ASCENTI

# Patient Safety Incident Response Policy

This policy supports the requirements of the NHS Patient Safety Incident Response Framework (PSIRF), setting out our approach to patient safety incidents and issues for the purpose of learning and improving patient safety.

**Classification:** Public
**Version:** 1.1
**Date:** January 2028
**Reference**: PP0110
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## About this document

Our Patient Safety Incident Response Policy outlines our commitment to maintain effective systems and processes for responding to patient safety incidents and issues, prioritising learning and improvement. Supporting the requirements of the Patient Safety Incident Response Framework (PSIRF), the policy encourages a data-driven response, fostering a culture of systematic patient safety management. Key aspects of our policy include compassionate engagement, systematic learning, appropriate responses to incidents, and strengthening of our response system.

The policy, applicable to all staff, strictly focuses on learning and improvement rather than attributing liability or accountability. The Executive Team, Chief Governance and Quality Officer, and the Clinical Governance Team share responsibility for patient safety. We promote an open, just, reporting, learning, and informed culture.

Our policy acknowledges that safety arises from a complex interplay of various factors rather than a single cause or human error. We employ systems-based approaches and human factors principles for incident management, promoting a culture of shared learning and improvement. Moreover, we engage with patients, families, and staff following a safety incident, ensuring transparency and support. Our policy also defines our approach to incident response activities, developing safety actions, information sharing, feedback, and cross-system responses. All these efforts are directed towards fostering a safe environment for our patients, and constantly improving our services.

## How to use this document

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## Accessibility

If you need this policy in a different language, another format or any help reading this document, then please get in touch with the People Team.

## Confidentiality

## Contents

## 1.0 Introduction

This policy supports the requirements of the Patient Safety Incident Response Framework (PSIRF) and sets out our approach to developing and maintaining effective systems and processes for responding to patient safety incidents and issues for the purpose of learning and improving patient safety.

PSIRF advocates a co-ordinated and data driven response to patient safety incidents. It embeds patient safety incident response within a wider system of improvement and prompts significant cultural shifts towards systematic patient safety management.

Our Patient Safety Incident Response Policy links to related organisational policies such as:

Incident Management Policy
Risk Management Policy
Concerns and Complaints Policy
Integrated Governance Policy

This policy supports development and maintenance of an effective patient safety incident response system that integrates the four key aims of PSIRF:

- Compassionate engagement and involvement of those affected by patient safety incidents.
- Application of a range of system-based approaches to learn from patient safety incidents.
- Consideration and proportionate responses to patient safety incidents and safety issues.
- Supportive oversight focused on strengthening response system functioning and improvement.

The purpose of this policy is to promote a climate that fosters a just culture to improve safety culture and drive improvements through shared learning that focuses on system-based issues.

## 2.0 Who this applies to

This policy applies to all staff and relates to responses to patient safety that are solely for the purpose of learning and improvement. Any responses that seek to find liability, accountability or causality is beyond the scope of this policy.

Aspects outside the scope of the patient incident response plan include:

- Human resources investigations
- Professional standards investigations

- Claims management
- Financial investigations
- Audits
- Complaints investigation where systems and process were not identified as a cause following information gathering phase. Responses under this policy follow a system - based approach.

In healthcare systems, safety is the result of a complex interplay of different factors (e.g., person, technology and tools, tasks, environmental, or organisational) and not from a single component or root cause. Responses do not take a person-focused approach where actions or inactions of people, or "human error", are stated as the cause of an incident.

Information from a patient safety response process can be shared with those leading other types of responses, but other processes should not influence the remit of a patient safety incident response.

## 3.0 Roles & Responsibilities

The **Executive Team** hold ultimate responsibility for ensuring the safety of patients in Ascenti and are responsible for ensuring systems and frameworks within Ascenti achieve these aims.

The **Chief Executive Officer (CEO)** is accountable for ensuring the operational effectiveness of our company frameworks to ensure patient safety is maintained, safeguarded, continually improved, and that lessons are learned. The CEO is also responsible for sharing findings of Patient Safety Incidents with the Executive Team and Board and providing assurances of our system. Collectively with the **Head of Clinical Governance**, they will maintain oversight of the Patient Safety system.

There may be occasions where we will need to collaborate with our **Integrated Care Boards** (ICBs).

The **Clinical Governance Team** are responsible for supporting staff and patients, ensuring the delivery of safe services.

All **Healthcare Staff** have their own part to play in ensuring they rigorously follow the correct policies, procedures and processes. Staff members are made aware of their individual responsibility and duty of care to ensure that they follow our policies, procedures and processes and maintain safe practice for all patients, service users, colleagues and visitors, at all times and in all settings.

As this is a framework, with each interacting component of our overall Governance system contributing to patient safety, where a component is defined by a policy, procedure,

framework or standard operating procedure, roles and responsibilities are defined within the corresponding document.

## 4.0 Key terms and definitions

| | |
|---|---|
| **PSII** | Means Patient Safety Incident Investigation |
| **PSIRF** | Means Patient Safety Incident Response Framework |
| **SEIPS** | The SEIPS model is a framework for evaluating and designing healthcare systems and processes to improve patient safety. SEIPS stands for Systems Engineering Initiative for Patient Safety. This model considers healthcare systems as being composed of five interconnected elements: people, tasks, tools and technologies, physical environment, and organisation. It is one of many such different investigation tools. |

## 5.0 Our Approach

Our approach to managing patient safety is linked with our wider systems of quality, clinical governance, management of risk, and integrated governance.

### 5.1 Our Patient Safety Culture

The company promotes a positive culture that is not based on blame. The company and all those involved in incident management must actively promote and maintain awareness of actions to ensure we achieve a/an:

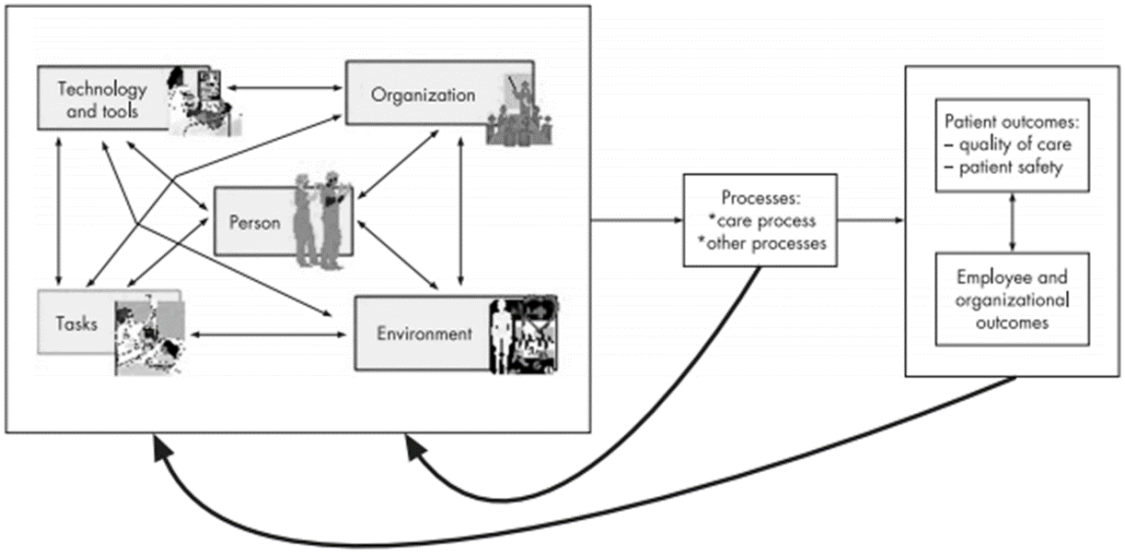
- **Open Culture:** Staff feel comfortable discussing incidents, raising awareness with colleagues, senior managers.
- **Just Culture:** Staff/patients treated fairly, with empathy and consideration when they have been involved in an incident.
- **Reporting Culture:** Staff have confidence in the incident reporting system and use it to notify incidents/near misses.
- **Learning Culture:** Organisation is committed to learn safety lessons, communicate to colleagues and remembered over time.
- **Informed Culture:** Organisation has learnt from past experience and has the ability to identify and mitigate future incidents because it learns from what has already happened.

### 5.2 Human Factors & Systems-Based Approaches

Human Factors is the scientific discipline concerned with the understanding of interactions among humans and other elements of a system. We apply these principles of human factors, human performance models, performance variability, and associated methodologies,

including systems-based approaches, to the management of safety incidents and risk. We therefore remain cognisant of the wider system, its interactions and emergent properties, when analysing incidents and deriving lesson learned. By doing so the company avoids reductionist and root-cause approaches to incidents. As well as identifying what went wrong, by utilising a human factors approach, the Company will seek to understand what also went right adding an important dimension to learning and improvement.

The SEIPS model is a theoretical model rooted in human-centred systems engineering or "human factors/ergonomics". The 3 major SEIPS components: i): the work system; ii) work processes; and iii) work outcomes. Work systems are comprised of interacting structural elements that together produce performance.




The following table illustrates some of the example features that can be considered within components of the SEIPS framework:

| **Component** | **Example** |
|---|---|
| Person | Education, skills, knowledge, motivation, physical / psychological characteristics |
| Organisation | Teamwork, coordination/collaboration/communication, organisational culture, work schedules, social relationships, supervisory / management styles, rewards / incentives |
| Technology/Tools | Info technologies, Patient Management System, medical devices. |
| Tasks | Variety, job content / design, challenge, utilisation of skills, autonomy, job control, participation, job demands (workload, time pressure, cognitive load, need for attention) |
| Environment | Layout, noise, lighting, temperature, humidity, air quality |
| Care & Other Processes | Process, improvements, information flow |
| Outcomes | Job satisfaction, job stress, burnout, turnover, profitability. Patient Safety, Outcomes, Quality of Care |

It is important to always place the individual at the centre and look at systems components as a whole, and not individually.

Understanding Human Factors helps us build better defences into our systems to prevent or reduce the likelihood of serious error resulting in harm to a patient by:

- Allowing us to understand errors and variability in performance
- Improving our safety culture within teams and the organisation
- Enhancing teamwork and communication
- Identify “what went wrong”
- Helping us predict “what could go wrong” in the future
- Improving the design of the system/processes we work in

Moreover, taking a systems-based approach to investigations facilitates targeted recommendations to prevent active failures (errors or mistakes committed by people who are directly interacting with a system or process at the time), reducing the propensity for latent conditions (hidden problems or defects that exist in systems, processes, or designs which can eventually contribute to accidents or errors when they combine with active failures) and facilitation of an open and visible system to improve the design of the system:

- To prevent errors
- To make errors readily visible
- To mitigate errors not being identified
- To mitigate the adverse effects in the event they are not identified

### 5.2.1 The Swiss Cheese Model (Reason, 1990)

In any system there are many levels of defence (for example checking of drugs before administration). Each level of defence has little ‘holes’ (latent conditions) which are caused by poor design, decision-making, procedures, lack of training, limited resources, staffing levels etc. If these holes become aligned over successive levels of defence, they create a window of opportunity for a patient safety incident to occur. Latent conditions also increase the likelihood that healthcare professionals will make ‘active errors’ (for example whilst delivering patient care). When a combination of latent conditions and active errors causes all levels of defences to be breached, a patient safety incident occurs.

## 6.0 Patient Safety Partners

As an organisation our services are distributed nationally, crossing boundaries with serval ICBs and health partnerships including Clinical Commissioning Groups (CCGs), Integrated Care Boards (ICBs), Instructing Parties, both medio-legal and private. We will share the

development of this policy, receive feedback, and adapt where necessary to ensure a collaborative approach to share our approach to patient safety.

### 6.1 Address Health Inequalities

We recognise that applying a more flexible approach and intelligent use of data can help identify any disproportionate risk to patients with specific characteristics, and how this information informs patient safety incident response. The triangulation of data will include survey feedback and social media responses which will be included in the development of our patient safety response plan. The annual review of safety actions will ensure that a Just Culture has been adhered to which will be supported by using SEIPs, that upholds a system-based approach. In addition, the Just Culture Guide is part of the PSII template ensuring staff involved are treated fairly.

## 7.0 Patient Safety Response Plan

Our Patient Safety Response Plan will inform the level of investigation required in response to incidents and safety issues through analysis of reported incidents and complaints as described in 6.2. Emerging trends can be identified through:

- Our Governance Committee, looking at data trend analysis.
- Meetings between Area Managers, Clinical Governance Officers and Service Leads, through review and analysis of performance.
- Reported through incidents logged on Datix.
- High risk feedbacks requiring PSII level of investigation are agreed by Managing Director/CEO or Head of Clinical Governance (HoCG) and logged as high-risk incident. A Panel is convened in line with the Incident Policy where appropriate.
- Any incidents involving patient safety, Patients must be consulted, and timeframes agreed, including point of contact.

Patient reported complaints and incidents are capture through our risk management database, Datix.

## 8.0 Patient Safety Incident Response

### 8.1 Reporting

Patient reported complaints and incidents are captured through our risk management database, Datix. Executive leaders and managers at all levels must enable and encourage all staff to record and share hazards, risks or incidents. Incidents can also be raised via our internal or external Whistleblowing process, or our Freedom to Speak Up systems.

Datix provides an integrated system for reporting, for example, complaints, incidents, whistleblowing, freedom to speak up and risk reporting – this allows for the linking of records and in combination with reporting capabilities, data visualisation capabilities, and tools for risk monitoring, facilities the triangulation of information ensuring risks are identified and managed in the most appropriate way.

 Incident Reporting form on Datix

### 8.2 Engaging & involving patients, families & staff following a patient safety incident

Our supporting processes encourage early engagement with patients and their carers, facilitated through our Clinical Governance Officers (CGO) to gain their version of events, explaining the process, addressing questions they wish to be answered as part of the investigation and agreeing timescales for response. All information gained will be recorded on the Datix record.

The following principles for engaging with those affected by patient safety incidents will be upheld:

- Fully informed about what happened
- Given the opportunity to provide their perspective on what happened.
- Communicated with in a way that takes account of their needs.
- Given an opportunity to raise questions about what happened and to have these answered openly and honestly.
- Helped to access counselling or therapy where needed.
- Given the opportunity to receive information from the outset on whether there will be a specific learning response and what to expect from the process.
- Signposted to where they can obtain specialist advice and/or advocacy and/or support from independent organisations regarding learning response processes.

Our Clinical Governance Officers are provided additional training required to appropriately support patients, their families/carers, and staff, involved in a patient safety incident.

Our Duty of Candour is recorded on Datix in line with supporting policies and procedures for managing moderate and high-risk incidents/complaints. Duty of Candour forms part of mandatory training for all clinical staff. PSIRF recognises that learning and improvement following a patient safety incident can only be achieved if supportive systems and processes are in place. It supports the development of an effective patient safety incident response system that prioritises compassionate engagement and involvement of those affected by patient safety incidents (including patients, families and staff). This involves working with those affected by patient safety incidents to understand and answer any questions they have in relation to the incident and signpost them to support as required.

 Duty of Candour Policy

### 8.3 Patient Safety Incident Response Activity

Our approach to responding to different types of patients is set out within our Patient Safety Incident Response Plan. Application of patient safety incident response activity is triggered according to 3 key objectives:

- **Learning to inform improvement** - Where contributory factors are not well understood and local improvement work is minimal, a learning response may be required to fully understand the context and underlying factors that influenced the outcome.
- **Improvement based on learning** - Where a safety issue or incident type is well understood (e.g. because previous incidents of this type have been thoroughly investigated and national or local improvement plans targeted at contributory factors are being implemented and monitored for effectiveness) resources are better directed at improvement rather than repeat investigation.
- **Assessment to determine required response** - For issues or incidents where it is not clear whether a learning response is required.

There are a variety of investigation options and tools available, and their use is directed by their utility to achieve learning and insight relevant to the incident. There are several system-based response methods that we have reviewed and recommend suitable for our service model to enable us to respond to patient safety incident or cluster of incidents:

| Method | Description |
|---|---|
| **Patient safety incident investigation (PSII)** | A PSII offers an in-depth review of a single patient safety incident or cluster of incidents to understand what happened and how. |
| **Incident Panel Review (IPR)** | An IPR review supports Clinical teams to learn from patient safety incidents that occurred in the significant past and/or where it is more difficult to collect staff recollections of events either because of the passage of time or staff availability. The aim is, through open discussion (and other approaches such as observations and walk throughs undertaken in advance of the review meeting(s)), to agree the key contributory factors and system gaps that impact on safe patient care. |
| **After action review (AAR)** | AAR is a structured facilitated discussion of an event, the outcome of which gives individuals involved in the event understanding of why the outcome differed from that expected and the learning to assist improvement. AAR generates insight from the various perspectives of the IPR and can be used to discuss both positive outcomes as well as incidents.<br>It is based around four questions: |

| | |
|---|---|
| | • What was the expected outcome/expected to happen?<br>• What was the actual outcome/what actually happened?<br>• What was the difference between the expected outcome and the event?<br>• What is the learning? |

These are applied where contributory factors are not well understood, and local improvement work is minimal and there is the greatest potential for new learning and improvement.

It is important to supplement finding out what happened using the methods described in the above table with an understanding of 'everyday work'. Everyday work describes the reality of how work is done and how people performing tasks routinely adjust what they do to match the ever-changing conditions and demands of work. Exploring everyday work shifts the focus from developing quick fixes to understanding wider system influences and is central to any learning response conducted to inform improvement. These should be used in conjunction with learning response methods (above) to explore the context in which work is conducted.

| Tool | Description |
|---|---|
| **Observation guide** | Observations help us move closer to an understanding of how work is actually performed, rather than what is documented in training, procedures or equipment operating manuals (work as prescribed), how we imagine work is conducted (work as imagined) or how people tell us work is performed (work as disclosed). |
| **Walkthrough guide** | Walkthrough analysis is a structured approach to collecting and analysing information about a task or process or a future development (e.g. designing a new protocol). The tool is used to help understand how work is performed and aims to close the gap between work as imagined and work as done to better support human performance |
| **Link analysis guide** | Link analysis creates a visualisation of the frequency of interactions observed in a specific location or environment. It can be used to highlight frequently used paths within an environment that are critical for safety. This can inform the design of the environment to locate items or areas based on what tasks are carried out most frequently. |
| **Interview guide** | This interview planning guide contains questions that help plan an interview with staff involved in a patient safety incident or with patients, families or carers. |
| **Hierarchical Task Analysis** | Hierarchical Task Analysis (HTA) is a structured method used for examining the tasks a user must perform in order to achieve a specific goal. The HTA process breaks down high-level tasks into sub-tasks in a hierarchical manner. Each task is examined and decomposed into smaller tasks, until the tasks are simple enough to be understood in terms of actions and cognitive processes. |

The following tools can be used to inform information gathering to support the synthesis of information to assist analysis:

| Tool | Description |
|---|---|
| **Timeline mapping** | A working document to help create a narrative understanding of a patient safety incident. This can be added to as further information is collected. It is useful for understanding any gaps in information and defining early thoughts on lines of enquiry |
| **Work system scan** | A checklist and documentation tool to ensure the full breadth of the work system is considered. The tool is used to indicate any aspects of the system design that hinder or support people in the work system to do their job (ie barriers and facilitators) |

The following tools can be used to respond to broad patient safety issues:

| Tool | Description |
|---|---|
| **Thematic review tips** | A thematic review may be useful for understanding common links, themes or issues within a cluster of investigations, incidents or patient safety data. Themed reviews seek to understand key barriers or facilitators to safety. The 'top tips' document provides guidance on how to approach a thematic review. |
| **Horizon scanning** | The Horizon Scanning Tool supports health and social care teams to take a forward look at potential or current safety themes and issues. It can be used to proactively identify safety risks |

We may wish to apply methods to support proactive risk assessment or develop specialised reviews (Deep Dive) to enable systematic data collection to inform wider improvement work. Examples may include painful treatments reviews and infection prevention and control reviews.

If we and the ICB are satisfied risks are being appropriately managed and/or improvement work is ongoing to address known contributory factors in relation to an identified patient safety incident type, and efficacy of safety actions is being monitored, it is acceptable **not** to undertake an individual learning response to an incident other than recording that it occurred and ensuring those affected are engaged as described in this policy.

In line with the Complaints and Concerns Policy all moderate or greater harm must fulfil our Duty of Candour obligations which is captured in Datix.

Please see the Patient Safety page for supporting information and library of tools.

### 8.4 Developing Safety Actions

The process and tools for brainstorming safety actions is similar for both local and organisational areas for improvement, although the development and implementation team will likely be different. While safety action development may be led by one individual (e.g. a learning response lead) or team, a wider team must be engaged during development, including the local team - Area Manager / Physiotherapy Development Lead (PDL), the Clinical Governance team and those with broader knowledge of ongoing improvement work

related to the defined areas of improvement, or whose work may be informed by the findings from the learning response under consideration.

| | **Local context** | **Organisation context** |
|---|---|---|
| **Definition** | Specific area for improvement highlighted by a single (or multiple) learning response. | Broader area for improvement identified across several learning responses – likely not in response to any single patient safety incident but incidents with common contributory factors across events. Likely require radical system redesign |
| **Examples of areas that may require improvement** | Environment layout and characteristics (e.g. light, noise), Tool design, Task design, Training | Deep routed organisational issues, likely with long histories and dynamics, e.g.:<br>• Staffing, rotas, etc<br>• IT infrastructure<br>• Workload<br>• Fatigue<br>• Culture<br>• Handovers<br>• Procurement<br>• Policies |
| **Development team** | Learning response team involvement of local team to design and implement quality improvement initiatives, including, potentially, the participation of those involved in the incident. | Learning response team involvement of local and broader team to design and implement (e.g. leadership, management) quality improvement across wider work system – including, potentially, the participation of those involved in the incident. Those affected by the incident |
| **Methods of developing safety action** | Interviews<br>Observations<br>Focus groups<br>Desktop reviews<br>Simulation/testing<br>Standards quality improvement methods such as PDSA cycles | Qualitative review of patient safety learning response findings Surveys<br>Literature reviews – what has worked well elsewhere?<br>Focus groups Consensus panel – reaches a wider group of members with experience of work |
| **Expectation for recording** | Included in learning response report (e.g. patient safety incident investigation (PSII) report) after an individual incident response or in wider safety improvement plan as appropriate | Included in a safety improvement plan bringing together findings from various responses |

Please also see:

- Appendix 1 – National event response requirements
- Appendix 2 – Guidance for Planning Safety Measures
- Appendix 3 – Tools / focus on systems (human factors intervention matrix)

### 8.4.1 Timeframes for learning responses

These timeframes are set out in our Incident Management Policy. However, learning responses must balance the need for timeliness and capture of information as close to the event as possible, with thoroughness and a sufficient level of investigation to identify the key contributory factors and associated learning for improvement. One of the most important factors in ensuring timeliness of a learning response is thorough, complete and accurate incident reporting when the circumstances are fresh in the minds of the incident reporter and the wider team. These principles are set out in the current incident reporting guidance but must be reinforced through the PSIRF.

 Incident Management Policy

## 8.5 Continuous Learning and Improvement

The findings of PSII's are embedded into a process of shared learning. Taking a human-factors and systems-based approach, these are translated into effective and sustainable actions that reduce patient and organisational risk and improvement, identifying where improvement is needed, what changes need to be made, how changes will be implemented and how to determine if those changes have the desired impact.

## 8.6 Information Sharing

We will ensure the appropriate underpinning frameworks are in place to facilitate the compliant sharing of information preventing any barriers to effective learning.

## 8.7 Feedback

We will seek feedback from patients, families and carers about our response to incidents (through liaison staff and/or written feedback following an incident) and ensure good practice is sustained and poor practice addressed.

## 8.8 Cross-system responses

We will work collaboratively with our partners to facilitate cross-system learning where are there are multiple organisations involved in a learning response. In each case, we will work to establish responsibilities and accountabilities to ensure roles are clearly defined and that learning responses are coordinated, timely and are collaborative.

## 9.0 Training

Training provision is in line with the prescribed training underpinned and defined by the NHS PSIRF. Appropriate staff will engage with continuous professional development to stay up to date with best practice.

## 10.0 Implementation and Monitoring

This policy will be disseminated by the method described in the Policy for the Development and Implementation of Policies and Procedural Documents. The implementation of this policy requires no additional financial resource. However, staff will need to complete the approved training programmes that may impact services.

**Training implications**

All staff are required to complete the approved training programme, "Essentials of Patient safety for all Staff" Level One. All staff undertaking PSII investigations must complete Level Two training module before commencing investigations. Training modules will be made available via Kallidus training platform (clinical staff) and PULSE page (non-clinical).

## 11.0 References

https://www.england.nhs.uk/patient-safety/incident-response-framework/

## Appendix 1 – National event response requirements

| Event | Action required | Lead body for the response |
|---|---|---|
| **Deaths thought more likely than not due to problems in care** (incidents meeting the learning from deaths criteria for PSII)5 | Locally-led PSII | The organisation in which the event occurred |
| **Deaths of patients detained under the Mental Health Act (1983) or where the Mental Capacity Act (2005) applies**, where there is reason to think that the death may be linked to problems in care (incidents meeting the learning from deaths criteria) | Locally-led PSII | The organisation in which the event occurred |
| **Incidents meeting the Never Events criteria 2018,** or its replacement. | Locally-led PSII | The organisation in which the Never Event occurred |

| | | |
|---|---|---|
| **Mental health-related homicides** | Referred to the NHS England Regional Independent Investigation Team (RIIT) for consideration for an independent PSII<br>Locally-led PSII may be required | As decided by the RIIT |
| **Child deaths** | Refer for Child Death Overview Panel review<br>Locally-led PSII (or other response) may be required alongside the panel review – organisations should liaise with the panel | Child Death Overview Panel |
| **Deaths of persons with learning disabilities** | Refer for Learning Disability Mortality Review (LeDeR)<br>Locally-led PSII (or other response) may be required alongside the LeDeR – organisations should liaise with this | LeDeR programme |
| **Safeguarding incidents** in which:<br>- babies, children, or young people are on a child protection plan; looked after plan or a victim of wilful neglect or domestic abuse/violence<br><br>- adults (over 18 years old) are in receipt of care and support needs from their local authority.<br>- the incident relates to FGM, Prevent (radicalisation to terrorism), modern slavery and human trafficking or domestic abuse/violence. | Refer to local authority safeguarding lead.<br>Healthcare organisations must contribute towards domestic independent inquiries, joint targeted area inspections, child safeguarding practice reviews, domestic homicide reviews and any other safeguarding reviews (and inquiries) as required to do so by the local safeguarding partnership (for children) and local safeguarding adults boards | Refer to your local designated professionals for child and adult safeguarding |

## Appendix 2 – Guidance for Planning Safety Measures

Before finalising a safety action, plan how you will evaluate its effectiveness and progress towards specific goals. Meaningful measures need to be identified that can be monitored through normal processes, to ensure that the benefits of change are sustained.

**Step 1. Identify measure.**

Consider what can be measured to increase confidence that the safety action is influencing what it was intended to. Importantly, you must measure the effectiveness of the safety

action – that is, has the safety action delivered the intended benefits? You must also consider whether there have been any unintended consequences of implementing the safety action. Focus more on the change associated with the activity undertaken, e.g., changes in observed behaviours, improved documentation (due to paperwork redesign), faster response time.

**Step 2. Prioritise and select safety measures.**
You are likely to identify several safety measures, but selecting one or two measures will be more practical than measuring all of them. To prioritise your safety measures, consider the practicalities and data availability. For example, are measures:

- currently collected and reported.
- collected, but not reported.
- available, but not collected.
- not currently available.

Further criteria for evaluating and identifying the best measures are given below. If the answers to these questions are predominantly 'yes', the measure is more favourable than one for which the answers are predominantly 'no'.

- Will there be enough data to identify trends?
- Will the quality of the data be good enough?
- Does the measure have a clear unambiguous definition?
- Is it easy to communicate what is being measured?
- Will it provide timely warning of deterioration?
- Does it measure what is intended?
- Will changes in the measure lead to action?
- Will the measure promote the desired behaviour?
- Do the benefits of the measure outweigh the costs of collecting and monitoring the data?

Several related measures may be identified. Rather than choosing one, consider whether combining the measures would be beneficial.

**Step 3. Define measures.**
Once a measure has been selected, it must be clearly defined so that it is consistently recorded, reported, and understood across the organisation. This will require input from all those involved in measuring, analysing, reporting, acting on and reviewing, to ensure that the measure is clearly understood, this includes senior management who wish to gain assurance from the measures.

The definition should include:

- A description of what is being measured.
- The purpose of the measure (i.e. what it is intended to manage and who it is intended to inform).
- The units of measurement and any formula for its calculation.

- Who is responsible for collecting, validating, analysing, reporting and acting on the measure. (these may be different people in different parts of the organisation)?
- Where or how the data should be collected.
- The frequency of collecting, analysing and reporting.
- If appropriate, the target value, goal, tolerances, and statistical tests that can be applied.
- Potential actions for when the measure deviates from the accepted tolerances, including when the deviation should be escalated.

**Writing safety actions**
Safety actions should be SMART (specific, measurable, achievable, relevant, timebound).
They should also:

- Be documented in a learning response report or in a safety improvement plan as applicable.
- Start with the owner, e.g. “Head of X to...”.
- Be directed to the correct level of the system: that is, people who have the levers to activate change (ideally this should include the person closest to the work and who has been empowered to act).
- Be succinct: any preamble about the safety action should be separate.
- Standalone: that is, readers should know exactly what it means without reading the report.
- Make it obvious why it is required (i.e. given evidence in the learning response report or safety improvement plan).

**Monitor and Review**
The safety actions and associated measure(s) should be reviewed as defined in the safety action summary table (Table 1) to ensure they continue to provide value by being the issues of most concern.

A review should be carried out periodically (typically annually) or when an organisation makes substantial changes. This may be following a reorganisation, the introduction of new technology or in conjunction with your patient safety incident response plan.

| **Areas for Improvement:** | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **Safety action description (SMART)** | **Safety action owner** | **Target date for implementation** | **Date Implemented** | **Tool/measure (e.g. audit)** | **Measurement frequency** | **Responsibility for monitoring** | **Review date** |
| | | | | | | | | |
| | | | | | | | | |

## Appendix 3 – Tools / focus on systems (human factors intervention matrix)

The Human Factors Intervention Matrix (HFIX) uses a series of questions to prompt thinking about how each area of improvement identified might be translated into possible safety actions to reduce risk. Table 2 gives a high-level version of HFIX adapted to align with the Systems Engineering Initiative for Patient Safety (SEIPS) work system categories.

**Table 1**

| Areas for Improvement | | Set out where improvement is needed |
|---|---|---|
| Work system | Person(s) | How **can individual or team characteristics** be modified or changed to reduce risk or improve performance? |
| | Tasks | How can the **task or activity** be modified or redesigned to reduce risk or improve performance? |
| | Tools and technology | How can **tools, equipment or technology** be modified or redesigned to reduce risk or improve performance? |
| | Internal environment | How can the **physical environment** be modified or redesigned to reduce risk or improve performance? |
| | Organisation | How can **organisational factors** be modified or redesigned to reduce risk or improve performance? |
| | External environment | How can **regulatory or societal factors** be modified or redesigned to reduce risk or improve performance? |

**Basis of Prioritisation.**

The number of safety actions for implementation is often high. Monitoring their implementation and tracking the resulting changes can be onerous. The iFACES tool can help quantify the potential value of each identified action using six criteria: inequality, feasibility, acceptability, cost/benefit, effectiveness, and sustainability:

| Criterion | Low | Medium | High |
|---|---|---|---|
| | 1 2 | 3 | 4 5 |
| Inequality<br>Does the intervention ensure fair treatment and opportunity for all? | The intervention is not accessible to the diverse population that will use it. | The intervention accommodates some inequalities but further investigation is needed. | Inequalities are reduced by this intervention. |
| Feasibility<br>Can the change be implemented relatively easily or quickly? | The intervention does not exist today nor is it likely to become available in the near future; it is highly impractical and not suitable for your organisation. | The intervention exists but is not readily available or will require modifications to better fit the context in which it is intended to be used. | The intervention is readily available and could be implemented in a relatively short period of time without much effort. |
| Acceptability<br>Will those being impacted by the intervention readily accept the change? | The intervention will not be tolerated by those it impacts. People are likely to consistently resist the change and attempt to work around the change. | The intervention will be tolerated by those it impacts. There may be moderate resistance but attempts to undermine the change will not be wide spread. | The intervention will be readily accepted by those it impacts. People are likely to welcome the change and make every attempt to ensure it works. |
| Cost/Benefit<br>Does the benefit of the intervention outweigh the costs? | The cost of the intervention is exorbitant relative to its minimal expected impact on safety and performance. | The intervention is moderately expensive but cost could be justified by its expected benefit. Return on investment (benefits) is relatively equal to cost. | The cost of the intervention is nominal relative to the expected impact on safety and performance. |
| Effectiveness<br>How effective will the intervention be at eliminating the problem or reducing its consequences | The intervention will not directly eliminate the problem or hazard and it relied heavily on wilful compliance with the change and/or requires humans to remember to perform the task correctly. | The intervention reduces the likelihood of the problem or hazard occurring but relies in part on human memory and/or wilful compliance with the change. | The intervention will very likely eliminate the problem or hazard and it does not rely on wilful compliance with the change or require humans to remember to perform the task correctly. |
| Sustainability<br>How well will the intervention last over time | The impact of the intervention will diminish rapidly after it is deployed and/or will require extraordinary effort to keep it working. | The benefits of the intervention may have a tendency to slowly dissipate over time and will require moderate efforts to maintain its benefits. | The impact of the intervention will persist over time with minimal efforts being required to maintain its benefits. |

## Policy Compliance

| | |
|---|---|
| **New or existing policy** | New |
| **Author** | Saras Kissun, Head of Clinical Governance |
| **Responsible Director** | Ian Thistlewood, Chief Executive Officer |
| **Approval** | |
| **Review date** | January 2028 |
| **Date issued** | |

**Consultation History**

The following committees, groups or individuals have been consulted:

| Name | Date consulted |
|---|---|
| | |

**Version History**

| Version no. | Lead | Date change implemented | Reason for change |
|---|---|---|---|
| V1.0 | - | - | - |
| V1.1 | Saras Kissun | | Review, update policy following organisational change. |
| | | | |

## Equality Impact Assessment

### Section One

| | |
|---|---|
| **Name of policy / project / service** | Patient Safety Incident Response (PSIRF) Policy |
| **Background and aims of policy / project / service** | The PSIRF is being implemented in accordance with the requirements set out in prescribed frameworks enforced through regulatory and contractual mechanisms. |
| **Persons responsible for policy decision, or advising on decision, and also responsible for equality analysis** | Clinical Governance. |

**Section Two** – to be completed and reviewed as policy / project / service development progresses:

| | **Likely effect:** | | | **Describe effect and provide evidence** | **Actions to mitigate adverse effects** | **Details of actions including dates** |
|---|---|---|---|---|---|---|
| | **Pos** | **Neg** | **Neu** | | | |
| **Age** | | **X** | | Applies universally to all demographics.<br><br>PSIRF is equally accessible to individuals with diverse needs.<br><br>Aligns with pre-existing organisational policies that have already undergone an EIA.<br><br>PSIRF incorporates culturally sensitive practices when dealing with incidents related to patients from diverse backgrounds. | n/a | n/a |
| **Disability** | | **X** | | | n/a | n/a |
| **Gender** | | **X** | | | n/a | n/a |
| **Gender reassignment** | | **X** | | | n/a | n/a |
| **Pregnancy & Maternity** | | **X** | | | n/a | n/a |
| **Race** | | **X** | | | n/a | n/a |
| **Religion or belief** | | **X** | | | n/a | n/a |
| **Sex** | | **X** | | | n/a | n/a |

| | | | | | | |
|---|---|---|---|---|---|---|
| **Sexual Orientation** | | **X** | | | n/a | n/a |
| **Marriage / Civil Partnerships** | | **X** | | | n/a | n/a |
| **Human Rights** | | **X** | | | n/a | n/a |

| | |
|---|---|
| **Did any information gaps exist?** | None |

**Section 3:**
Based in the information in section two, what is the decision of the EHRI assessor? (select one option)

| | |
|---|---|
| ☒ | No equality or human right impact (your analysis shows there is no impact) |
| ☐ | No major change required (analysis shows no potential discrimination, harassment) |
| ☐ | Adverse impact but continue (recorded justification for continuing despite the impact) |
| ☐ | Adjustment required to mitigate potential effect -progress after changes made |
| ☐ | Place on hold and seek advice |

| | |
|---|---|
| **Conclusion** | The Patient Safety Incident Response Framework (PSIRF) has been rigorously assessed for its impact on equality across all characteristics defined in the Equality Act 2010. The framework applies universally and ensures equitable access to all patient demographics. Through stakeholder consultations, data-driven assessments, and alignment with existing organisational policies, the PSIRF demonstrates a commitment to neutrality and non-discrimination. Provisions for ongoing monitoring, staff training, and redress mechanisms further support its neutrality. Therefore, it is concluded that the PSIRF does not adversely impact any particular group and is consistent with the principles of fairness, equality, and legal compliance. |
| **How will you review and measure the impact after implementation?** | Will be monitored in line with scheduled policy reviews. |

**Sign off**

| | | | |
|---|---|---|---|
| **Completed by:** | Joel Booth | **Date** | 25/09/2023 |
| **Checked and signed off by Compliance:** | Joel Booth | **Date** | 25/09/2023 |