

Patient Safety Incident Response Framework (PSIRF)

Today (16 August) NHS England has published its [Patient Safety Incident Response Framework \(PSIRF\)](#), which replaces the Serious Incidents Framework (SIF). The new framework aims to provide guidance to local healthcare systems on how to conduct “strategic, preventative, collaborative, fair and just, credible and people focused” investigations into any safety breaches. This follows the [introductory version of the PSIRF](#), published in 2020, which was piloted with 17 early adopter organisations, whose feedback helped inform this final version.

This briefing summarises the key points from the framework – which is made up of [eight framework documents and 22 learning response tools](#) and resources - along with NHS Providers’ view and [press statement](#).

If you have any questions about this briefing or the implementation of the PSIRF, please email Keegan Shepard, policy advisor for quality (keegan.shepard@nhsproviders.org).

Key points

- [The Patient Safety Incident Response Framework \(PSIRF\)](#) – a core element of the [NHS Patient Safety Strategy](#) – establishes the NHS’s approach to the development and maintenance of mechanisms for responding to patient safety incidents (PSIs) to maximise learning and improvement.
- The PSIRF is a contractual requirement and is mandatory for providers of NHS-funded care. All trusts will be expected to begin implementing this framework from September 2022.
- The new framework replaces the [Serious Incident Framework \(SIF\)](#). The PSIRF is less prescriptive than its predecessor, encourages learning from PSIs, and no longer differentiates between PSIs and serious incidents.
- Additionally, unlike the SIF, the PSIRF requires a degree of training to ensure that those conducting investigations – as well as those providing oversight of the process – have an adequate level of knowledge and experience to ensure that investigations lead to learning and improvement.
- The PSIRF has four key aims with regards to patient safety incidents: compassionate engagement and involvement of those affected; a system-based approach to learning; considered and proportionate responses; supportive oversight focused on strengthening response systems and improvement.

- It is not expected that organisations will fully implement the PSIRF on the day of its publication. The implementation process will begin from September 2022 and will take approximately twelve months. Implementation phases are outlined within the [preparation guide document](#).
- PSIRF represents a significant change in approach for trusts. NHS England will be offering support throughout the implementation period, including through a series of webinars and [via a series of tools published today](#).

Background

The PSIRF establishes the NHS's approach to the development and maintenance of effective systems and processes for responding to patient safety incidents (PSIs) in a way which facilitates learning and improvements to patient safety. It replaces the existing SIF, with the aim of focusing on learning within and across organisations. The PSIRF aims to introduce a more proportionate approach to investigating PSIs by balancing the resources allocated to learning with those needed to deliver improvement.

The PSIRF is less prescriptive than its predecessor. Significantly, it no longer maintains the "serious incidents" classification and threshold, and does not differentiate between PSIs and "serious incidents". It changes how NHS responds to PSIs for learning and improvement, including by:

- advocating for a co-ordinated and data-driven response to incidents, prioritising compassionate engagement with those affected;
- embedding patient safety incident response within a wider system of improvement and prompting a cultural shift towards systematic patient safety management.

To comply with the PSIRF, organisations must develop an understanding of their patient safety incident profile, ongoing safety actions in response to investigation recommendations, as well as established programmes of improvement. To facilitate this, organisations will be expected to collect information from a multitude of sources, including broad engagement with relevant stakeholders.

About the PSIRF

Achieving effective learning and improvement using PSIRF

The [PSIRF's core document](#) brings together the following four main aims:

- 1 Compassionate engagement and involvement of those affected by patient safety incidents
- 2 Application of a range of system-based approaches to learning from patient safety incidents
- 3 Considered and proportionate responses to patient safety incidents

- 4 Supportive oversight focused on strengthening response system functioning and improvement

What are trusts required to do?

The PSIRF is a contractual requirement under the [NHS Standard Contract](#) and is mandatory for the provision of services under this contract, including all acute, mental health, community and ambulance trusts, as well as maternity and specialised services across the NHS. Organisations are required to apply and embed the PSIRF into the development and maintenance of their PSI response policy and plan, via the following:

Patient safety incident response policy

This should describe an organisation's overall approach to responding to and learning from PSIs, as well as to identify the systems and processes in place to integrate the four key aims of PSIRF. It should outline how those affected by an incident will be engaged, what governance processes for oversight are in place and how learning responses are translated into improvement and integrated into wider improvement work across the organisation. A [national policy template](#) is available.

Patient safety incident response plan

This should specify how an organisation will maximise learning and improvement. It should be based on a thorough understanding of the organisation's patient safety incident profile, ongoing improvement priorities, available resources and the priorities of stakeholders, including patients and local Healthwatch. A [national plan template](#) is available.

Plans will need to be updated to incorporate any new learning, the changing risk profile of an organisation, as well as any ongoing improvement initiatives. This will ensure that incident response becomes a key element of the organisation's approach to wider safety management.

PSIRF and inequalities

The PSIRF has been developed to provide a mechanism to help address inequalities in patient safety through the following:

- Its flexible approach makes it easier to address concerns specific to health inequalities, and it provides the opportunity to learn from PSIs that did not meet the definition of a 'serious incident';
- It prompts consideration of inequalities in the development and maintenance of patient safety incident response policies and plans, and in the learning response process it describes;
- It gives guidance on engaging those with diverse needs; and

- The framework endorses a system-based approach (instead of a 'person focused' approach). This will support the development of a just culture and aims to reduce gaps in rates of disciplinary action between ethnic groups across the NHS workforce.

Accompanying guidance

Alongside the core PSIRF document, the following pieces of accompanying guidance provide information for trusts to support implementation:

- 1 Preparation guide
- 2 Oversight roles and responsibilities specification
- 3 Guide to responding proportionately to patient safety incidents
- 4 Patient safety incident response standards
- 5 Engaging and involving patients, families and staff following a patient safety incident

This briefing will summarise these five main framework documents and will outline the tools available to help trusts navigate the process of implementation.

Preparation guide

The PSIRF represents a sizeable shift in the NHS's approach to responding to PSIs for learning and improvement. It is not prescriptive and instead advocates for a coordinated and data-driven approach to PSI response. It embeds a PSI response within a wider system of improvement, and prompts trusts to manage patient safety in a systematic way.

The new framework cannot be implemented over a short period as it requires trusts to design and implement a new set of systems and processes. Building upon the insight from the 17 early adopter organisations, who piloted the introductory version of this framework starting in 2020, NHS England developed a [preparation guide](#) to support trusts to implement the PSIRF over a twelve-month period from September 2022. This preparation guide provides a structure and timeline for those leading PSIRF implementation within their trusts.

The table below provides a breakdown of the phases that those leading the PSIRF will need to work through to deliver the new way of working.

TABLE 1: PURPOSE OF PSIRF PREPARATION PHASES

Phase	Duration	Purpose
PSIRF orientation	Months 1–3	To help PSIRF leads at all levels of the system familiarise themselves with the revised framework and associated requirements. This phase establishes important foundations for PSIRF preparation and subsequent implementation.
Diagnostic and discovery	Months 4–7	To understand how developed systems and processes already are to respond to patient safety incidents for the purpose of learning and improvement. In this phase strengths and weaknesses are identified, and necessary improvements in areas that will support PSIRF requirements and transition are defined.
Governance and quality monitoring	Months 6–9	Organisations at all levels of the system (provider, ICB, region) begin to define the oversight structures and ways of working once they transition to PSIRF.
Patient safety incident response planning	Months 7–10	For organisations to understand their patient safety incident profile, improvement profile and available resources. This information is used to develop a patient safety incident response plan that forms part of a patient safety incident response policy.
Curation and agreement of the policy and plan	Months 9–12	To draft and agree a patient safety incident response policy and plan based on the findings from work undertaken in the preceding preparation phases.
Transition	Months 12+	Organisations continue to adapt and learn as the designed systems and processes are put in place.

NHS England does not expect trusts to strictly adhere to the phases as set out in the timetable above.

Reflecting the new statutory framework following the passage of the [Health and Care Act](#) earlier this year, NHS England intend this guide to be used to support collaboration within and across integrated care systems (ICs).

Oversight roles and responsibilities specification

The leadership and management functions of PSIRF oversight are now much broader and multi-faceted when compared to its predecessors. When implementing and using the PSIRF, trusts should design their oversight systems in a way which evidences improvement rather than compliance. Trusts are encouraged to not only explore what needs to be improved, but also what they should stop doing.

Oversight approach

When designing and maintaining the PSIRF oversight systems and processes, NHSE has outlined six principles which trusts should consider. These are:

- 1 Use a variety of data
- 2 Reduce the information collection burden
- 3 Oversight is not 'one size fits all'
- 4 Capture meaningful insight from patients, families, and staff
- 5 Metrics require clarity and purpose
- 6 Beware of perverse incentives

Organisational responsibilities

NHS England has outlined several organisational responsibilities for an effective governance structure. Trust boards should be mindful of the following:

- **Appointment of a PSIRF executive lead:** This may be the individual with an overarching responsibility for quality or patient safety, and they must be a member of the board or equivalent leadership team.
- **PSIRF executive lead responsibilities:** The PSIRF executive lead should ensure the organisation meets national patient safety incident response standards, overseeing the development, review and approval of the organisation's policy and plan for patient safety incident response. They should ensure PSIRF is central to overarching safety governance arrangements, and that patient safety incident reporting and response data, learning response findings, safety actions, safety improvement plans, and progress are discussed at the board or leadership team's relevant sub-committee(s). Finally, they should quality assure learning response outputs.

This guidance also provides a series of questions that can be used to guide provider boards and/pr leadership teams in overseeing patient safety incident response. These questions, and more information on the responsibilities for ICBs, NHSE local teams, the NHS national patient safety team, the Care Quality Commission (CQC) and the oversight of maternity patient safety incident response, can be found in the guidance on [oversight roles and responsibilities specification](#).

Other types of review and/or investigation

There are existing types of incident trigger mandated specific responses; however, the PSIRF does not change the requirements for these. Trusts may find that in some circumstances, learning responses under PSIRF will coincide with other responses.

Improving incident response through collaborative external review

A key element of improving the process of learning from PSIs involves external peer review of a sample of learning response reports which have been previously signed off by a trust board. Trusts should outline the proportion of responses that will be externally reviewed and outline the approach within their [patient safety incident response policy](#).

Guide to responding proportionately to patient safety incidents

The PSIRF does not mandate investigation as the sole method to produce meaningful learning from PSIs, nor does it prescriptively outline what can and cannot be investigated. Instead, it is a framework which supports the development and maintenance of a patient safety incident response system. This guidance describes what is meant by a system-based approach to learning and taking a proportionate approach to a patient safety incident response, as well as how to achieve these aims through robust patient safety incident response planning.

It should be used in accordance with the [national patient safety incident response policy and plan templates](#).

What is a 'system-based approach' to learning?

Unlike the Serious Incident Framework (SIF), which had a defined threshold for serious incidents, the PSIRF instead focuses on a system-based approach, which involves an examination of the components of a system - including a person(s), tasks, tools and technology, the environment and the wider organisation – to gain a deeper understanding of how their interdependencies might impact patient safety. This suggests that patient safety emerges from complex interactions and is not a result of an individual cause, such as one person. As a result, the PSIRF no longer utilises root cause analysis (RCA) and differs from it in the following ways:

- They recognise that outcomes in complex systems result from the interaction of multiple factors – learning should not focus on uncovering a (root) cause, but instead should explore multiple contributory factors
- They do not distinguish between care and service delivery problems. Instead, they explore contributory factors, including 'individual acts' in the context of the whole system
- They use tools to explore multiple interacting contributory factors rather than forcing a single analytical pathway

- A framework based on the well-established [SEIPS \(Systems Engineering Initiative for Patient Safety\)](#) replaces the contributory factors classification framework, a guide for which can be found in the [patient safety incident response toolkit](#)

What does 'considered and proportionate response' mean?

The PSIRF supports organisations to respond to PSIs using an approach which will maximise learning and improvement not based on subjective definitions of harm. While some events and issues will arise which will require a special type of response as dictated by policies or regulations (such as the [Never Events](#) or [learning from deaths criteria](#)), the PSIRF helps organisations conduct investigations relevant to their context and the populations they serve.

There are no new national rules of thresholds to determine what type of response is necessary and organisations can now balance effort between learning through responding to incidents or exploring issues and improvement work.

Patient safety incident response planning

Under the PSIRF, each organisation's patient safety incident response plan will outline how they will respond to PSIs over a period of 12 to 18 months. The four stages of planning response methods are:

- 1 Examine patient safety incident records and safety data
- 2 Describe safety issues demonstrated by the data
- 3 Identify improvement work underway
- 4 Agree response methods

The plan for patient safety incident response must be approved by the relevant integrated care board (ICB), other commissioning leads, and the board of the organisation.

Trusts should review their plans frequently in the early stages of implementation, and NHSE suggest the plan remains a "living document" - which can be amended and improved according to the needs of the organisation. Trusts should review their plan every 12 to 18 months.

Patient safety incident response activity

While full method guides should be reviewed in full within the [patient safety incident response toolkit](#), patient safety incident response activity can be divided into three overarching categories:

- **Learning to inform improvement:** Several system-based learning response methods are available for trusts to respond to a PSI.

- **Improvement based on learning:** Where an incident type is well understood, resources may be better directed at improvement rather than an investigation.
- **Assessment to determine required response:** When an organisation is unable to easily identify where an incident fits into their plan – for example, if a learning response is required – they may need to perform an assessment to determine if there were any problems in care that require further exploration and action.

Patient safety incident response standards

To ensure that providers meet the minimum expectations of the PSIRF, NHSE has outlined standards for trusts to uphold on: policy, planning and oversight; competence and capacity; engagement and involvement of those affected by patient safety incidents; and proportionate responses.

Each of these aspects cover many requirements for trusts, and so while we provide a short summary below, we would suggest reading the guidance in its entirety when implementing this framework.

Policy, planning and oversight

Trusts are required to develop a patient safety incident response policy which describes the systems and processes they have established to facilitate learning and improvement following a PSI. These should create the foundations for effective incident response from the outset. Where patient safety incident response standards are not reached at the time the policy is approved, a 'road map' outlining feasible targets for this to be achieved must be created.

When using the PSIRF, trusts, ICBs and regulators should design their systems for oversight "in a way that allows organisations to demonstrate [improvement], rather than compliance with prescriptive, centrally mandated measures".

Competence and capacity

Learning response leads, those leading engagement and involvement, as well as those in PSIRF oversight roles, are required to have specific knowledge and experience. Organisations may differ in how they approach engagement and involvement, and this activity may be led by the person leading a learning response, or by a family/staff liaison officer, or someone similar. The patient safety incident response standards distinguish between the training requirements and competencies for these two roles but recognise they might be fulfilled by the same individual.

The PSIRF calls for significant resourcing and staff time to ensure that the learning responses from PSIs are carried out to standard, and a table overview of training requirements is detailed in full in the Appendix to [the Patient safety incident response standards](#).

Engagement and involvement of those affected by patient safety incidents

The engagement and involvement with those affected by PSIs, as outlined within the [relevant guidance](#), should be led by individuals with a specified level of training. All organisations are required to ensure that the [Duty of Candour](#) is upheld.

Proportionate responses

The PSIRF outlines guide timelines for patient safety learning responses and asks for them to begin as soon as possible after the incident is identified. The response methodology outlined in the framework asks that responses are conducted for the sole purpose of learning and identifying improvements that reduce risk and/or prevent or significantly reduce recurrence and that they do not seek to determine liability and blame.

Training requirements

A key element of the PSIRF is that those conducting investigations – as well as those providing oversight – will now be required to have specific knowledge and experience gained through training, including developing knowledge of systems thinking and system-based approaches to learning from PSIs.

Engaging and involving patients, families and staff following a patient safety incident

To lead to meaningful improvement and learning following a PSI, the PSIRF rightly emphasises the need for robust systems and processes to be established which prioritise a compassionate engagement and involvement approach.

This guidance focuses on outlining how organisations can achieve compassionate engagement and involvement through:

- supporting organisations to ensure they have an effective process of engagement and involvement with those affected by PSIs
- providing practical advice to support compassionate engagement with those affected by PSIs
- providing practical advice to enable meaningful involvement as part of a patient safety incident investigation (PSII)

Creating the right foundations

The PSIRF highlights the foundations required for effective and compassionate engagement, including leadership, training and competencies, support systems, ensuring inclusivity, information resources, processes for seeking and acting on feedback, as well as processes for managing dissatisfaction.

Additionally, the [patient safety incident response standards](#) outlined the required competencies for engagement leads – which must be applied in all forms of communication with those affected by PSIs.

Engagement and involvement process

The PSIRF details the process of engaging and involving affected individuals and emphasises the importance of treating staff and families seriously as well as with compassion and understanding. When a family or staff member informs an organisation that something has gone wrong, they must be taken seriously from the outset and treated with compassion and understanding.

Aligned with the [Duty of Candour](#), the guidance outlines the process for achieving compassionate engagement with those affected by PSIs.

The guidance also provides an itemised list of useful resources and references, as well as includes a section on additional considerations, which outline further detail to inform other practical elements of engagement, including keeping good records, addressing communication barriers, as well as utilising language services.

Response tools and additional resources for PSIRF

NHS England developed several tools and resources to support trusts to successfully implement the PSIRF over the next twelve months from September 2022.

Response tools

TABLE 2

Type of response tool	Individual resources and links
Patient safety incident investigation report template	<ul style="list-style-type: none"> – Patient safety incident investigation (PSII) report template
System Engineering Initiative for Patient Safety (SEIPS) framework	<ul style="list-style-type: none"> – SEIPS quick reference guide and work system explorer – SEIPS blank template

Preparation	<ul style="list-style-type: none"> – Information reference log – Stakeholder map (simple) – Stakeholder map (visual) – Terms of reference (ToR) for investigation
Learning responses	<ul style="list-style-type: none"> – After action review – After Action Review – Learning handbook – Multidisciplinary team (MDT) review – Patient safety incident investigation – Swarm huddle
Everyday work guides	<ul style="list-style-type: none"> – Interview tool – Brief guide to link analysis – Brief guide to conducting observations – A brief guide to walkthrough analysis
Responding to broad patient safety issues	<ul style="list-style-type: none"> – Horizon scanning tool – Thinking thematically: top tips for completing a thematic review
Synthesis:	<ul style="list-style-type: none"> – Timeline mapping – Work system scan and interaction map
Developing safety actions	<ul style="list-style-type: none"> – Safety action development guide – SHARE debrief tool

Additional resources

To support providers to start the process of preparing for the PSIRF, NHS England will be hosting a [webinar on 5 September 2022 at 2pm](#). This will introduce the PSIRF and accompanying guidance, an outline of the six preparation phases, details of available support, and the opportunity to ask questions. Similar sessions will be held quarterly.

NHS Providers view

We welcome the Patient Safety Incident Response Framework (PSIRF) as it enables a valuable shift in how providers respond to patient safety incidents through the emphasis on effective learning and improvement. The PSIRF replaces the methodology of root cause analysis with a systems-based patient safety incident investigation (PSII) approach.

In particular, we welcome the broader and more inclusive approach towards incidents and investigations. This includes the expansion of the set of criteria for an investigation beyond those set out in the previous Serious Incidents Framework (SIF), which now include all incidents which caused, or could lead to, harm. There is also a helpful emphasis on supporting those involved in investigations and the need for investigators to have adequate training. Investigations will also benefit from more appropriate timescales and a refreshed approach to governance.

NHS England has worked extensively with early adopter organisations to ensure that their feedback helped shape the nationally rolled out framework. Additionally, we welcome the flexibility of the transition period from the SIF to the PSIRF, which takes place over the next twelve months. Furthermore, trusts will appreciate the quarterly webinars run by NHS England to provide a platform to address any queries or concerns. Throughout this roll out, we will ask that NHS England is mindful of the pressures that trusts face and provide proportionate support and flexibility as they implement these important changes.

NHS Providers press statement

Commenting on the Patient Safety Incident Response Framework, the interim deputy chief executive of NHS Providers, Miriam Deakin said:

“Securing better patient safety and outcomes is a top priority for trust leaders and so we welcome this comprehensive framework, which will help ensure that investigation processes and responses by trusts lead to effective learning and improvement.

“This framework has key differences from its predecessor, the Serious Incident Framework, including making better use of data, supporting appropriate patient safety training where it is needed, and focusing work into areas in which the most impact may be achieved.

“It is good to see a renewed focus on avoiding a blame culture to one that is just and recognises wider systemic failings, and the commitment to giving trusts the autonomy to target resources on investigations that will lead to organisational learning and improvements.

“The use of early adopter organisations since 2020, including several trusts, will help ensure that this framework will be a useful and meaningful tool.

“Given the operational pressures that trusts are currently facing, it is welcome that flexibility has been built into the implementation process, with a twelve-month timeline starting next month.

“However, implementation will be challenging without a bolstered workforce and adequate time for staff to attend training. This is yet another example of why we urgently need to see a fully costed and funded workforce plan.

“Beyond staffing, national bodies must remain engaged with trusts to understand the challenges they face and the risks they manage, and to ensure that trusts have the necessary resources, capacity and time required to ensure that this framework is properly embedded.”