed that the answer has been found.

'... the surgeon may have seen the information he and others usually focus on such as size, material, and expiry, and not seen or processed any other information, such as the manufacturer or packaging design.'
Implantation of wrong prostheses during joint replacement surgery (HSIB, 2018a).

Inattentive blindness is the inability to see something unexpected that is visible. This occurs when a person's attention is elsewhere, and it is difficult to attend to all the stimuli available.

‘The ST5 told the investigation this was a “failure in X-ray interpretation ... my mental model was consolidation”. They had mainly been focused on the right-hand side of the chest, and not where the NG tube was located (in the left lung).’
Placement of nasogastric tubes (HSIB, 2020c).

It is challenging for people to recognise the impact of heuristics. To reduce reliance on heuristics, environments and equipment must be designed to move thinking from the unconscious to the conscious (McLeod, 2015). Critical information such as the distinguishing features of implants must be clearly and easily available to support effective and timely decision making.

Staff knowledge

Theme 2 (common): Not all staff had adequate training to undertake the clinical task key to the Never Event

Investigations found that individual staff may not have had the knowledge required to undertake certain aspects of their work.

‘Neither doctor appeared to have understood the meaning of the purple syringe or the procedures for dispensing oral and IV medicines; therefore, they did not detect the multiple cues available.’
Inadvertent administration of an oral liquid medicine into a vein (HSIB, 2019d).

In some cases staff had knowledge of particular tasks but were unfamiliar with undertaking them in certain contexts.

‘The ST2 was not aware a tampon had been or could be used for a perineal repair ... The technique the ST2 was trained in for repairing an episiotomy or perineal tear did not require a tampon or swab to be left inside the vagina during the procedure.’
Detection of retained vaginal swabs and tampons following childbirth (HSIB, 2019b).

This lack of knowledge or unfamiliarity with tasks will have been influenced by other work system factors. The provision of training within organisations or externally is explored later.

Staff fatigue

Theme 3: Fatigue contributed to Never Events happening

Staff fatigue and its impact on safe working is well recognised and was found to be a potential contributor in the Never Events investigated by HSIB.

‘The incident occurred at a time when there was a greater risk of fatigue-related error. The investigation concluded that the 12-hour night shifts may have been a factor in this incident.’
Detection of retained vaginal swabs and tampons following childbirth (HSIB, 2019b).

Investigations also found that low levels of staff arousal may have created conditions for errors to occur. This is because of low levels of attention and is explored further under ‘task familiarity’ (see section 4.2.3).

4.1.2 Team factors

Theme 4 (common): Variation in team composition and unclear roles and responsibilities impaired team performance

A team is a group of staff working together to reach a specific treatment goal for the patient. The investigations found that challenges faced by teams included variability in the staff members who formed the

team day to day and during a specific case, poor morale, lack of practical training, and unclear roles and responsibilities.

Team cohesion, the collective spirit that develops from continued working together, was important and has the potential to support safety (Salyers et al, 2017).

‘The circulating nurse spoke about relationships and teamwork in the operating theatres. She described the theatre team as like a family.’
Implantation of wrong prostheses during joint replacement surgery (HSIB, 2018a).

Variability in healthcare team composition and therefore reduced cohesion is a risk as the NHS faces challenges with recruitment and redeployment.

While team cohesion was found to have potential advantages, the investigations also found that familiarity within a team could lead to reduced attention when undertaking tasks.

‘Several of the staff interviewed speculated whether the familiarity and trust between the operating team had led them to be complacent about checking.’
Implantation of wrong prostheses during joint replacement surgery (HSIB, 2018a).

4.1.3 Patient factors

Safety note: A patient's circumstances, requirements and comorbidities add further complexity to the work system

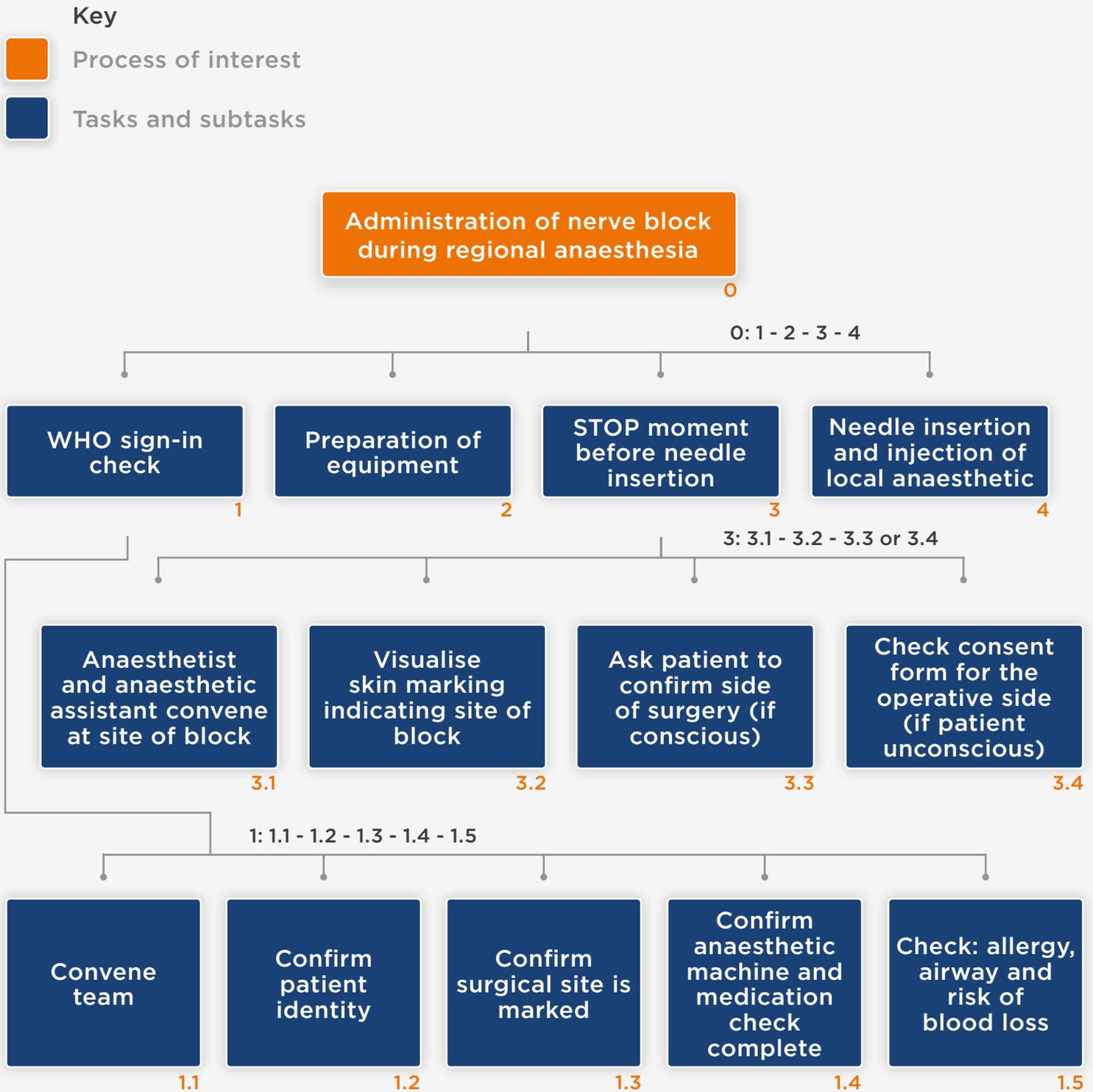
The exploration of patient factors in the investigations included consideration of aspects such as a patient's condition or behaviour and how these might have influenced other people within the work system. For example, had the patient who received the wrong site anaesthetic block been conscious, they might have highlighted the potential error.

While no specific patient theme was identified, the patients to whom the Never Events occurred had specific factors that complicated the management of their care.

4.2 Tasks

In the analysis of the investigations, a task was defined as a single piece of work being undertaken by a person. At least 30 different tasks were identified across the processes in the investigations. For example, figure 5 shows how the process of administering a nerve block during regional anaesthesia is made up of multiple tasks.

Fig 5 Example of the tasks that underpin the process of administration of a nerve block (RA-UK, 2015; National Patient Safety Agency, 2009b) using a hierarchical task analysis



4.2.1 Interruptions

Theme 5 (common):

Interruptions were common, resulting in unintentional or missed actions during tasks

Interruptions include intrusions and distractions (Jett and George, 2003). Some interruptions in the investigations may have been intentional and required, such as in an emergency. However, some occurred without the intent to interrupt the thought processes of staff.

Examples of interruptions included noise in the local environment, the need to find missing equipment, and staff entering and exiting rooms.

‘Multiple handovers of the swab and instrument trolley were conducted, and these handovers were also staggered as staff arrived at and left the theatre. It was likely the multiple handovers were a source of distraction and contributed to staff not detecting that a tampon had been used.’
Detection of retained vaginal swabs and tampons following childbirth (HSIB, 2019b).

Interruptions can result in positive outcomes, for example information sharing. They can also create conditions in which errors can occur. Interruptions will be specific to a context and may not be considered interruptions, for example background music.

Design of internal environments is important in making them more resilient to interruptions and this is explored later.

4.2.2 Variability

Theme 6 (common): Variability in task performance resulted from organisational influences and individual beliefs

In the Never Events investigated by HSIB, variability arose from staff having their own particular way of doing something. Examples included variation in the calling of patient names in clinics, counting of teeth prior to extraction and tasks undertaken prior to insertion of local anaesthetic blocks in the operating theatre.

‘There were recognised variations in practice between anaesthetists at the Trust on whether to use blue tape and when in the SBYB [stop before you block] process the blue tape was placed on the patient.’
Administering a wrong site nerve block (HSIB, 2018b).

The way tasks were undertaken also varied from how the task was described in standard operating procedures (SOPs). There was often a disconnect between how tasks are imagined in SOPs and how they are actually undertaken in practice (Hollnagel, 2016).

Clinical teams need to customise procedures to the individual

needs of the patient based on their clinical judgement. However, standardisation is beneficial for mitigating risks during key parts of a procedure where there are known risks, for example when selecting a prosthesis or checking for any retained swabs.

4.2.3 Familiarity

Theme 7: Overfamiliarity with a task resulted in low attention and can impair task performance

Within the investigations familiarity related to the quality of an individual's knowledge and experience of a task. While experience of a task is beneficial, familiar and highly routine tasks were undemanding which made sustained attention on the task a challenge.

'Low arousal [stimulation] can occur during monotonous or routine tasks which have limited mental stimulation for an individual. The instrumental delivery by forceps and perineal repair were perceived by theatre staff to be routine, easy tasks.' Detection of retained vaginal swabs and tampons following childbirth (HSIB, 2019b).

The Never Events investigated often involved tasks that staff undertook routinely. Familiarity with the tasks and the potential for low demand on the attention of those undertaking them will therefore have been common.

4.3 Tools and technology

In the context of the investigations, tools and technology refers to those pieces of hardware, software and documentation used to perform the tasks, for example syringes, electronic prescribing systems and guidelines. Multiple examples of tools and technology existed in the investigations. A common tool was the checklist. The investigations did not identify issues with the design of the checklists. This suggests that the context within which the checklist was being used was more of a factor. Checklists are explored further in figure 6.

Fig 6 The checklist

The healthcare checklist has become a ubiquitous tool, often implemented in response to incidents as an administrative barrier to prevent recurrence. Checklists offer assistance to staff when carrying out tasks by reducing the reliance on memory and attention. There is evidence that checklists do improve patient outcomes, and improve secondary outcomes such as communication, when they are used and followed thoroughly (Bergs et al, 2014; Thomassen et al, 2014). However, to be effective, the rationale for their use, their design and how they are implemented within complex sociotechnical systems need to be considered.

Checklists work best when they are used at critical moments and should be specific to the tasks being undertaken (Catchpole and Russ, 2015). They require motivated teams whose members are already familiar with the tasks and processes. They should lead to physical changes or actions at the critical points; they are not designed to be team-building tools. They also require a local culture that empowers staff to speak up when they have concerns and ensures they are listened to when they do so.

The nature of checklists evidenced in HSIB's investigations is that they act just before the potential point of an error occurring. For example the wrong patient may have been brought to theatre, but it is only identified at the point that the anaesthetic is about to begin. Greater emphasis needs to be placed on preventing situations such as this rather than relying on checklists to identify them. Checklists can also have consequences that increase the risk of incidents happening. They may increase automaticity - the mindless checking that results in missed steps (Catchpole and Russ, 2015). They also take time, make cases take longer and therefore put added pressure on staff. To be done thoroughly checklists need time and cannot be rushed. However, there is often a trade-off of thoroughness for efficiency.

Checklists are administrative barriers. They are not strong and systemic barriers and will therefore not always prevent Never Events.

4.3.1 Design

Theme 8 (common): The design of technology, including its usability, created risk and contributed to its misuse

Design refers to how the specifics of tools and technology, such as how they present information, made errors more likely to occur. While the investigations did not explore the intricacies of design issues, they did identify where design played a part in the outcomes. Examples of design issues included where devices could be misconnected.

'Air and oxygen flowmeters connect to tubing using the same connector design; this represents a further source of risk.'
Piped supply of medical air and oxygen (HSIB, 2019a).

Examples also included technology that did not support a user to perform a task safely and efficiently.

'The usability and experience of the use of pH strips among professionals was considered poor ...'
Placement of nasogastric tubes (HSIB, 2020c).

Where software had a role in the Never Event, issues with warning alarms were identified. Investigations found that warning alarms did not always support staff in identifying that they were about to undertake an incorrect action.

‘On this occasion no auto-population occurred as the selected lens corresponded to the incorrect eye; the software did not provide any warning to the user.’

Insertion of an incorrect intraocular lens (HSIB, 2018c).

‘Clinical staff at the observation sites and clinical subject matter experts commented on how a greater range of stock increases the risk of error.’

Implantation of wrong prostheses during joint replacement surgery (HSIB, 2018a).

The risk of error was increased where labels or packaging looked alike, or did not clearly provide critical information. This was seen with implants, prostheses and insulin pen devices. This demonstrates that even where standards for labelling exist, they may not be enough to ensure usability.

Even when standardised equipment or packaging was available, errors still occurred. For example, when similar packaging for oral and intravenous medicine preparations had been addressed, this was not an effective barrier to errors occurring.

‘... the safety barrier provided by the different packaging is undermined by dispensing both forms of midazolam into syringes, effectively ‘joining them up again’ at a conceptual level.’ Inadvertent administration of an oral liquid medicine into a vein (HSIB, 2019d).

Investigations found that standardisation of technology alone, while beneficial, was not enough to prevent incidents occurring.

4.3.2 Variability

Theme 9: Similar tools and technology with different designs and similar labelling introduced risks of mis-selection

Healthcare organisations often have similar tools and technology, regularly from different manufacturers. Examples in the investigations included different pH papers for testing of nasogastric aspirate to confirm nasogastric tube placement, and prostheses from different manufacturers that resulted in insertion of incompatible implants. Some variability is necessary, such as the different prostheses, while some variation is unnecessary and potentially dangerous, such as the two types of pH paper.

4.3.3 Availability

Safety note: When technology was not immediately available it resulted in workarounds

The absence of certain technology led to staff having to adapt. Such absences may be due to organisational factors associated with ordering and replenishment. Examples in the investigations included needle tops for insulin pen devices and oral/enteral syringes. Limited availability of technology further influenced variability in tasks.

‘The availability of oral/enteral syringes can be limited and therefore IV [intravenous] syringes may be [incorrectly] used instead. This erodes the distinction between the different functions of the two syringe types.’
Inadvertent administration of an oral liquid medicine into a vein (HSIB, 2019d).

4.4 Internal environment

In the context of the Never Events HSIB investigated, internal environment refers to the immediate physical workspace, for example an operating theatre or hospital ward, in which the persons were undertaking the tasks and using the tools and technology.

4.4.1 Design of work area

Theme 10 (common): Physical workplaces that have been designed without consideration of the people working within them created risks

The physical layout of the work areas where the Never Events occurred impacted on staff being able to see key information, particularly where that information may not be clearly displayed. Examples in investigations included viewing of patient identifiers on notes, visibility of white boards for counting equipment used in procedures, and the reading of prosthetic details on the packaging.

‘... the prostheses boxes presented for verification may be up to three metres from the scrub practitioner and surgeon. Therefore, the design of labels and the visibility of key information (size, side, expiry date) are of critical importance.’
Implantation of wrong prostheses during joint replacement surgery (HSIB, 2018a).

The position of similar tools and technology close together may also have led to mis-selection errors in the investigations.

‘In hospitals the terminal unit for oxygen is situated next to the terminal unit for air.’
Piped supply of medical air and oxygen (HSIB, 2019a).

Similar technologies were also seen in close proximity in store areas. This was only relevant in those Never Events where a piece of equipment had to be selected, but was not just seen with implants and prostheses.

‘... boxes of pH testing strips, both CE marked and non-CE marked, were kept together in a basket in the enteral feeding cupboard. The pH strips were very similar in appearance.’
Placement of nasogastric tubes (HSIB, 2020c).

4.4.2 Environmental conditions

Theme 11: When undertaking tasks, the work environment impacted on a person’s performance

Environments can be noisy and cause distraction, as discussed under ‘tasks’ (see section 4.2.1). In the incidents investigated some noise could not be controlled, but other sources could have been.

‘Noise comes from other sources too – conversations between staff, electric or air-powered surgical equipment, hammers, suction apparatus, anaesthetic monitors, and alarms – all of which may impede hearing. Furthermore, there is often music playing in theatres.’
Implantation of wrong prostheses during joint replacement surgery (HSIB, 2018a).

A further example identified how lighting in the environment could create unsafe conditions. Limited lighting made tasks more difficult for staff to complete safely.

‘[The investigation] observed one nurse moving around their patient’s bed space, holding a pH testing strip in an area with greater light levels to accurately interpret the testing strip.’
Placement of nasogastric tubes (HSIB, 2020c).

4.4.3 Signage

Safety note: Labels, signs and posters were not effective barriers to preventing incidents

Signs and posters are often used in clinical practice to convey safety messages. These were not always found to be effective in preventing the Never Events occurring. An example from an investigation was where a sign was being used to prevent mixing up of different oral and intravenous preparations of midazolam.

‘The sign was misleading and inaccurate; the addition of the handwritten ‘IV’ suggested that only intravenous preparations of the drug were kept in the cupboard, whereas oral midazolam was stored in a bottle in addition to ampoules of IV midazolam. It also did not correlate with the strengths available ...’
Inadvertent administration of an oral liquid medicine into a vein (HSIB, 2019d).

4.5 Organisation

Organisation refers to the conditions created by a particular healthcare institution, for example a hospital, to structure its processes. In the investigations this included planning and resourcing. It also included considerations around cultural norms and values.

4.5.1 Co-ordination and variability

Theme 12 (common): Local responses to national policy, guidance and alerts varied, were sometimes limited and created risks

National expectations in relation to the processes of interest in the investigations were often disseminated via policy, guidance and alerts. There were examples of limited or uncoordinated changes locally in response to national expectations. Investigations found that some of these limited responses were potentially a result of ambiguity in the national expectations. This is explored further in 'external environment' (see section 4.6.2).

'Some trusts interpreted the three barriers as options from which they could select those they felt were required locally.' Piped supply of medical air and oxygen (HSIB, 2019a).

Examples were also found where local implementation had not involved those working within the relevant clinical area. It is recognised as good practice to acknowledge 'work as done' when implementing new ways of working (Chartered Institute of Ergonomics and Human Factors, 2020a).

'The investigation observed organisations where a cataract surgery version of the WHOSSC [surgical checklist] had been introduced. Although staff had been made aware of the checklist, there had been no specific training to support its introduction.'

Insertion of an incorrect intraocular lens (HSIB, 2018c).

Variability was identified as a subtheme within co-ordination and planning. This was similar to the variability explored under 'tasks' (see section 4.2), but from the perspective of the organisation work system. Variability arose when there were documented standard operating procedures (SOPs) to follow for a task, but those SOPs varied depending on location despite the task being the same.

'... the Trust had SOPs for cataract surgery, but the SOPs were different for the two sites.' Insertion of an incorrect intraocular lens (HSIB, 2018c).

Variability also arose from staff using workarounds. Workarounds circumvent or temporarily 'fix' perceived workflow hindrances to meet a goal or to achieve it more readily (Debono et al, 2013). Workarounds occurred when staff took their own, alternative steps in attempts to overcome problems and to improve efficiency.

'The HSIB investigation team observed occasions where nurses were trying to save time by preparing medications for multiple patients.'

Inadvertent administration of an oral liquid medicine into a vein (HSIB, 2019d).

In some contexts workarounds may be perceived as improvisations to overcome a problem to successfully implement care. In others they may be counterproductive (Debono et al, 2013). Workarounds will often result from poor design, for example of the usability of electronic systems (Fraczkowski et al, 2020).

4.5.2 Demand influencing performance

Theme 13: Actual and perceived pressure to meet performance targets resulted in trade-offs with safety

Investigations identified how patient flow and the quest to meet performance targets created pressure on staff to work quickly.

This pressure was both actual and perceived. This potentially resulted in trade-offs between thoroughness and efficiency.

'One scrub nurse described the theatre as "hectic" when she arrived for her day shift. She commented there were a lot of conversations about the next task and a pressure to quickly turn the room around.'

Detection of retained vaginal swabs and tampons following childbirth (HSIB, 2019b).

There was limited evidence of staff being asked to do more work than was doable. Rather there were other factors that put them under pressure, such as availability of patient notes or rooms to assess patients, availability of key staff and access to technology.

'... [there was] no computer mouse available for the theatre computer. This meant the patient's surgical records could not be completed.'

Insertion of an incorrect intraocular lens (HSIB, 2018c).

4.5.3 Induction and training

Theme 14: Staff were not prepared for their roles as induction and training did not address safety-critical requirements

As explored under 'persons', 'external environment' and in this section, SEIPS revealed multiple

factors that resulted in staff not having appropriate knowledge or training. Within the organisation work system this included the contribution of mandatory training and induction to staff knowledge. Investigation findings included staff not being aware of, or not having been trained in, the use of equipment that was meant to act as a barrier to a Never Event.

‘The investigation team spoke to undergraduate [students] and postgraduate doctors who commented that they were unfamiliar with oral ‘purple’ syringes and are unaware of the rationale for their introduction.’ Inadvertent administration of an oral liquid medicine into a vein (HSIB, 2019d).

4.5.4 Resource

Safety note: Varied availability of staff and technology created further challenges

In the context of the investigations, resourcing refers to stocks, supplies and the availability of staff. Issues were identified with varied availability of stocks and supplies, and their procurement.

‘... its critical care unit was using both non-CE marked and CE marked pH testing strips. The non-CE marked pH testing strips were not specifically designed for gastric sample testing. The use of two different types of pH strip could have been a possible cause of an incorrect pH reading.’ Placement of nasogastric tubes (HSIB, 2020c).

Only one investigation identified low staffing levels as a resource issue. In this particular case the low staffing levels resulted in low morale. The investigation commented on how agency and locum staff introduced variability as they were not used to working in a specific environment.

4.5.5 Culture

Safety note: The different values and norms between professional groups potentially had a role in Never Events occurring

The culture of professional groups was explored by some investigation reports, commenting on how different healthcare professions had their own beliefs and practices, some of which might have undermined safety.

‘Interview evidence suggested that it was accepted practice among teams for a surgeon to leave theatre before the end of a procedure. A scrub nurse said that in general there were occasions when those who were present for the procedure were not all present for the WHO sign out.’

Detection of retained vaginal swabs and tampons following childbirth (HSIB, 2019b).

4.6 External environment

External environment relates to factors from outside a healthcare institution, including policy, economical and societal factors.

4.6.1 Barriers to Never Events

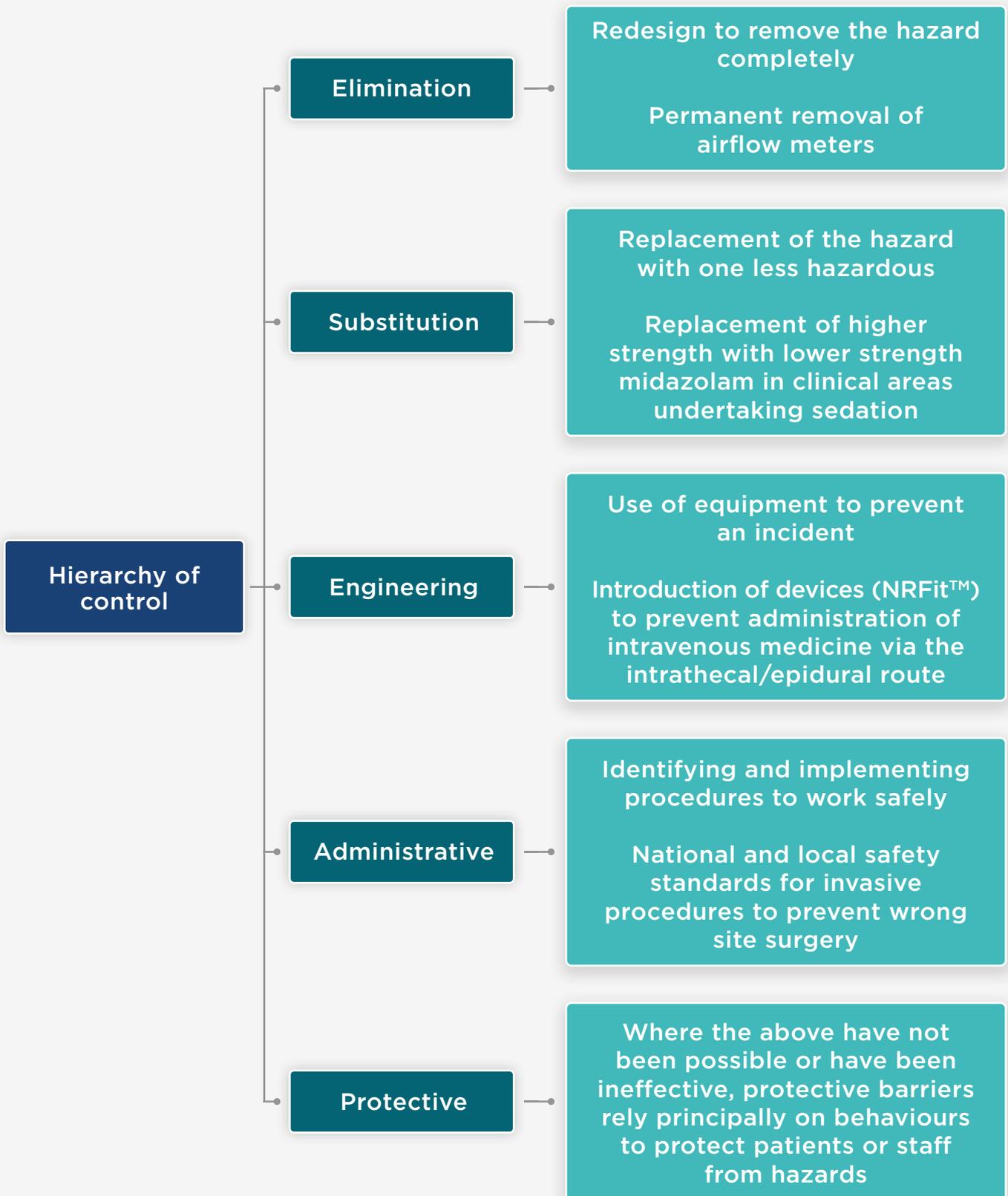
Theme 15 (common): Barriers to the Never Events explored by HSIB were ineffective in preventing the Never Events

The hierarchy of control (figure 7) helps to explore the barriers (the controls) expected to eliminate Never Events (adapted from Health and Safety Executive, 2011). The barriers to the investigated Never Events were either limited in their effectiveness or did not exist. They commonly acted immediately prior to the Never Event occurring, which limited their effectiveness, and relied on human behaviour. Common barriers were administrative in nature; examples included the use of a checklist, as explored in figure 6, or second-checking of a task.

‘During the observational visits, two-person checking was rarely seen to be independent. On one occasion, checks were done by three separate people. The continuous presence of the second checker was not always possible ...’

Inadvertent administration of an oral liquid medicine into a vein (HSIB, 2019d).

Fig 7 Hierarchy of controls (adapted from Health and Safety Executive, 2011) applied to Never Events



In some of the investigations of Never Events there were examples of engineering barriers developed to prevent their occurrence. While these barriers related to design and could be considered under tools and technology, they are included here as part of the exploration of barriers. Examples included the introduction of syringes for measurement and administration of liquid medicines via oral and enteral routes; barriers to prevent inadvertent connection of oxygen tubing to air flowmeters such as capping wall outlets; and CE-marked pH paper for confirmation of correct nasogastric tube placement. However, despite these barriers the Never Events still occurred as a result of other contributory factors.

It may not always be possible to implement elimination or substitution barriers to a particular hazard. As evidenced in this report, barriers at the engineering level of the hierarchy of controls are not always effective. Barriers at the administrative and protective levels are not strong and systemic. However these may be the only barriers that are possible. Where a hazard cannot be eliminated a layered approach with barriers is likely to be more effective.

‘Despite the national initiatives previously implemented, the repeated incidents of wrong route error of oral medication into a vein would suggest that there are opportunities for improvement. The case has highlighted an opportunity for wider system learning in relation to safe medications practice.’
Inadvertent administration of an oral liquid medicine into a vein (HSIB, 2019d).

4.6.2 National policy, guidance and alerts

Theme 16: National policy and guidance considering safety-critical elements of processes were unavailable, lacked detail or allowed for too much local variation

A wealth of national policy and guidance existed to support introduction of barriers to the Never Events investigated. There was particular reliance on policies supporting the use of checklist, and alerts. These focused on directing human behaviour as a preventative barrier to Never Events.

‘... national guidance was mainly focused on the ‘change the way people work’ levels, which are less likely to be effective and provide weaker mitigation.’
Detection of retained vaginal swabs and tampons following childbirth (HSIB, 2019b).

Other investigations found further examples of limitations relating to national implementation and subsequent evaluation of interventions. These included limitations with the implementation of patient safety alerts, and the evaluation of the effectiveness of the actions taken in organisations.

‘There has been no national assessment of the effectiveness of the patient safety alerts regarding the introduction of oral syringes.’ Inadvertent administration of an oral liquid medicine into a vein (HSIB, 2019d).

Multiple investigations identified a lack of or limited directions for how to carry out certain critical tasks. This was particularly noted in association with checking processes and again added to variability at a local level.

‘Both the NICE [National Institute for Health and Care Excellence] and UKOA [UK Ophthalmology Alliance] documents focus on checks to confirm the information on the lens box in theatre matches the selection made, rather than if the correct IOL has been accurately selected.’ Insertion of an incorrect intraocular lens (HSIB, 2018c).

4.6.3 National training programmes

Theme 17: A lack of national training programmes prevented organisations from ensuring their staff were competent for the work expected of them

The absence of certain national, competency-based training programmes was identified in investigations. This influenced staff knowledge when undertaking tasks.

‘No other staff member had received formal training in ophthalmology. A national programme for training theatre staff in ophthalmology does not exist.’

Insertion of an incorrect intraocular lens (HSIB, 2018c).

The recommendations made by many serious incident investigations undertaken in institutions focus on staff training or retraining. However, there may not always be appropriate national training available or national direction to guide local training.

4.6.4 Safety culture in the NHS

Safety note: The NHS allowed organisational autonomy, creating variability without the ability to share best practice

The analysis of the investigations suggested that some national directions issued by the NHS allowed individual healthcare organisations to interpret and prioritise the directions, resulting in local variation. This exists alongside challenges with the wide sharing of best practice.

‘An overall observation from analysis of the process for medicines safety is that the structure and culture of the NHS make it difficult to share best practice. It appears hard to communicate, implement or monitor the effects of systemic improvement.’

Inadvertent administration of an oral liquid medicine into a vein (HSIB, 2019d).

Limited sharing creates difficulty in migrating towards best practice as there is limited dissemination of effective solutions which may often be known to localities only.

4.7 Summary

The analysis of the HSIB Never Event investigations identified 17 work system themes that contributed to the occurrence

of the Never Events. Common themes across the investigations related to: decision making, staff knowledge, team composition and roles, interruptions, variability in task performance, design of technology, design of workplaces, co-ordination and variability in organisational responses, and ineffective barriers to Never Events. The theme of variability was seen across the task, technology and organisation work systems.

The number of themes found in this analysis helps to describe the multitude of work system factors that contributed to the Never Events. There were multiple factors for each Never Event. Figure 8 demonstrates how interconnected and complex the healthcare system is.

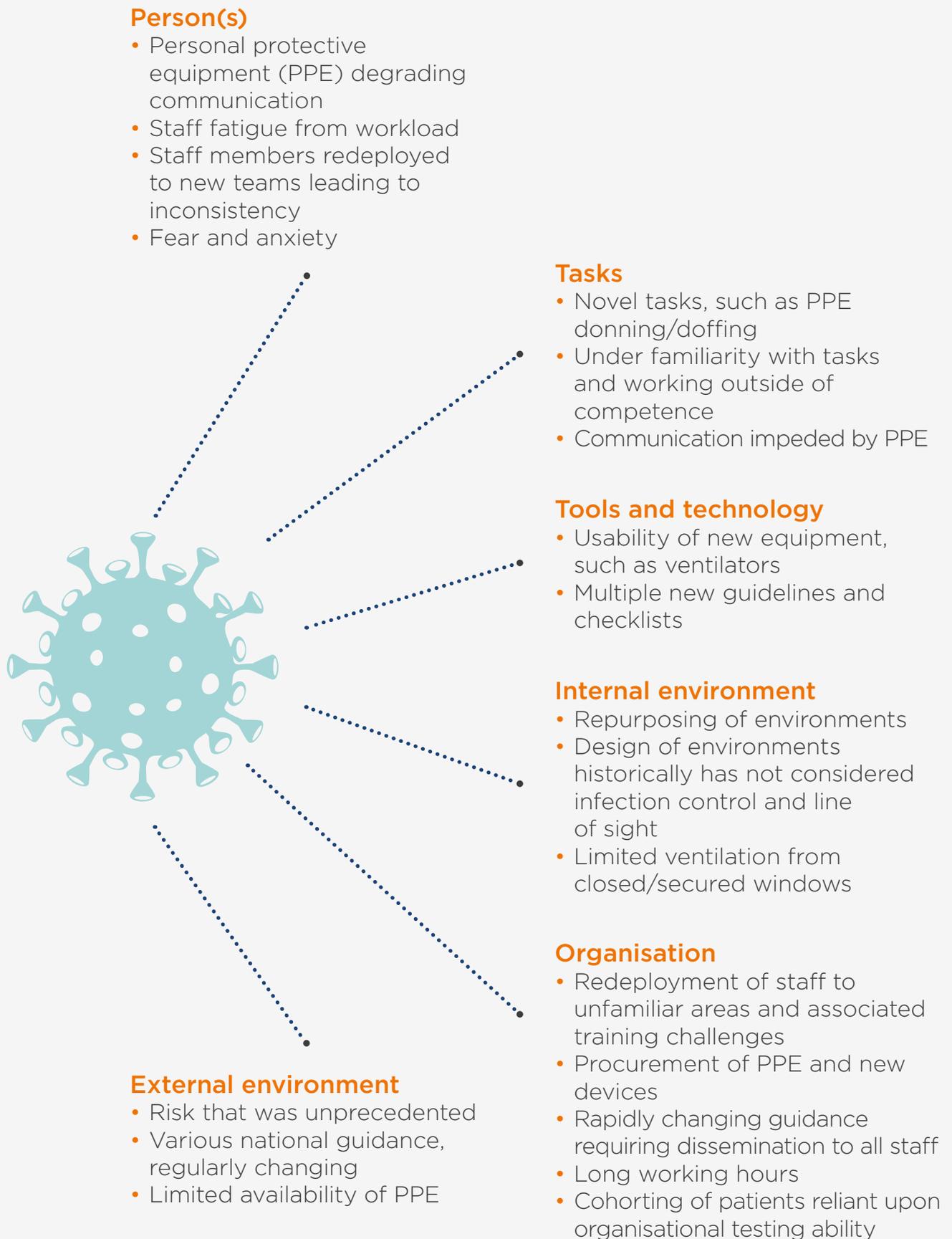
Fig 8 Work system themes identified for each of HSIB's investigations



By understanding the work system themes described in this national learning report, there is potential to make improvements to help reduce the risk of Never Events. However, the themes also demonstrate the challenges faced when trying to ensure these incidents never happen.

These HSIB investigations were undertaken prior to the COVID-19 pandemic. HSIB has heard of Never Events occurring as a result of factors relating to COVID-19, including when organisations have attempted to revert back to normal care delivery. The influence of COVID-19 cannot be underestimated and is briefly explored in figure 9.

Fig 9 Examples of the effects of COVID-19 on the work system



5 Exploring HSIB's findings

5.1 Comparison with previous work

The findings described in this national learning report are based on a structured qualitative analysis of 10 independent investigations carried out by HSIB. This report identified 17 work system themes that contributed to the occurrence of the Never Events. This was a novel and rigorous method for clearly identifying what contributes to Never Events and explains why the barriers that are expected to stop them from occurring are not strong and systemic.

Putting the work system factors identified into context, there are similarities with other reviews that have been published on this subject. Examples from other institutions include:

- NHS England's report of the Never Events Taskforce (2014), which highlighted a lack of standardisation/excess variability and the need to standardise, educate and harmonise.
- The Care Quality Commission's 'Opening the door to change' report (2018), which made a formal recommendation for bodies to look at what governance processes can and should be standardised, as well as recommending a more standardised approach to alerts and safety guidance.

- NHS Improvement's 'Learning from surgical Never Events' report (2018c), which reviewed 38 cases and identified themes around standardisation of practices such as surgical marking and guidelines, resolving time pressures, reducing distractions and reducing variation in selection and storage of implants.

All of these institutions have identified a need for 'harmonisation' and for the prioritisation of patient safety throughout - as the Care Quality Commission (2018) states, 'embedding an effective safety culture at every level from senior leadership to the frontline'.

5.2 The nature of Never Events

Through this analysis of Never Events it is evident that there are different barriers or controls (see the hierarchy of controls, figure 7), of different strengths, for the different Never Events. There are some barriers which help engineer out a risk, such as limiting the opening of windows to prevent falls. Other barriers eliminate or substitute a risk, such as not allowing high-strength potassium solutions in a clinical area. These types of Never Event, where an effective barrier exists, often involve processes where the particular risk can be managed. This will potentially be successful in reducing future unintended outcomes. However, it can also lead to unintended consequences

and trade-offs, for example locked windows preventing the circulation of fresh air.

In contrast there are some Never Events where barriers or controls, for example checklists, are principally based on human interactions and behaviours. These are administrative and/or behavioural barriers. These Never Events involve processes where the inherent complexity of healthcare and the practicalities of its delivery may not allow strong and systemic barriers to be put in place to remove the risk.

HSIB has investigated seven types of Never Events for this report. The eight Never Events not investigated account for around 4% of the Never Events that occur (NHS England and NHS Improvement, n.d.). This implies that the barriers for those are stronger, such as restrictions on windows and limiting access to high-strength potassium.

HSIB has instead investigated the more common types of Never Events. Given the multiple work system themes described in this report that contributed to the Never Events, they occurred within complex situations and the barriers designed to prevent them were unable to address that complexity. The Care Quality Commission (2018) came to a similar conclusion and recommended that NHS

Improvement should review the Never Events framework to take this into account.

In 2015 the language in the Never Events framework changed from incidents that were 'largely preventable' to 'wholly preventable' (NHS England, 2015c). They are described to be preventable because of strong and systemic barriers. Those barriers are described in the 2018 framework as:

- 'physical barriers'
- 'time and place barriers'
- 'systems of double or triple checking only where supported by visual or computerised warnings, standardised procedures, or memory/communication aids.'

The third barrier relies on humans and the Never Event framework acknowledges that **'as all human action is vulnerable to human error ... processes that rely solely on one staff member checking the actions of another or referring to written policies are not strong barriers'** (NHS Improvement, 2018a). Safety science would cast doubt on whether any human process can provide a strong and systemic barrier, even when supported with triple checking or other aids.

HSIB's conclusion is that for many Never Events, including all those investigated for this report, there are no strong and systemic barriers. There is evidence presented that barriers involving human processes which exist with variable if any technical support are weak. This report also presents evidence that barriers which are thought to be more effective, such as some physical/technological barriers, are also unreliable. Some of these barriers can be worked around or do not function, for example decanting oral medication from an oral/enteral syringe into an intravenous syringe when the original syringe did not connect to an intravenous line.

The fact that the Never Events investigated by HSIB continue to occur has consequences. The discordant language between the use of the word 'never' and the fact that the available barriers are not effective enough to prevent all these events from occurring has implications for patients, staff, organisations and others involved in these incidents and associated processes, such as coroners. The word 'never' can imply that someone has done something wrong and implies blame and liability. For patients this can suggest they may have been harmed by negligence. For staff it can lead to a feeling that they are to blame and can cause

moral injury (NHS Leadership Academy, 2020). For some investigators it can make it more difficult to approach these incidents objectively and lead to assumptions that there must be someone at fault. This will not support a safety culture where investigations are done without a presumption of blame or liability.

Never Events also have a profound impact on organisations. Historically there have been financial penalties for the occurrence of Never Events and they also result in organisations being placed under significant scrutiny. While scrutiny is important to ensure ongoing improvements in the quality of care, the focus on Never Events may be misplaced. Never Events make up a small proportion of the total incidents across the NHS and more harm occurs from incidents that are not Never Events. This harm is exemplified in multiple other investigations undertaken by HSIB.

5.3 Moving away from Never Events

All the Never Events included in this report do not have strong and systemic barriers and do not meet the current definition of a Never Event. Therefore, they should be removed from any Never Events list.

HSIB makes the following safety recommendation

Safety recommendation R/2021/111:

It is recommended that NHS England and NHS Improvement revises the Never Events list to remove events, such as those presented in this national learning report, that do not have strong and systemic safety barriers.

Despite this safety recommendation it is still important to recognise the significance of these incidents and learn from them. They act as indicators of safety and the Care Quality Commission has concentrated on how hospitals have responded to these incidents as a marker of their prioritisation of a safety culture. Patients who have been close to being harmed, or actually physically or psychologically harmed, may want to know that there has been appropriate scrutiny, investigation and learning. Staff involved may also want to see learning to help develop themselves, improve the system and for their own support following incidents. These incidents therefore remain important and should be investigated.

In HSIB's analysis, 17 themes were found that contributed to a work system that allowed these Never Events to happen. Given that finding, it is difficult to see how many of these Never Events could ever have strong

and systemic barriers. However, for some of the Never Events in this report and some other patient safety incidents, it may be possible to develop stronger and systemic barriers. Potential examples could include ways of removing piped air from clinical environments (Healthcare Safety Investigation Branch, 2019a), scanning prostheses before insertion (Healthcare Safety Investigation Branch, 2018a), and tagging swabs in a way that makes them easier to identify and prevents them from being retained (Healthcare Safety Investigation Branch, 2019b). The promotion of strong and systemic barriers to incidents, which was an intention of the Never Event framework, is something that should continue to be supported. HSIB therefore makes the following safety recommendation.

HSIB makes the following safety recommendation

Safety recommendation R/2021/112:

It is recommended that NHS England and NHS Improvement develops and commissions programmes of work to find strong and systemic safety barriers for specific incidents where barriers are felt to be possible but are not currently available.

5.4 A focus on variation

A consistent theme throughout HSIB's Never Event investigations was that of variation. Variation was seen within the task, tools and technology, and organisation

work systems. Of particular relevance was the variation seen in the performance of tasks and processes associated with invasive procedures.

To prevent Never Events associated with invasive procedures, such as wrong site surgery, the World Health Organization (WHO) Surgical Safety Checklist was introduced in 2010. However, a marked decrease in the associated Never Events was not seen and so the National Safety Standards for Invasive Procedures (NatSSIPs) were launched in 2015 (NHS England, 2015a). The intention of NatSSIPs was for individual organisations to develop their own local standards (Local Safety Standards for Invasive Procedures (LocSSIPs)), in harmony with the national standards. The aim was for standardisation of clinical practice throughout the NHS.

As this national learning report evidences, NatSSIPs have not led to as much standardisation as was intended. The development of more detailed individualised LocSSIPs has allowed variation in approaches to generic procedures across the NHS. This is further compounded by the fact that in 2018 only 67% of institutions that responded to a survey had developed LocSSIPs (NHS Improvement, 2018e).

HSIB recognises that standardisation is not always a solution and can lead to potential problems such as the assumption that variation is undesirable (Wears, 2015). Variation is necessary in certain circumstances that require staff to adapt their approach, reacting and responding to what they find using their own clinical judgement. Variation may also be clinically driven, such as the need for varying sizes of prostheses. However, this variation can be exacerbated by the availability of prostheses from multiple different manufacturers which can cause confusion and unintended outcomes. Variation may also be unnecessary, such as the presence of two brands of pH paper with different colours and qualities, which can also contribute to unintended outcomes.

The standardised components of tasks and processes should include those that are fundamental to minimising the risk of incidents. For example, during surgery the identification of the patient, confirmation of any prostheses, site of procedure, and counting of swabs and instruments should be standardised to reduce poor outcomes. This standardisation should not just be a policy or procedure – ‘work as imagined’ – but result in standardised practice as implemented in the workplace – ‘work as done’.

HSIB makes the following safety recommendation, acknowledging that this will not prevent all incidents. Rather its aim is to attempt to mitigate the risk of incidents occurring.

HSIB makes the following safety recommendation

Safety recommendation R/2021/113:

It is recommended that the Centre for Perioperative Care reviews and revises the National Safety Standards for Invasive Procedures (NatSSIPs) policy to increase standardisation of safety-critical steps that are common across all procedures.

5.5 SEIPS as a method of investigation

The Chartered Institute of Ergonomics and Human Factors (CIEHF) recognises that to analyse complex sociotechnical systems, appropriate methods are required to explore the interactions between factors that contribute to incidents (Chartered Institute of Ergonomics and Human Factors, 2020b). The CIEHF gives SEIPS as one example of an appropriate method.

HSIB's experience of using SEIPS to explore the work system factors that contributed to Never Events was positive. It supported exploration in a structured way that brought attention to all aspects of the work system equally and without blame.

HSIB makes the following safety observation

Safety observation O/2021/093:

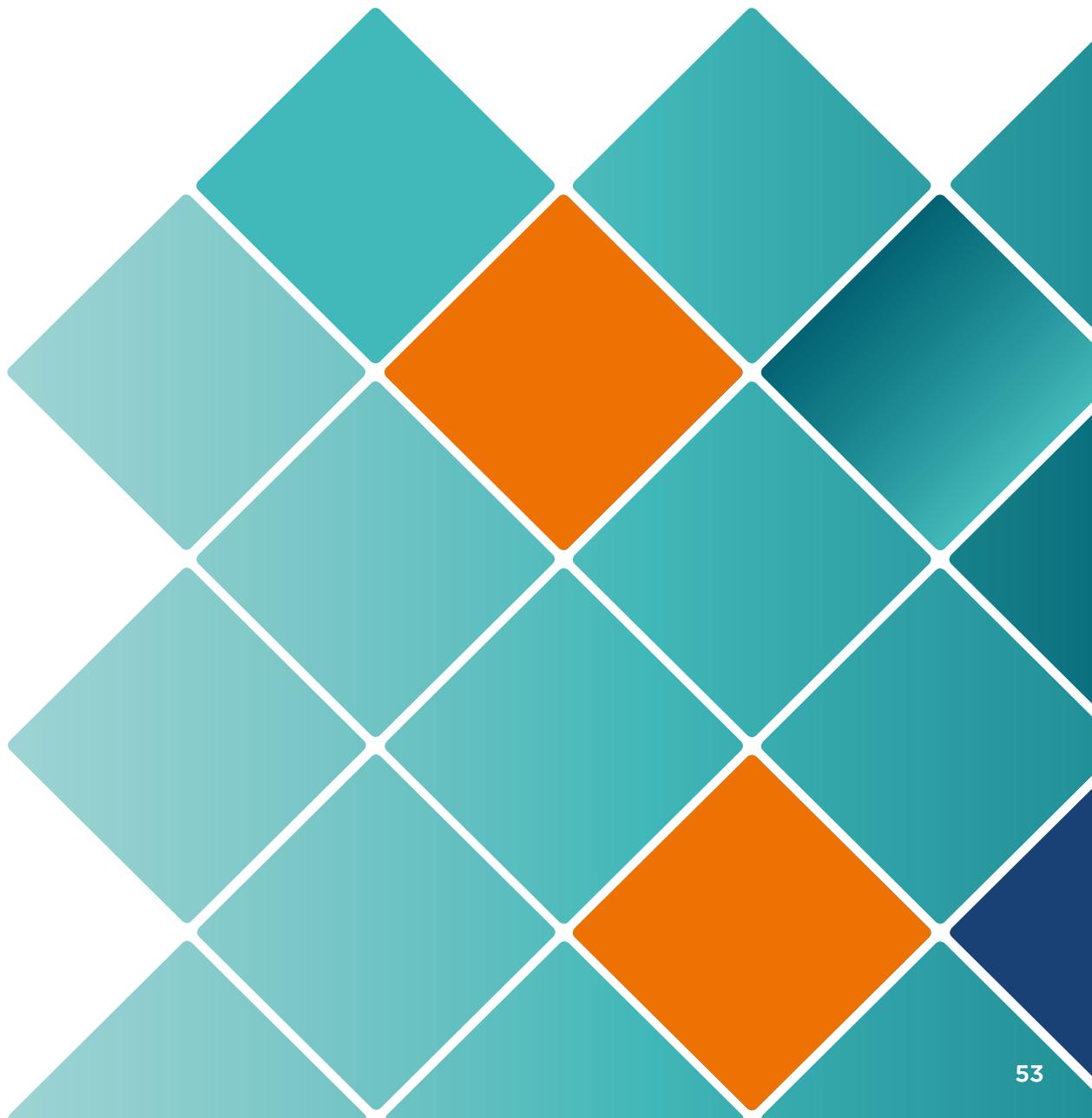
It would be beneficial if significant safety events, such as those presented in this national learning report, continue to be reported and investigated by NHS organisations without apportioning blame or liability, using a recognised systems-based approach such as the Systems Engineering Initiative for Patient Safety (SEIPS) as used in this report.

5.6 Limitations

The findings of this national learning report specifically relate to the 10 Never Events investigated by HSIB. These are single incidents in individual units and the findings will not be representative of all the work system factors that can contribute to Never Events. However, the themes in this report are similar to those found by other institutions.

The analysis in this report has focused on the processes just before the Never Events occurred. This is because the barriers developed to prevent Never Events often act at these points. This in itself is a limitation of those barriers. There may be processes which are more distanced from the Never Event that have the potential to provide stronger barriers which were not considered here.

Finally, HSIB's investigations into Never Events have generally taken a Safety I approach, which focuses on what causes things to go wrong. Looking at work systems from a Safety II approach – that is, analysing ways in which they successfully deliver positive outcomes – may provide further learning and contribute to this area.



6 Conclusions and safety recommendations

6.1 Conclusions

To date HSIB has carried out 10 investigations into seven of the more common Never Events. Using the Systems Engineering Initiative for Patient Safety (SEIPS) this national learning report has identified 17 work system themes that contributed to the Never Events investigated. Those themes originated from all parts of the work system and demonstrate the complexity of the systems within which the Never Events occurred.

HSIB has challenged the definition of the incidents investigated as Never Events. None of the incidents had evidence of barriers that were strong and systemic, and that could have prevented the incidents from happening. Thinking about these incidents differently will potentially support increased reporting and learning through a change in safety culture.

HSIB has also challenged the degree of autonomy given to institutions when developing processes locally in line with National Safety Standards for Invasive Procedures (NatSSIPs). While some variation is required to adapt to changes and challenges in clinical care, certain components of processes could be standardised nationally. These components include those safety-critical checks

that must be undertaken effectively to minimise the risk of incidents such as wrong site surgery.

HSIB's findings in this national learning report should not be seen as a challenge to the significance of these incidents and the learning which still needs to be taken from them. While the incidents investigated by HSIB do not fit the definition of Never Events, they still remain incidents that can have profound effects on patients and staff. The Never Events policy and framework has provided a focus for improvement. It has supported some barriers being developed and will have prevented some Never Events occurring.

Beyond the safety recommendations in this report, the work system themes identified provide further intelligence to inform future HSIB investigations and analysis. It may not be possible to ensure the incidents never happen, but preventative actions should still be explored to mitigate their future risk.

6.2 Safety recommendations

HSIB makes the following safety recommendations

Safety recommendation R/2021/111:

It is recommended that NHS England and NHS Improvement revises the Never Events list to remove events, such as those presented in this national learning report, that do not have strong and systemic safety barriers.

Safety recommendation R/2021/112:

It is recommended that NHS England and NHS Improvement develops and commissions programmes of work to find strong and systemic safety barriers for specific incidents where barriers are felt to be possible but are not currently available.

Safety recommendation R/2021/113:

It is recommended that the Centre for Perioperative Care reviews and revises the National Safety Standards for Invasive Procedures (NatSSIPs) policy to increase standardisation of safety-critical steps that are common across all procedures.

HSIB makes the following safety observation**Safety observation O/2021/093:**

It would be beneficial if significant safety events, such as those presented in this national learning report, continue to be reported and investigated by NHS organisations without apportioning blame or liability, using a recognised systems-based approach such as the Systems Engineering Initiative for Patient Safety (SEIPS) as used in this report.

7 Glossary

Term	Definition/description
Barriers	Those parts of a system that prevent deviations from the expected processes occurring (Ruijter and Guldenmund, 2016).
Culture	The set of values and priorities placed on safety shared by a group or organisation. Sometimes referred to as ‘The way we do things round here’ (Clinical Human Factors Group, 2018).
Heuristics	A simple, efficient, mental shortcut based on innate learning or past experience, such as following a ‘rule of thumb’. It allows people to solve problems and make judgements quickly and efficiently (Clinical Human Factors Group, 2018).
Hierarchy of control	A hierarchical representation of barriers or controls to protect people from particular hazards and risks. Those at the top of the hierarchy are more effective and protective. The hierarchy in descending order is: elimination, substitution, engineering, administrative and protective. See figure 7.
Investigation	HSIB conducts independent investigations of patient safety concerns in NHS-funded care across England. HSIB’s investigations identify the contributory factors that have led to harm or have the potential to cause harm to patients. Safety recommendations are then made improve healthcare systems and processes in order to reduce risk and improve safety (Healthcare Safety Investigation Branch, n.d).
National Safety Standards for Invasive Procedures (NatSSIPs)	National standards to support the development of local safety standards to standardise processes for patients undergoing invasive procedures (NHS England, 2015a).
Never Event	Patient safety incidents that are wholly preventable where guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and have been implemented by healthcare providers (NHS Improvement, 2018a).
Process	A series of tasks undertaken by people using various technologies in physical and organisational environments (Carayon et al, 2020).
Qualitative analysis	Analysis of generally non-numerical data from sources such as interviews, focus groups, documents and observations.

Term	Definition/description
Safety I	The safety principle that focuses on trying to make sure things do not go wrong to minimise the number of incidents (Hollnagel et al, 2015).
Safety II	The safety principle that focuses on success under varying conditions by making sure things go right rather than preventing them from going wrong (Hollnagel et al, 2015).
SEIPS	The Systems Engineering Initiative for Patient Safety. A framework for integrating human factors in healthcare quality and patient safety improvement (Carayon et al, 2020).
System and sociotechnical system	A system is a set of interdependent elements that interact to achieve a common aim. These may be human, processes or procedures, technology, equipment, or policy and regulatory requirements (Clinical Human Factors Group, 2018). Sociotechnical systems refer to the interactions between people and technology in the surrounding work areas.
Thematic analysis	A method for identifying, analysing and reporting patterns (themes) within data (Braun and Clarke, 2006).
Work-as-imagined versus work-as-done	Work-as-imagined is what is believed to happen or should happen; it becomes the basis for design and training. Work-as-done is what actually occurs in practice (Hollnagel, 2016).
Work system	The different elements within a system and their interactions. In SEIPS these include persons, tasks, tools and technology, physical environment, organisational conditions and the external environment (Carayon et al, 2020).

8 Appendices

8.1 Description of HSIB's Never Event investigations

8.1.1 Implantation of wrong prostheses during joint replacement surgery (Healthcare Safety Investigation Branch, 2018a).

- Never Event: wrong implant/prosthesis.
- National safety requirements: World Health Organization (WHO) surgical safety checklist (National Patient Safety Agency, 2009b), National Safety Standards for Invasive Procedures and Local Safety Standards for Invasive Procedures (NatSSIPs/ LocSSIPs) (NHS England, 2015a).
- During a hip replacement, four prostheses were required to create the patient's new hip joint. The operating theatre team collected the first and second prostheses from the stock room, checked they were correct and inserted them. Later the third and fourth prostheses were collected, checked and inserted. The check did not identify that these later prostheses were from a different manufacturer and therefore not compatible. The patient did not require a further operation.

8.1.2 Administering a wrong site nerve block (Healthcare Safety Investigation Branch, 2018b).

- Never Event: wrong site surgery.

- National safety requirements: WHO surgical safety checklist (National Patient Safety Agency, 2009b), national/local safety standards for invasive procedures (NatSSIPs/LocSSIPs) (NHS England, 2015a) and Stop Before You Block (SBYB) (RA-UK, 2015).

- During elective ankle surgery the patient required two local anaesthetic nerve blocks (for pain relief). The first nerve block was administered correctly by a registrar while the patient was awake and lying on his front. The second nerve block was inserted by a consultant after the patient had a general anaesthetic and while lying on his back. The second nerve block was carried out on the wrong leg. At the time of the second nerve block, the patient's oxygen levels had also decreased and so the registrar was separately repositioning the patient's airway to address this.

8.1.3 Insertion of an incorrect intraocular lens (Healthcare Safety Investigation Branch, 2018c).

- Never Event: wrong implant/prosthesis.
- National safety requirements: WHO surgical safety checklist (National Patient Safety Agency, 2009b) and national/local safety standards for invasive procedures (NatSSIPs/LocSSIPs) (NHS England, 2015a).
- A patient attended for an elective operation to remove a cataract

from her left eye and insert a new lens. Prior to surgery the consultant selected a lens for the eye inadvertently using information for the right (incorrect) eye. During surgery, the assisting nurse identified the discrepancy, however, the surgeon decided that the discrepancy was within tolerable limits and continued. There was unlikely to be significant effect on the patient's vision.

8.1.4 Piped supply of medical air and oxygen (Healthcare Safety Investigation Branch, 2019a).

- Never Event: unintentional connection of a patient requiring oxygen to an air flowmeter [device that measures how much air is delivered].
- National safety requirements: patient safety alert for reducing the risk of oxygen tubing being connected to air flowmeters (NHS Improvement, 2016a) that describes the need to implement three barriers to prevent connection of air flowmeters.
- Following a fall at home, a patient with chronic lung disease attended hospital. While on the ward she was found to have low oxygen levels and required supplemental oxygen. The nurse administered what was thought to be oxygen via the nose. Around an hour later another nurse, just starting on duty, identified that the patient's oxygen saturations had not improved and she was being administered air

rather than oxygen from the adjacent wall-mounted supply. Oxygen was then administered to the patient and no long-term effects resulted from the episode.

8.1.5 Detection of retained vaginal swabs and tampons following childbirth (Healthcare Safety Investigation Branch, 2019b).

- Never Event: retained foreign object post procedure.
- National safety requirements: WHO surgical safety checklist (National Patient Safety Agency, 2009b), national/local safety standards for invasive procedures (NatSSIPs/LocSSIPs) (NHS England, 2015a) and a patient safety alert for reducing the risk of retained swabs after vaginal birth and subsequent suturing (National Patient Safety Agency, 2010a) that describes the need for written procedures for swab, swab audits, education and training, and consideration of X-ray detectable swabs.
- During the delivery of her baby by forceps, a woman required an episiotomy [surgical cut of the vagina]. Following the birth, a surgical tampon was inserted into the vagina by a consultant to improve the view of the episiotomy and two stitches were inserted. A trainee doctor was then asked to complete the suturing and the consultant left the operating theatre. At five days after the birth the woman was in significant pain

and reattended the hospital. It was identified that the surgical tampon was still in her vagina and it was removed. She subsequently spent time in and out of hospital with associated urological problems.

8.1.6 Prescribing and administering insulin from a pen device in hospital (Healthcare Safety Investigation Branch, 2019c).

- Never Event: overdose of insulin due to abbreviations or incorrect device.
- National safety requirements: patient safety alert for safe administration of insulin (National Patient Safety Agency, 2010b) and risk of harm and death due to withdrawing insulin from pen devices (NHS Improvement, 2016b). The alerts include the requirement for insulin to be measured and administered using an insulin syringe or commercial insulin pen device.
- A patient was admitted to hospital as an emergency with abdominal pain. She had insulin-treated type 2 diabetes and required high-dose insulin (500 units per ml) from an insulin pen device. The ward the patient was on did not stock disposable pen needles and the patient had none left. The nurse improvised by using an insulin syringe to withdraw insulin from the pen device and administer it to the patient. They did not notice the insulin was five times the normal strength and the patient experienced low blood sugar events requiring treatment.

8.1.7 Inadvertent administration of an oral liquid medicine into a vein (Healthcare Safety Investigation Branch, 2019d).

- Never Event: administration of medication by the wrong route.
- National safety requirements: patient safety alert for promoting measurement and administration of liquid medicines via oral and other enteral [via the gastrointestinal tract] routes (National Patient Safety Agency, 2007) which introduced oral and enteral syringes and feeding systems.
- A child required a kidney biopsy with a plan to administer intravenous midazolam to make the child sleepy for the biopsy. The midazolam was prescribed intravenously [into a vein], but the nurse instead drew up oral midazolam into a purple syringe marked 'enteral' thinking it was to be given via the mouth. A two-person check was carried out between doctor and nurse, but did not identify that oral midazolam had been prepared. The doctor attempted to inject the midazolam into the vein, but because the purple syringe is incompatible with an intravenous line, could not. The doctor therefore decanted the contents into an intravenous syringe and started to administer it, at which point they realised the error. The patient suffered no apparent adverse effects.

8.1.8 Wrong site surgery – wrong patient (Healthcare Safety Investigation Branch, 2020a).

- Never Event: wrong site surgery.
- National safety requirements: WHO surgical safety checklist (National Patient Safety Agency, 2009b) and national/local safety standards for invasive procedures (NatSSIPs/LocSSIPs) (NHS England, 2015a).
- A patient (patient A) attended an outpatient department for treatment. Another patient (patient B) also attended at similar time for a different procedure. The two patients had similar names. On calling for patient B, patient A stood and attended with the nurse. Patient A received the treatment intended for patient B.

8.1.9 Wrong site surgery – wrong tooth extraction (Healthcare Safety Investigation Branch, 2020b).

- Never Event: wrong site surgery.
- National safety requirements: WHO surgical safety checklist (National Patient Safety Agency, 2009b) and national/local safety standards for invasive procedures (NatSSIPs/LocSSIPs) (NHS England, 2015a).
- A child was referred by a general dental practitioner to a district care trust for dental treatment.

Following an initial appointment at the health centre, a senior dentist made a treatment plan which included a referral for advice to an orthodontic specialist, fillings and tooth extractions. During the fifth and final appointment, the plan was to remove a single milk tooth that was showing signs of gross decay. During that procedure, the neighbouring adult tooth was removed in error. The tooth was re-implanted after a short period outside the mouth and, at the time of the investigation, was healthy.

8.1.10 Placement of nasogastric tubes (Healthcare Safety Investigation Branch, 2020c).

- Never Event: misplaced naso- or oro-gastric tubes.
- National safety requirements: patient safety alert for nasogastric tube misplacement (NHS Improvement, 2016c) and a resource set for initial placement checks for nasogastric [nose to stomach] and orogastric [mouth to stomach] tubes (NHS Improvement, 2016d). The patient safety alert included the need for an organisation-wide response to include training, documentation and access to CE-marked pH test strips. CE marking shows a product complies with European Union safety requirements.
- A patient was admitted to hospital following a fall from his bicycle. He required admission to the critical care unit and had a nasogastric

tube inserted. Following a period of agitation, the patient removed his own nasogastric tube and a new tube was inserted. The placement of the tube was confirmed as being in the stomach by testing the pH [measure of acidity] of the aspirate; the pH test may have been misread. After insertion of the second tube, the patient's condition started to deteriorate and X-rays were taken of his chest; initial review of these X-rays did not identify that the nasogastric tube was inadvertently in the patient's lungs and feed was being delivered into his lung. Following later discovery and removal of the tube and feed, the patient remained in critical care and was later discharged.

8.2 Further detail on analysis methods

A qualitative, thematic analysis approach was taken to identify the factors that contributed to the occurrence of the Never Events investigated by HSIB. Thematic analysis was undertaken using the Systems Engineering Initiative for Patient Safety' (SEIPS) (Carayon et al, 2020; Holden et al, 2013; Carayon et al, 2006) as the framework, focusing on themes within the work system.

SEIPS is a prevalent human factors model of person-centred sociotechnical systems and has been used in many projects (Holden et al, 2013). It has evolved over the years from SEIPS 1.0 (Carayon et al,

2006), to 2.0 (Holden et al, 2013) and finally to 3.0 (Carayon et al, 2020). Within this report 'SEIPS' refers to version 2.0.

8.2.1 Analytical approach

Prior to undertaking any analysis, each Never Event investigated by HSIB was considered as part of the SEIPS framework in relation to work system factors, processes and outcomes. Each Never Event can be considered as an unintended outcome which deviated from the intended goal. That outcome was the result of a variety of processes, each with particular work system factors that influenced their progression. Within those work systems were a variety of tasks being undertaken by the persons involved.

Thematic analysis (Braun and Clarke, 2006) was undertaken by two HSIB reviewers who had not been involved in the earlier investigations. Both reviewers were medically qualified and had experience in patient safety, incident investigation and human factors.

The reviewers read the investigation reports and initial themes were generated by qualitative analysis software (NVivo, n.d.) utilising the work system factors of the SEIPS 2.0 framework (Holden et al, 2013). Three reports were themed by the reviewers together and then one reviewer themed the other reports; their findings were confirmed with

the second reviewer. A consensus was reached by both reviewers and final draft themes presented.

The draft themes were presented internally at HSIB to the Intelligence Unit and national investigators involved in the initial investigations. This provided an opportunity to review and challenge the themes. Themes were finalised following this review and are provided in this report.

While the prevalence of a factor that contributed to the Never Events does not necessarily make it a theme (Braun and Clarke, 2006), the number of investigation reports within which a factor was found is acknowledged in this report. It was identified during analysis that certain factors were only applicable to certain Never Event types. For example, issues with storage of pieces of equipment were only relevant in Never Events such as incorrect intraocular lens insertion.

8.3 HSIB's Never Event investigations and their goals, outcomes, processes and barriers

	Intended goal	Outcome in HSIB investigation	Process of interests	Barriers (NHS Improvement, 2018d)
Implantation of wrong prostheses during joint replacement surgery (HSIB, 2018a).	Hip replacement with prosthetic implant	Incorrect hip implant inserted not resulting in a need for further management	Selection of hip implant for insertion	WHO surgical safety checklist (NPSA, 2009b) NatSSIPs and LocSSIPs (NHS England, 2015a)
Administering a wrong site nerve block (HSIB, 2018b).	Administration of nerve block to the correct site	Nerve block administered to the wrong leg resulting in no long-term effects	Checking site for insertion of nerve block	WHO surgical safety checklist (NPSA, 2009b) NatSSIPs and LocSSIPs (NHS England, 2015a) Stop Before You Block (RA-UK, 2015)
Insertion of an incorrect intraocular lens (HSIB, 2018c).	Correct lens inserted into correct eye	Correct lens inserted into correct eye	Selection of intraocular lens for insertion	WHO surgical safety checklist (NPSA, 2009b) NatSSIPs and LocSSIPs (NHS England, 2015a)
Piped supply of medical air and oxygen (HSIB, 2019a).	Patient receives oxygen	Patient received medical air instead of oxygen resulting in no long-term effects	Administration of oxygen to a patient	Implementation of three barriers: cap medical air wall outlets, remove medical air flowmeters, fit air flowmeters with labelled, movable flap (NHS Improvement, 2016a)

	Intended goal	Outcome in HSIB investigation	Process of interests	Barriers (NHS Improvement, 2018d)
Detection of retained vaginal swabs and tampons following childbirth (HSIB, 2019b).	Removal of swabs and tampons following surgery	Retained tampon following episiotomy resulting in urological problems	Removal of tampons following procedure	WHO surgical safety checklist (NPSA, 2009b) NatSSIPs and LocSSIPs (NHS England, 2015a) Swab procedures, swab audits, education and training and X-ray detectable swabs (NPSA, 2010a)
Prescribing and administering insulin from a pen device in hospital (HSIB, 2019c).	Patient receives correct dose of insulin	Patient received a five-times overdose of insulin resulting in hypoglycaemia and treatment	Preparation of insulin for administration in hospital	Requirement for insulin to be measured and administered using an insulin syringe or commercial insulin pen device and associated training (NHS Improvement, 2016b; NPSA, 2010b)
Inadvertent administration of an oral liquid medicine into a vein (HSIB, 2019d).	Patient receives correct medication via correct route	Patient received oral medication via their intravenous cannula resulting in no long-term effects	Administration of medication in a day-case setting	Oral/enteral syringes and feeding systems with organisational procedures, training and audit (NPSA, 2007)

	Intended goal	Outcome in HSIB investigation	Process of interests	Barriers (NHS Improvement, 2018d)
Wrong site surgery - wrong patient (HSIB, 2020a).	Correct patient receives correct procedure	Wrong patient identified resulting in wrong patient having the procedure	Identification of patient in outpatient setting	WHO surgical safety checklist (NPSA, 2009b) NatSSIPs and LocSSIPs (NHS England, 2015a)
Wrong site surgery - wrong tooth extraction (HSIB, 2020b).	Removal of correct tooth	Wrong tooth identified resulting in wrong adult tooth being extracted and needing reimplantation	Identification of the tooth in a community dentistry setting	WHO surgical safety checklist (NPSA, 2009b) NatSSIPs and LocSSIPs (NHS England, 2015a)
Placement of nasogastric tubes (HSIB, 2020c).	Correct placement of a nasogastric tube	Nasogastric tube inserted into lungs and not identified resulting in pneumonia from feed	Checking placement of nasogastric tube using pH paper	Implementation of an organisation-wide response to ensure training, documentation and access to CE-marked pH test strips (NHS Improvement, 2016c) Resource pack was also developed (NHS Improvement, 2016d)

Abbreviations

HSIB: Healthcare Safety Investigation Branch

LocSSIPs: Local Safety Standards for Invasive Procedures

NatSSIPs: National Safety Standards for Invasive Procedures

NPSA: National Patient Safety Agency

WHO: World Health Organization

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