South West Yorkshire Partnership NHS Foundation Trust

Document name:	**Patient safety incident response policy**
Document type:	Policy
What does this policy replace?	New policy
Staff group to whom it applies:	All staff within the Trust
Distribution:	The whole of the Trust
How to access:	Intranet
Issue date:	December 2023
Next review:	November 2026
Approved by:	Executive Management Team 23 November 2023
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1. Introduction

This policy supports the requirements of NHS England's Patient Safety Incident Response Framework (PSIRF) and the NHS standard contract. It explains South West Yorkshire Partnership NHS Foundation Trust's (the Trust) approach to developing and maintaining effective systems and processes for responding to patient safety incidents and safety issues for the purpose of learning and improving patient safety.

2. Purpose

Patient safety incidents are any unintended or unexpected events which could have, or did, lead to harm for one or more patients receiving healthcare. The policy document follows the national PSIRF policy template.

The 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 a significant cultural shift towards systematic patient safety management.

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

- compassionate engagement and involvement of those affected by patient safety incidents
- application of a range of system-based approaches to learning from patient safety incidents
- considered and proportionate responses to patient safety incidents and safety issues
- supportive oversight focused on strengthening response system functioning and improvement

There are a number of other Trust policies which include detail about the management of specific types of patient safety incidents. When these policies are next reviewed, the language will be updated to reflect that some patient safety incidents may require a learning response as set out in the Trust's Patient Safety Incident Response Plan. A link to the plan should be included. Specific details of learning responses will not be included in separate policies due to potential for changes to our plan.

3. Definitions

A glossary of terms used in included at the end of this document.

4. Principles

4.1. Scope

This policy is specific to patient safety incident responses conducted solely for the purpose of learning and improvement and applies to all services across the Trust.

Incidents that do not relate to patient safety are not covered by this policy. Staff should refer to the Incident reporting, management and learning response procedure and the Health and Safety policy.

This policy is supported by a range of other policies and procedures including:

- Incident reporting and management
- Learning responses
- Involving and engaging with those affected by patient safety incidents
- Duty of candour
- Learning from healthcare deaths

Responses under this policy follow a systems-based approach. This recognises that patient safety is provided by interactions between components of a complex healthcare system and not from a single component. Responses do not take a 'person-focused' approach where the actions or inactions of people, or 'human error', are stated as the cause of an incident.

Other reviews, investigations and responses that are conducted for the reasons listed below, differ from the aims of a patient safety response and are therefore outside the scope of this plan, but we acknowledge a learning response may be shared to support other processes as needed.

- Complaints management
- Claims handling
- Human resources investigations into employment concerns
- Professional standards investigations
- Coroner's inquests
- Criminal investigations

4.2. Our patient safety culture

Culture is a huge factor in the safety of a healthcare system. An environment where all staff feel supported and psychologically safe, will be one that fosters inclusivity, with all staff confident to be open, honest and transparent when incidents occur and where they feel able to speak up.

We have been moving towards a restorative and just culture that underpins how we will approach our incident responses. We foster a culture in which people feel they can highlight incidents knowing they will be psychologically safe.

We encourage staff to raise concerns and risks about patient safety where they are worried about something that has the potential to cause harm. We have a range of methods of reporting patient safety incidents or concerns including our incident reporting system (where staff can report anonymously if they wish to), line management structures and freedom to speak Up guardians. Our patient safety support team can also be approached to raise issues directly.

As a Trust, we are working towards becoming a trauma informed organisation which means:

- Developing a culture of compassionate leadership supporting clinical and non-clinical staff.
- Safeguarding all staff against adverse workplace experiences such as stress, burnout and vicarious trauma.
- All staff are provided with opportunities for supervision and support; to reflect, learn and recover/discover.
- Focus on “what happened to you” rather than “what’s wrong with you”.
- Environment, facilities, policies and corporate functions avoid re-traumatisation and ensure a sense of safety for all.

We want the Trust to be a great place to work for everyone. Colleagues tell us they want to feel safe at work and this includes a workplace that is free from bullying or harassment. Our People policies support the Trust's values and encourage a culture based on civility and respect. We have implemented a resolution process that reflects a learning culture.

4.3. Patient safety partners

We are excited to welcome the role of Patient Safety Partners (PSPs) to contribute alongside our staff, patients, families and carers to improving and influencing safety across our range of services.

PSPs can be patients, service users, carers, family members or other lay people. We see their role as a true partnership, drawing on their experience and having an active role in highlighting good practice and challenging where care, treatment or our processes are not as we would hope for, to ensure that the patient voice is heard throughout.

We aim to recruit a minimum of two PSPs and we hope they will be representative of the population we serve. We will be supporting our selected PSPs with bespoke training and continuous mentoring to ensure that they can help us with:

- developing the PSP role
- working collaboratively with our patient safety support team
- being part of our patient safety groups, including our committee
- reviewing our approach to PSIRF plan and policy implementation

- safety improvement work
- co-design our patient safety developments with the patient voice at the forefront of what we do

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

The 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) and considers individual and specific needs. 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.

When a patient, family or staff member tell us that they are concerned about a patient safety incident, such as where something did not appear to have gone as was intended or expected, or they are concerned about a patient safety risk, they will be taken seriously from the outset, and treated with compassion and understanding.

We will adapt our approach to meet the circumstances of each patient safety incident and the individuals affected. We are developing procedures on how we will engage and involve those affected by patient safety incidents. This will be available separately.

We will make sure we are open and honest about any patient safety incident. Many of our staff are accountable for this as part of their professional registrations. We will still ensure that we maintain our statutory (and personal professional) duty of candour for any incident that meets the threshold for a notifiable safety incident.

We will continue to develop the foundations of a system that supports compassionate engagement and involvement of those affected (in line with the Patient Safety Incident Response standards).

Procedures to support patients, families & carers affected by patient safety incidents

We recognise and acknowledge the significant impact patient safety incidents can have on patients, service users, their families, and carers.

PSIRF asks that we engage in a meaningful way with those affected by any patient safety incident; this means showing compassion and involving them to understand and answer any questions they have in relation to an incident.

This will aid our learning and improvement but, more importantly, allow us to support patients, service users, families and carers effectively. We want to be open and transparent with those affected by a patient safety incident because it is the right thing to do. This is regardless of the level of harm caused by an incident.

We have existing processes for engaging and involving patients, families and carers in our investigation processes which we are reviewing to ensure they are strengthened and expanded to meet the requirements of PSIRF for any patient safety incident. This will include how to involve and support those affected throughout a learning response.

Procedures to support staff affected by patient safety incidents

As a Trust we have been establishing a restorative just culture in response to incidents where something did not appear to have gone as was intended or expected. The Trust is committed to ensuring that patient safety incident learning responses are conducted for learning and improvement purposes only.

We have existing processes for engaging and involving our staff in investigations and to provide support when traumatic incidents occur. We are reviewing these processes to ensure they meet the requirements of PSIRF guidance which will be developed into our procedures. This will include how to involve and support staff throughout a patient safety incident learning response.

We have developed guidance on our new learning response methods which include prompts on the importance of creating psychological safety to allow for full openness and transparency.

Our staff are valued and they can give us key insights into their work on a day to day basis. For those affected who need additional support, we will provide information in our engaging and involving staff procedures. This will include using our excellent and well-established health and wellbeing services to signpost for any specific concerns that may arise. We want everyone's voice to be encouraged, valued and listened to, helping us to continually learn, inspire change and improvement.

Staff are encouraged to report patient safety incidents whether they resulted in harm or not, and they can expect to receive feedback from the reviewing manager. We also have the facility for staff to report incidents anonymously. Staff can also raise concerns about patient safety in other ways including through line managers and senior management teams, the Trust Whistle blowing policy, Freedom to Speak up Guardians and networks. Patient Safety Support Team can also be contacted for advice.

4.5. Patient safety incident response planning

PSIRF supports organisations to respond to incidents and safety issues in a way that maximises learning and improvement, rather than basing responses on arbitrary and subjective definitions of harm. Beyond nationally set requirements, the Trust will explore patient safety incidents relevant to our context and the populations we serve rather than only those that meet a certain defined threshold.

Resources and training to support patient safety incident response

A significant risk to successfully implementing PSIRF is continuing to investigate as many things as possible but simply calling them something else. A key part of developing our PSIRF plan has been understanding the amount of patient safety activity we have

undertaken over the last few years. This enabled us to plan appropriately and to ensure that we have the people, system and processes to support the new approach, which will develop over time.

The patient safety related activity prior to PSIRF included undertaking serious incident investigations. These accounted for less than 0.5% of all patient safety incidents reported. This type of investigation was very time-consuming and often resulted in common action themes. This disproportionate focus on a small number of all patient safety incidents significantly limited time to learn thematically from the other 99.5% of patient safety incidents. The same was seen in our service level investigations which took service resource to undertake but often saw similar action themes to serious incidents.

PSIRF helps us to focus on the areas where we need to identify new learning; where something is not well understood already; or where we don't have improvement work underway.

We commissioned Consequence UK to deliver our PSIRF training. From this we will develop a condensed in-house training package for delivery to staff with a role in undertaking a learning response. This includes specialist advisors, ward/team managers and those in quality and governance roles. Managers and quality and governance roles will also receive training on engaging and involving those affected by patient safety incidents delivered by Consequence UK later in the year.

Our patient safety incident response plan

Our PSIRF plan sets out how the Trust intends to respond to patient safety incidents over a period of 12 months. The plan applies to all Trust services. It is not a permanent set of rules that cannot be changed. We will remain flexible and consider the specific circumstances in which each patient safety incident occurred and the needs of those affected.

In order to develop our plan, we examined patient safety incident records and safety data, engaged with stakeholders, described our safety issues demonstrated by the data, identified our existing improvement work related to these safety issues and agreed our response methods, where we want to identify new learning. Further details are available in our PSIRF plan.

4.6. Responding to patient safety incidents

Patient safety incident reporting arrangements

It is the responsibility of the Trust to ensure that all incidents and near misses are reported, reviewed and actioned to prevent or minimise similar instances in the future. NHS England defines patient safety incidents as *"… any unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving healthcare."*

Staff should use the Trust's incident reporting system to report all patient safety incidents in line with the Incident reporting, management and learning response procedure.

The Trust also has clear and well developed 'freedom to speak up' arrangements, which are fully supported by senior leaders and communicated to staff during induction.

Patients, families, carers and the public are also advised and encouraged to record and share information about patient safety incidents through our customer services team.

The Trust reports patient safety incidents to external agencies in line with national guidance. This includes to:

- NHS England - National Reporting and Learning System (NRLS) or Learn From Patient Safety Events (LFPSE)
- Care Quality Commission (CQC)

Our Incident reporting, management and learning response procedure includes links to the full list.

4.7. Patient safety incident response decision-making

Patient safety incidents will be reported and reviewed on Datix. When potential patient safety incidents are identified through the complaints, claims or inquest process, the customer service team or legal services team will escalate as required.

Some incidents (based upon severity/level of harm or concern) will have additional level of information completed to aid decision making. This is called the Manager's 48-hour review. Most incidents will not require this level of information.

Patient safety incidents which meet our PSIRF plan will need to be considered for a learning response.

For most incidents, the incident record and, where relevant, the Manager's 48 hour review, will be used to help decide if a learning response is required. This information helps to understand if there are known contributory factors to the incident.

Staff will refer to the PSIRF plan (figure 8) to determine if the patient safety incident meets the requirements for consideration of a learning response.

Where a patient safety incident appears in the PSIRF plan, we will consider if the known contributory factors are covered in existing improvement work. Where this is the case, no individual learning response will be required, however we will provide feedback to those affected and update the incident record with the conclusion.

Where there are early contributory factors, concerns or questions identified, a learning response is likely to be required because there is opportunity to gather new learning. The most appropriate method will be selected in line with the plan. In some cases, an individual learning response will not be required as it will be reviewed as part of retrospective thematic review to explore wider systems learning. This will be set out in the plan.

Some patient safety incidents may meet the criteria for an individual patient safety incident investigation. Information (described above) will be screened initially by the patient safety support team and information shared with the patient safety oversight group to discuss the incident and if it meets the requirements for an individual PSII or other local learning response. Further detail is available in the Trust's Incident reporting, management and learning response procedure.

Appendix E illustrates an overview of our decision making process.

There will be patient safety incidents which do not appear in the PSIRF plan. This is usually because we understand the contributory factors well and have improvement work underway. These incidents will follow the normal incident reporting process and will not usually require a learning response.

However, there may be times when we identify emerging risks/concerns that are new or different. These need to be escalated for consideration initially through the care group governance structure. This is because we can include situations like this under PSIRF as an exception. We may agree to monitor the issue for a period to gather new intelligence before agreeing any learning response under PSIRF.

4.8. Patient safety incident investigation types

Patient safety incident investigations (PSIIs) are system-based responses to a patient safety incident for learning and improvement.

In line with our PSII training, we have identified two types of Patient Safety Incident Investigation (PSII) in our PSIRF plan, which sets out the circumstances when each will apply. Both types include in-depth systems analysis:

Individual PSII – for cases meeting the national priorities for PSII or a small number of locally defined individual patient safety incidents. These will be led by a Patient Safety Incident Investigator with relevant subject matter experts.
Thematic PSII project – systematic safety improvement project (regarding a broader theme or safety concern). These will be led by an Assistant or Associate Director from the nursing quality and professions directorate, supported by a patient safety incident investigator and project team. The scope of each thematic PSII project will be defined by the project lead and team.

4.9. Local learning responses types

We have a range of other local learning responses (see Appendix D) which will be used dependent upon the circumstances defined in the PSIRF plan.

4.10. Timeframes for learning responses

Individual PSII

Where an individual PSII is required (as defined in the PSIRF plan for both local and national priorities), we will firstly scope the incident by gathering information to inform our discussion with the patient and/or family. We will agree the start date and anticipated timeline for completion with the patient and/or family/carer.

Individual PSIIs will ordinarily be completed within one to three months of their commencement date, however in exceptional circumstances a longer timeframe may be required for completion of an individual PSII. In this case, any extended timeframe will be agreed between the Trust and the patient, family member or carer.

No individual PSII should take longer than six months. A balance will be drawn between conducting a thorough PSII, the impact that extended timescales can have on those involved in the incident, and the risk that delayed findings may adversely affect safety or require further checks to ensure findings remain relevant.

Where external bodies (or those affected by patient safety incidents) cannot provide information, to enable completion within six months or the agreed timeframe, the PSII lead will work with all the information they have to complete the response to the best of their ability; it may be revisited later should new information indicate the need for further investigative activity.

In rare and exceptional circumstances, where there is an external investigation into a patient safety incident, the Trust's PSII will not commence until permission from the external agency has been granted.

Thematic PSII project

Where we carry out a Thematic PSII systems analysis project for wider themes, the timescales will be agreed by the patient safety oversight group and the project lead. It is anticipated this approach will take between 6-12 months to conclude.

Details of timeframes for other local learning responses are set out in Appendix D.

4.11. Responding to cross-system incidents/issues

Where a patient safety incident occurs that involves more than one NHS organisation, we will work together to identify the lead organisation; this will usually be where the incident originated. All relevant stakeholders involved will work together in line with the PSIRF principles and our Memorandum of Understanding agreements. Wherever possible, we will undertake one single investigation or learning response. Areas for improvement identified through any learning response will be assigned to the relevant organisation to consider. We

will use our existing patient safety networks across the Trust's geography to support this. We will seek support from the Integrated Care System to help facilitate discussions as needed.

4.12. Safety action development and monitoring improvement

Learning responses may result in 'areas for improvement', where changes within the work system could reduce risk or potential harm.

Areas for improvement can be specific to local context or that of the wider organisation. We have developed a flowchart (Appendix E) to describe how we will use learning responses to inform improvement. We will further develop this to illustrate how we intend to monitor safety actions and safety improvement plans. Further details will be included in our procedures.

We have established systems for monitoring actions which we will continue to build upon. However, we recognise that we need to align our quality improvement and patient safety approaches more directly and PSIRF will strengthen this.

We will:

- Ensure that areas for improvement are always focussed on the work system
- Check first if an area for improvement is already included in a Trust safety improvement plan before we commence developing a safety action. This will reduce duplication of safety actions
- Where an area for improvement is already included in a safety improvement plan, new safety actions will not be required. We will note on Datix which safety improvement plan the issue aligns with
- Where an area for improvement requires a safety action, we will develop guidance on this
- All safety actions will be linked to the incident record on Datix (patient safety support team can advise on how to do this)
- Those affected by the patient safety incident will be updated to tell them how an area for improvement is being addressed, either through local safety action or through Trust wide safety improvement plan
- Through our patient safety governance and oversight processes, we will monitor and review safety actions and safety improvement plans to ensure the actions are impactful, sustainable and delivering the intended effect rather than focussing on monitoring the completion of specific activities or tasks
- Any issues with delivery will be escalated through patient safety governance and oversight processes
- All safety improvements should consider health inequalities and any disproportionate risk to patients with specific characteristics

4.13. Safety improvement plans

Safety improvement plans bring together findings from various responses to patient safety incidents and issues.

We have developed an overarching Trust safety improvement plan summarising our improvement work with links to topic specific plans, which either already exist, or were identified through developing our patient safety incident profile. An overview of this is included in our PSIRF plan. This approach has been taken due to the diverse nature of the services we offer. It allows us to align the oversight of specific improvement plans with the subject's existing governance structures, with oversight from the patient safety oversight group. This will support alignment of improvement efforts across the organisation. Our safety improvement plans will draw upon continuous knowledge gained through collectively reviewing the output from learning responses, safety actions, underlying, interlinked systems issues and other relevant intelligence. In some cases, we may align elements of our improvement plans with wider work across the local system or with the Integrated Care Board to consolidate safety actions and improvement work.

This aligns with our quality improvement approach and our journey to align patient safety with quality improvement, by introducing task and finish groups to drive improvement forward. Each specific safety improvement plan (by topic) has a lead person and is aligned to a Trust specialist governance group who will monitor progress with improvement work.

The lead for each safety improvement plan and/or relevant specialist governance group will escalate any concerns with delivery to the patient safety oversight group. Examples may include situations where resources are insufficient to robustly implement actions or influence improvement, e.g. where an investment in technology or a widespread systemic change may be the better option but is out of reach or scope of local expertise and funds.

Measurement is fundamental to any improvement programme. Without it, we may invest time and effort implementing changes that have little or no impact or, in the worst case, increase the risk of further harm.

Those responsible for designing and implementing improvement plans, as well as those designing safety actions in the Trust, will be trained in best practice approaches; this will include support in how to establish appropriate measures to enable meaningful and effective monitoring to determine whether the safety actions implemented are sustainable and are having the intended effect. Both outcome and process measures should be used to interpret the impact of actions and improvements and to inform how actions should be adapted if they fail to have the intended effect. We are developing training and further guidance for staff on managing safety actions and safety improvement plans.

5. Duties of those in oversight roles and their responsibilities

The leadership and management functions of Patient Safety Incident Response Framework (PSIRF) oversight are wider and more multi-faceted compared to previous response approaches. This section aligns with the requirements of NHS England for oversight roles and responsibilities. Detail of staff and managerial responsibilities in relation to application of the framework can be found in the Incident reporting, management and learning response procedures.

Trust Board

The Trust Board (or those with delegated responsibility, including members of board quality sub-committees), is responsible and accountable for effective patient safety incident management. This includes supporting and participating in cross-system/multi-agency responses and/or independent patient safety incident investigations (PSIIs) where required.

Our Trust board has identified our Chief Nurse/Director of Quality and Professions as our executive lead for PSIRF, who has specific responsibilities as defined below.

Executive lead for PSIRF

Our Chief Nurse/Director of Quality and Professions is our executive lead for PSIRF. There is a requirement that they must have the safety skills, knowledge and experience as described in the patient safety incident response standards.

It is the PSIRF executive lead's responsibility to:

- Provide direct leadership, advice, and support in complex/high profile cases, and liaise with external bodies as required.
- Ensure the organisation meets national patient safety incident response standards.
- The PSIRF executive lead oversees the development, review and approval of the organisation's policy and plan for patient safety incident response, on behalf of the Board, supported by the rest of the leadership team.
- Ensure PSIRF is central to overarching safety governance arrangements.
- Ensure that we have systems that support the engagement and involvement of those affected by patient safety incidents.
- Ensure that patient safety incident reporting and response data, learning response findings, safety actions, safety improvement plans, and progress are discussed at the quality and safety committee.
- Ensure roles, training, processes, accountabilities, and responsibilities of staff are in place to support an effective organisational response to patient safety incidents.
- Mechanisms for the ongoing monitoring and review of the patient safety incident response plan, delivery of safety actions and improvement must form part of the overarching quality governance arrangements and be supported by clear financial planning to ensure appropriate resources are allocated to PSIRF activities and safety improvement.
- The executive lead and their leadership team should monitor the balance of resources going into patient safety incident response versus improvement. Repeat responses should be avoided when sufficient learning is available to enable the development and implementation of a safety improvement plan.
- Updates to the policy and plan will be made as required as part of regular oversight processes.
- An overall review of the patient safety incident response policy and plan should be undertaken at least every four years alongside a review of all safety actions.
- Sign-off of all individual PSIIs is the responsibility of the Board of the organisation(s) involved, however the PSIRF executive lead will be responsible for reviewing PSII reports in line with the patient safety incident response standards and signing it off as

finalised on behalf of the Trust. They will be supported in this by relevant colleagues as appropriate.

- Patient safety incidents reviewed using learning responses other than PSII, will not require the approval of the PSIRF executive lead or leadership team, however they will ensure mechanisms are in place to evaluate the quality of response methods using a sampling approach.
- Organisations must have processes to ensure that all safety actions implemented in response to learning or wider safety improvement plan(s) are monitored, to check they are delivering the required improvement. Progress on individual actions will be reviewed at appropriate intervals using relevant data, and an overall assessment of the delivery of all safety actions as part of our review of our patient safety incident response plan.

The Trust has clear roles and responsibilities in relation to its response to patient safety incidents and learning response methods. Further details are provided in the Incident reporting, management and learning response procedure.

We will work collaboratively and share information with relevant stakeholders, including the relevant Integrated Care Board (ICB), Care Quality Commission (CQC) and others in relation to patient safety incidents through a range of routes including engagement meetings, reporting to NHS England and contract and quality reporting.

We will support continuous development across local systems and contribute to developing ideas and mutual support and learning through local patient safety networks.

Integrated Care Board/System (ICB)

Our ICB/s have oversight responsibilities, which will include:

- Collaborating with the Trust in the development, maintenance and review of our patient safety incident response policy and plan.
- Agreeing our patient safety incident response policy and plan including agreeing a transition date with the Trust.
- Overseeing and supporting the effectiveness of systems to achieve improvement following patient safety incidents.
- Supporting co-ordination of cross-system learning responses.
- Sharing insights and information across organisations/services to improve safety.

The Trust will share learning collated from our learning responses with the ICB at agreed intervals.

Care Quality Commission (CQC)

We will work with the Care Quality Commission (CQC) who will consider our ability to respond effectively to patient safety incidents, including whether change and improvement follow its response to patient safety incidents. CQC teams will assess the strength of the Trust's systems and processes for preparing for and responding to patient safety incidents in line with PSIRF and the related standards. CQC will be informed of high profile and complex

incidents as part of the co-ordinated response, as well as being provided with all statutory notifications as required by the Health and Social Care Act (2008) and set out in CQC's guidance on statutory notifications. CQC will assess how we can support the needs of those affected and take meaningful action in response to patient safety incidents. Where it specifically considers PSIIs, CQC's review will consider how these meet the national patient safety incident response standards.

Other types of review

Certain types of incidents will trigger mandated responses. PSIRF does not change existing requirements for these. In some circumstances learning responses under PSIRF will coincide with other responses, and when they do, co-operation and collaboration between partner agencies is essential to minimise duplication, uncertainty and/or confusion relating to the different processes, particularly for those affected.

Ideally, one learning response should be undertaken (by a team comprising representatives of relevant agencies) that meets the needs/requirements of all parties. In practice this can be difficult to achieve because learning responses have different aims/purposes, and none must be conflated to accommodate others. Where it is not possible to undertake a single investigation, duplication of effort should still be minimised, particularly with regards to communication with and requests made to those affected. In some circumstances, NHS England can advise and/or support where multiple external agencies are involved.

Healthcare Safety Investigation Branch (HSIB) or Health Services Safety Investigations Body (HSSIB)[1]

We will work with the Healthcare Safety Investigation Branch (HSIB) or its replacement (Health Services Safety Investigations Body [HSSIB]) on any national investigations regarding a patient safety concern as requested.

Coroners

The focus of any learning response method under PSIRF focusses on learning and improvement and will not make any judgement about cause of death.

The coroner's role is to find out who died and how, when, and where they died, particularly in relation to unnatural or violent deaths, where the cause of death remains unknown, or because the death took place in prison, police custody or another type of state detention, such as a mental health hospital. This may include an inquest hearing.

We have good relationships with our local coroners and have shared information about work to develop our patient safety incident response plan.

We will continue to review reported deaths in line with our Learning from Healthcare Deaths policy which follows national guidance. This includes a range of review methods, some of which will also be learning responses under PSIRF. Where a local learning response identifies that a death was thought to be more likely than not to have been due to problems in

[1] The Health Services Safety Investigations Body will build on the work of the Healthcare Safety Investigations Branch when it comes into effect.

care, it will be responded to with a Patient Safety Incident Investigation (PSII) in line with the nationally defined PSII criteria in our PSIRF plan.

We will respond when HM Coroner requests information, providing any requested document or, in cases where we have not generated a specific learning response, we will gather information to respond to the coroner's questions. Where the coroner suggests that there may have been patient safety issues, we will consider if a learning response method would be appropriate.

Medical examiners

Medical examiners are employed within acute hospitals. They are supported by medical examiner officers, and work to:

- Listen to the bereaved, increasing transparency and offering them the opportunity to raise concerns about care
- Improve the quality and accuracy of the medical certificate of cause of death
- Ensure notification of deaths to the coroner where appropriate

We will begin working with medical examiners in the identified acute hospitals for our services from April 2024. We will create guidance for staff as this develops.

Medical examiners do not carry out in-depth reviews, but when they identify concerns, they refer them to appropriate governance leads. This may include the Trust's Chief nurse or Chief medical officer, patient safety specialist and/or the Trust PSIRF lead. These leads will then ensure the death is considered for a response in line with the Trust's learning from deaths policy and patient safety incident response plan.

Where evidence, however identified, suggests problems in care were more likely than not to have led to the death occurring at the time that it did, a PSII must be undertaken, as described in the information above.

Improving incident response through collaborative peer review

An essential part of improving how we learn from patient safety incidents is external peer review of a sample of learning response reports that have been signed off by our executive lead. External review improves quality and reduces siloed approaches to learning that can embed unintentional bias. It can also anticipate future problems by reflecting on systems in place and any risks they carry. For example, from reviewing incident findings, areas for improvement and safety actions developed in other organisations, we can review our own practice to ascertain if 'this could happen here'.

As the nature of the services provided by the Trust differs across our footprint, we will work with our partner organisations to peer review a small sample of each other's learning responses to support collaborative learning. This will be facilitated initially through our local patient safety networks.

We will follow our plan and seek peer review of a minimum of five learning responses of varying methods. We will partner with the most appropriate organisation dependent upon the incident type and location.

We will also use this principle to support internal peer review across the Trust's footprint, where care groups and patient safety investigators can seek peer review from each other.

There may be cases where we seek external peer review where a learning response is not required, such as to seek another clinical opinion on the management of a case. This will be arranged on a case-by-case basis.

6. Process of developing, approving and reviewing policies

This policy has been developed in line with NHS England's patient safety incident response framework. It follows the national template.

Addressing health inequalities

Some patients are less safe than others in a healthcare setting. Our patient safety incident response processes aim to support health equality and reduce inequality supported by:

- Applying a flexible approach and intelligent use of data to help identify any disproportionate risk to patients with specific characteristics
- Introducing the new national Learn From Patient Safety Events (LFPSE) system which will give us improved data within our local risk management system in the future
- Applying PSIRF's more flexible approach to locally defining which incidents will require a learning response should make it easier to address concerns specific to health inequalities
- Our learning responses under PSIRF will uphold a system-based approach (not a 'person focused' approach). We will ensure staff have the relevant training and skill development to support this approach. This will support the development of a just culture and a positive effect on staff groups who have traditionally faced disproportionate disciplinary actions
- Ensuring that our learning response methods prompt consideration of inequalities, including when developing safety actions
- Considering the different needs of those affected by patient safety incidents through our approach to engaging and involving patients, families and staff as this develops
- Responding to any issues related to health inequalities as part of the implementation and review of our patient safety incident response policy and plan

An Equality Impact Assessment has been developed, available in Appendix A.

7. Dissemination and Implementation arrangements

This procedure will be disseminated in accordance with the Trust Policy for the development, approval and dissemination of policy and procedural documents (policy on policies). Once approved, the Quality Improvement & Assurance Team (QIAT) will be responsible for ensuring the updated version is added to the document store on the intranet and will be communicated to staff via the Headlines weekly communication to staff.

8. Process for monitoring compliance with effectiveness

Complaints and appeals

The Trust listens and responds to patients, their carers and staff to help improve the services we deliver.

Any patient or their family member or carer can make any comments, compliments or raise concerns about our approach to the Trust's patient safety incident response process, through our Customer Services Team:

Freephone number: 0800 587 2108
Email: customerservices@swyt.nhs.uk

Staff members can provide feedback about our approach to the Trust's patient safety incident response process through:

- Identified leads conducting a learning response
- Line managers or through the care group governance/management structure
- Patient safety support team
- Patient safety specialists
- Freedom to speak up guardians
- Staff support processes
- Executive lead for PSIRF

A living and responsive plan

Our patient safety incident response plan is a 'living document' that will be appropriately amended and updated as we use it to respond to patient safety incidents.

Issues that emerge that are not currently covered by the plan, will be logged for future review and consideration for inclusion in future versions.

We will evaluate our learning response outputs after a minimum of 6 months of use using a recognised tool for this purpose.

Emerging patient safety risks will be considered for escalation through our local care group governance processes and may be escalated to the patient safety oversight group. The resulting discussion and action may include a range of options:

- Ongoing data collection and monitoring.
- Establish a task and finish group to request further exploration of the concerns and identifying any improvement areas.
- Reviewing findings of task and finish groups to agree next steps and if the patient safety incident response plan will remain unchanged, if additions are required or if further improvement work is needed.

9. Review and revision arrangements

This Patient safety incident response policy will be considered and agreed by relevant representatives from internal and external stakeholder groups before being approved by the Trust Board. This document will be published on the Trust's website alongside our PSIRF plan.

Review date

Our patient safety incident response policy will also evolve over time as we become more familiar with working under PSIRF, and in the spirit of the framework, we will reflect and learn from our experience to make improvements. We will undertake an overall review of the patient safety incident response policy and plan at least every four years to allow time for ongoing improvement work to embed which should then change our patient safety incident profile.

However, we will carry out an interim review of our PSIRF plan around 12-18 months post implementation to reflect on our journey so far and allow us to make any adjustments to our patient safety priorities, improvement work and learning response methods.

As we continue to develop, the related procedure documents will be updated. Updated plans will be published on our website, replacing the previous version.

10. References

Patient Safety Strategy
Engaging and involving patients and families following a patient safety incident procedure (under development)
Engaging and involving staff following a patient safety incident procedure (under development)
Duty of candour policy (under development)
Incident reporting, management and learning response procedure
Learning from Healthcare Deaths policy
Freedom to Speak up strategy
Customer Services policy (complaints, concerns, compliments)
Health and safety policy

11. Associated documents

Patient Safety Strategy NHS England
Patient Safety Incident Response Framework (PSIRF) and associated documents
Never Event Policy and Framework. NHS Improvement
A Just Culture Guide NHS England

Appendix A - Equality impact assessment (EIA)

Date of EIA: 8/8/2023 **Review Date: August 2026**

Completed By: Helen Roberts Patient Safety Specialist

	QUESTIONS	ANSWERS AND ACTIONS
1	**What is being assessed?** Prompt: what is the function of this document (new or revised)	The Patient Safety Incident Response Policy is a new overarching policy, which is a component of the Trust's Patient Safety Strategy. It sits alongside a Patient Safety Incident Response Plan. An EIA was completed for the Patient Safety Strategy in 2020. The existing related EIA has been reviewed and updated. The Patient Safety Incident Response Policy will have a series of related Standard Operating Procedures aligned with it, which will use the same updated EIA.
2	**Description of the document** Prompt: What is the aim of this document	The Patient Safety Incident Response Policy arises from elements of the Trust's patient safety strategy which aligns directly with NHS England's Patient Safety Strategy (July 2019) and as such we have referred to that document's Equality Impact Assessment. The **Patient Safety Incident Response Framework** introduces new approaches and expectations with particular relevance to patients, families and carers including: • The ability to take a broader system or theme-based approach to responding to incidents. • consideration of protected characteristics • Need for improved transparency and support for those affected. • Timescales for patient safety incident investigations agreed wherever possible with patients, families and carers. We know that nationally it is recognised that some patients are less safe than others in a healthcare setting. Our patient safety incident response processes aim to support health equality and reduce inequality supported by: Our plan sets out how we aim to apply a flexible approach and intelligent use of data to help identify any disproportionate risk to patients with specific characteristics. The introduction of a new national Learning From Patient Safety Events (LFPSE) system which will give us improved data within our local risk management system in the future. The PSIRF's more flexible approach to locally defining which incidents will require a learning response should make it easier to address concerns specific to health inequalities. All our learning responses under PSIRF will uphold a system-based approach (not a 'person focused' approach). We will support the development of a just culture and a positive effect on staff groups who have traditionally faced disproportionate disciplinary actions. All safety improvements should consider health inequalities and any disproportionate risk to patients with specific characteristics. We will consider the different needs of those affected by patient safety incidents through our approach to engaging and involving patients, families and staff as this develops. Under the Equality Act 2010 we have analysed the potential impact of the Patient Safety Incident Response Policy and Plan on health equality and on groups with protected characteristics. We have

		considered each element separately and used available evidence to inform our assessment. This assessment demonstrates that the Patient Safety Incident Response Policy and Plan will make an overall positive contribution to advancing equality in relation to patient safety incident learning and improvement. We do not anticipate its implementation will have any negative impact on equality for people with protected characteristics.
3	**Lead contact person for the Equality Impact Assessment**	Chief Nurse/Director of Quality and Professions
4	**Who else is involved in undertaking this Equality Impact Assessment**	Associate Directors of Nursing, Quality and Professions, Deputy Director of Nursing Quality and Professions, Assistant Directors for Nursing Quality and Professions, Patient Safety Specialist
5	**Sources of information used to identify barriers etc** Prompts: service delivery equality data – refer to equality dashboards (BI Reporting - Home (sharepoint.com) satisfaction surveys, complaints, local demographics, national or local research & statistics, anecdotal. Contact InvolvingPeople@swyt.nhs.uk for insight **What does your research tell you about the impact your proposal will have on the following equality groups?**	To inform this equality impact assessment we have reviewed: • Equality dashboards • Staff Survey 2022 • Incident equality data for those affected (staff and patient) as included in annual incident reports incident annual incident reports. Managers are reminded in training to check and update information when approving incidents to improve equality data quality. • Apparent suicide analysis report – by protected characteristics. • Learning from Healthcare Deaths policy annual reports • NHS England Patient Safety Strategy equality impact assessment • Investigation outcomes Patient Safety data analysis (as part of PSIRF preparation work including protected characteristic data as described above): • Patient safety incident data • Themes from action plans (Serious Incident, Service Level Investigations, Significant Event Analysis, Structured Judgement Reviews) • Complaints from patients, families, and carers • Claims • Risks • Freedom to Speak up data • Human resource processes • Shared learning • Quality Improvement and Assurance data • Existing improvement plans Our findings from research are detailed in the sections below:
	QUESTIONS	**ANSWERS AND ACTIONS**
5a	**Disability Groups:** Prompt: Learning Disabilities or Difficulties, Physical, Visual, Hearing disabilities and people with long term conditions such Diabetes, Cancer, Stroke, Heart Disease etc. Accessible information standard	There does not appear to be anything within this policy which could unfairly affect people with a disability. The Datix system layout is designed to be accessible to those with a visual impairment where section headings and fields are differentiated using different tones, and any important points of advice on data entry are set in bold text rather than just colour in line with accessible information standards. Data held regarding patients who felt abused based on this factor was 0.08% (,5) of all patient safety incidents (Aug 22 – Jul 23) We do not anticipate the implementation of PSIRF to have any negative impact on equality for people with this protected characteristic.

<table>
<tr>
<td>5b</td>
<td>Gender:

Prompt: Female & Male issues should be considered</td>
<td>There does not appear to be anything within this policy which could unfairly affect people from the named protected characteristic group.
Analysis of data from 2022/23 showed the gender of patients affected by incidents as below (this is a percentage of all patient’s affected by incidents in the year):
<table>
<tr><td>Male</td><td>53%</td></tr>
<tr><td>Female</td><td>44%</td></tr>
<tr><td>Transgender</td><td>1.1%</td></tr>
<tr><td>Person lives and works permanently in a gender other than that assigned at birth</td><td>0.8%</td></tr>
<tr><td>Not stated unknown</td><td>0.7%</td></tr>
<tr><td>Not completed</td><td>0.06%</td></tr>
</table>
Incident reporting will continue to be important source of data within PSIRF and we hope to see benefits from the collection of improved data about those affected through the new national Learn From Patient Safety Events. We do not anticipate the implementation of PSIRF to have any negative impact on equality for people with this protected characteristic.
Analysis of patients affected by incidents shows 44% were female, 53% male, 1.1% transgender and 0.8% living/working permanently in a gender other than that assigned at birth. Information was not recorded or not disclosed for the remainder of records.
Datix includes a question for reporters ‘Did this incident involve abuse or hate against an individual based on their protected characteristics?’ This includes all of the listed protected characteristics. Data is reviewed weekly at Clinical risk panel.
Data held regarding patients who felt abused based on this factor was 0.16% (10) of all patient safety incidents (Aug 22 – Jul 23)</td>
</tr>
<tr>
<td>5c</td>
<td>Age:

Prompt: Older people & Young People issues should be considered</td>
<td>There does not appear to be anything within this policy which could unfairly affect people from the named protected characteristic group.
Analysis of data from 2022/23 showed the age of patients affected by incidents as below (this is a percentage of all patient’s affected by incidents in the year):
<table>
<tr><td>Under 25</td><td>9.2%</td></tr>
<tr><td>25 to 34 years</td><td>9.6%</td></tr>
<tr><td>35 to 44 years</td><td>7%</td></tr>
<tr><td>45 to 54 years</td><td>5.9%</td></tr>
<tr><td>55 to 64 years</td><td>5.5%</td></tr>
<tr><td>65 to 74 years</td><td>6.8%</td></tr>
<tr><td>75 years and over</td><td>13.5%</td></tr>
<tr><td>Age not recorded</td><td>42%</td></tr>
</table>
Incident reporting will continue to be important source of data within PSIRF and we hope to see benefits from the collection of improved data about those affected through the new national Learn From Patient Safety Events. We do not anticipate the implementation of PSIRF to have any negative impact on equality for people with this protected characteristic.
Datix includes a question for reporters ‘Did this incident involve abuse or hate against an individual based on their protected characteristics?’ This includes all of the listed protected characteristics. Data is reviewed weekly at Clinical risk panel.
Data held regarding patients who felt abused based on this factor was 0.03% (<5) of all patient safety incidents (Aug 22 – Jul 23)</td>
</tr>
</table>

<table>
<tr><td></td><td></td><td></td></tr>
<tr><td>5d</td><td>Sexual Orientation:

Prompt: Heterosexual, Bisexual, Gay, Lesbian groups are included in this Category</td><td>There does not appear to be anything within this policy which could unfairly affect people from the named protected characteristic group.
Datix includes a question for reporters ‘Did this incident involve abuse or hate against an individual based on their protected characteristics?’ This includes all of the listed protected characteristics. Data is reviewed weekly at Clinical risk panel.
Data held regarding patients who felt abused based on this factor was 0.24% (15) of all patient safety incidents (Aug 22 – Jul 23)</td></tr>
<tr><td>5e</td><td>Religion & Belief:

Prompt: Main faith groups and people with no belief or philosophical belief issues should be considered</td><td>There does not appear to be anything within this policy which could unfairly affect people from the named protected characteristic group.
Datix includes a question for reporters ‘Did this incident involve abuse or hate against an individual based on their protected characteristics?’ This includes all of the listed protected characteristics. Data is reviewed weekly at Clinical risk panel.
Data held regarding patients who felt abused based on this factor was 0.11% (7) of all patient safety incidents (Aug 22 – Jul 23)</td></tr>
<tr><td>5f</td><td>Marriage and Civil Partnership

Prompt: Single, Married, Co-habiting, Widowed, Civil Partnership status are included in this category</td><td>There does not appear to be anything within this policy which could unfairly affect people from the named protected characteristic group.
Datix includes a question for reporters ‘Did this incident involve abuse or hate against an individual based on their protected characteristics?’ This includes all of the listed protected characteristics. Data is reviewed weekly at Clinical risk panel.
There was no data held for this group Aug 22 – Jul 23</td></tr>
<tr><td>5g</td><td>Pregnancy and Maternity

Prompt: Currently pregnant or have been pregnant in the last 12 months should be considered</td><td>There does not appear to be anything within this policy which could unfairly affect people from the named protected characteristic group.
Datix includes a question for reporters ‘Did this incident involve abuse or hate against an individual based on their protected characteristics?’ This includes all of the listed protected characteristics. Data is reviewed weekly at Clinical risk panel.
There was no data held for this group Aug 22 – Jul 23</td></tr>
<tr><td>5h</td><td>Gender Re-assignment

Prompt: Transgender issues should be considered</td><td>There does not appear to be anything within this policy which could unfairly affect people from the named protected characteristic group.
Analysis of data from 2022/23 showed that gender re-assignment for patients affected by incidents as below (this is a percentage of all patient’s affected by incidents in the year):
<table><tr><td>Transgender</td><td>1.1%</td></tr><tr><td>Person lives and works permanently in a gender other than that assigned at birth</td><td>0.8%</td></tr></table>Datix includes a question for reporters ‘Did this incident involve abuse or hate against an individual based on their protected characteristics?’ This includes all of the listed protected characteristics. Data is reviewed weekly at Clinical risk panel.
Data held regarding patients who felt abused based on this factor was 0.08% (<=5) of all patient safety incidents (Aug 22 – Jul 23)</td></tr>
<tr><td>5l</td><td>Carers</td><td>There does not appear to be anything within this policy which could unfairly affect people from the named protected characteristic group.
Although this data is not available in relation to patient safety incidents, we envisage this policy and working under PSIRF will support carers</td></tr>
</table>

	Prompt: Caring responsibilities paid or unpaid, hours this is done should be considered	with raising concerns about patient safety incidents. Datix includes a question for reporters 'Did this incident involve abuse or hate against an individual based on their protected characteristics?' and this includes caring. This includes all of the listed protected characteristics. Data is reviewed weekly at Clinical risk panel.
5j	**Race** Prompt: Indigenous population and BME Groups such as Black African and Caribbean, Mixed Heritage, South Asian, Chinese, Irish, new Migrant, Asylum & Refugee, Gypsy & Travelling communities.)	There does not appear to be anything within this policy which could unfairly affect people from the named protected characteristic group. Analysis of patients affected by incidents shows 76% were white – English/Welsh/Scottish/Northern Irish/British. Other groups ranged from 4.7% (Asian/Asian British Pakistani) to 0.01% (White - Gypsy or Irish Traveller). Information was not recorded or not disclosed for 13% of patient's linked to incidents. Incident reporting will continue to be important source of data within PSIRF and we hope to see benefits from the collection of improved data about those affected through the new national Learn From Patient Safety Events. We do not anticipate the implementation of PSIRF to have any negative impact on equality for people with this protected characteristic. Datix includes a question for reporters 'Did this incident involve abuse or hate against an individual based on their protected characteristics?' This includes all of the listed protected characteristics. Data is reviewed weekly at Clinical risk panel. The REACH staff network is available as a source of advice in relation to cultural and environmental impacts as required. Advice is also available from Equity Guardians as required. Data held regarding patients who felt abused based on this factor was 1.29% (81) of all patient safety incidents (Aug 22 – Jul 23)

6. Action Plan

EIAs are now reviewed using a grading approach which is in line with our Equality Delivery System (EDS). This rates the quality of the EIA. This means that the team can review the EIA and make recommendations only. The rating and suggested standards are set out below:

- **Under-developed** – red – **No data**. **No strands** of equality
- **Developing** – amber – **Some census data plus workforce**. **Two strands** of equality addressed.
- **Achieving** – green – **Some census data plus workforce. Five strands** of equality addressed.
- **Excelling** – purple –**All the data and all the strands** addressed

Potential themes for actions: Geographical location, built environment, timing, costs of the service, make up of your workforce, stereotypes and assumptions, equality monitoring, community relations/cohesion, same sex wards and care, specific issues/barriers.

Who will benefit from this action? (tick all that apply)		**Action 1: This is what we are going to do**	**Lead/s**	**By when**	**Update -outcome**	**RAG**
Age	x	Implementation of the Learn From Patient Safety Events national data collection within Datix. This will include age, sex and self-reported ethnic group of the patient affected by an incident. This will be entered by reporters if available or updated by the responsible manager.	Helen Roberts	31/3/2024		
Disability						
Gender reassignment						
Marriage and civil partnership						
Race	x					
Religion or belief						
Sex	x					
Sexual Orientation						
Pregnancy maternity						
Carers						

Who will benefit from this action? (tick all that apply)		Action 2: This is what we are going to do	Lead/s	By when	Update -outcome	RAG
Age	x	We will review our PSIRF plan 12 months after implementation and this will include a review of the annual data on those affected by incidents by age, sex and ethnicity by the selected areas identified in our PSIRF plan.	Helen Roberts	30/11/2024		
Disability						
Gender reassignment						
Marriage and civil partnership						
Race	x					
Religion or belief						
Sex	x					
Sexual Orientation						
Pregnancy maternity						
Carers						

Who will benefit from this action? (tick all that apply)		Action 3: This is what we are going to do	Lead/s	By when	Update -outcome	RAG
Age	x	Implementation of patient safety partners in 2023/2024 will support the equality agenda.	Emma Cox	30/11/2024		
Disability	x					
Gender reassignment	x					
Marriage and civil partnership	x					
Race	x					
Religion or belief	x					
Sex	x					
Sexual Orientation	x					
Pregnancy maternity	x					
Carers	x					

7. Involvement & Insight: New or Previous

(please include any evidence of activity undertaken in the box below)

Alongside the implementation of PSIRF, we are in the process of recruiting patient safety partners who will:

Be actively involved in supporting the organisation to provider safer healthcare.
Support the Trust with safety governance by sitting on relevant committees, by support appropriate challenge to ensure the Trust are learning and developing in line with national and Trust strategy and policy.
ensure that the need of families, carers and service user are prioritised in committee or groups they are members of.

8. Methods of Monitoring progress on Actions

12 monthly review of PSIRF plan
Ongoing service development
Annual review of team function
Supervision sessions
Audit of data which is available via Trust reports
Review of feedback from various sources such as compliment and complaints.

9. Publishing the Equality Impact Assessment

Intranet/Internet as an appendix to PSIRF policy
The Equality Impact Assessment will be shared on the Trust website.
This EIA will be shared with **InvolvingPeople@swyt.nhs.uk** who will publish as they see fit.

The EIA has been graded as Developing by Aboo Bhana, Equality and Involvement Manager

10. Signing off Equality Impact Assessment:

Helen Roberts
Patient Safety Specialist
August 2023

Appendix B - Checklist for the review and approval of policy document

To be completed and attached to any policy document when submitted to EMT for consideration and approval.

	Title of document being reviewed:	Yes/No/ Unsure	Comments
1.	**Title**		
	Is the title clear and unambiguous?	Yes	
	Is it clear whether the document is a guideline, policy, protocol or standard?	Yes	
	Is it clear in the introduction whether this document replaces or supersedes a previous document?	Yes	
2.	**Rationale**		
	Are reasons for development of the document stated?	Yes	
3.	**Development Process**		
	Is the method described in brief?	Yes	
	Are people involved in the development identified?	Yes	
	Do you feel a reasonable attempt has been made to ensure relevant expertise has been used?	Yes	
	Is there evidence of consultation with stakeholders and users?	Yes	
	Is there evidence that a trauma-informed 'lens' has been applied? e.g. through use of language etc.	Yes	
4.	**Content**		
	Is the objective of the document clear?	Yes	
	Is the target population clear and unambiguous?	Yes	
	Are the intended outcomes described?	Yes	
	Are the statements clear and unambiguous?	Yes	
5.	**Evidence Base**		
	Is the type of evidence to support the document identified explicitly?	Yes	
	Are key references cited?	Yes	

	Are the references cited in full?	Yes	
	Are supporting documents referenced?	Yes	
6.	**Approval**		
	Does the document identify which committee/group will approve it?	Yes	
	If appropriate have the joint People Directorate Human Resources/staff side committee (or equivalent) approved the document?	Yes	
7.	**Dissemination and Implementation**		
	Is there an outline/plan to identify how this will be done?	Yes	
	Does the plan include the necessary training/support to ensure compliance?	Yes	
8.	**Document Control**		
	Does the document identify where it will be held?	Yes	
	Have archiving arrangements for superseded documents been addressed?	Yes	
9.	**Process to Monitor Compliance and Effectiveness**		
	Are there measurable standards or KPIs to support the monitoring of compliance with and effectiveness of the document?	Yes	
	Is there a plan to review or audit compliance with the document?	Yes	
10.	**Review Date**		
	Is the review date identified?	Yes	
	Is the frequency of review identified? If so is it acceptable?	Yes	
11.	**Overall Responsibility for the Document**		
	Is it clear who will be responsible implementation and review of the document?	Yes	

Appendix C - Version control sheet for policy document

This sheet should provide a history of previous versions of the policy and changes made

Version	Date	Author	Status	Comment / changes
1	Nov 2023	Patient Safety Specialist	Final	New PSIRF policy based on national template. Will link to updated Standard Operating Procedures and guidance when ready ahead of go live provisionally 1/12/2023

Appendix D – Patient safety learning responses

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.

Learning Response methods	Description	Lead	Approval	Complete by	Duration
Learning Responses 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.					
Debrief (immediate incident review)	A team debrief initiated as soon as possible after an incident whilst staff remain on site or as soon as reasonably practicable. Involves all disciplines/grades of staff present. Staff come together quickly to check how everyone is, gather immediate thoughts about what went to plan and what didn't, identify any immediate actions or changes that need to be made to ensure continued safety and support needs are met. Used where incidents are unexpected or unusual, or result in patient harm. The output is recorded on Datix. Learning can contribute to an After Action Review at a later date.	Led by the most appropriate person on duty (supported by managers or other colleagues, those in quality and governance or specialist roles as required and/or available)	No approval required	As soon as possible, within 24 hours	Allow around 15 - 45 minutes (dependant on nature of incident)

Learning Response methods	Description	Lead	Approval	Complete by	Duration
	Consider staff completing a memory capture document to preserve their recollections at this early stage.				
After action review	A structured, facilitated discussion of an incident which gives individuals involved the ability to reflect on and contribute to the understanding about what happened with the aim of learning and improvement. A prompt sheet is available to guide the discussion. A template will be available with prompts for capturing discussions.	Lead to be agreed by the care group quality governance team May involve specialist input as relevant to the incident, if required	Reviewed/ approved within care group	Within 1 calendar month of the incident	Allow around 60 - 90 minutes approximately
Specialist learning review	Supports teams to learn from multiple incidents or a safety theme (e.g. clusters in one team or a single incident that involved a number of teams) that occurred in the past and/or where it is more difficult to collect staff recollections of events either because of the passage of time or staff availability. Involves staff and any other	Led by the most appropriate specialist for the incident type (e.g. specialist advisor, patient safety, quality and governance	Clusters/incidents within one care group, reviewed/ approved within care group. Clusters/incidents across range of	Set-up initial meeting within 1 calendar month	Allow approximately 60-90 minutes May lead to multiple follow up meetings to review outcomes, as required. Will be dependent upon the nature of the review.

Learning Response methods	Description	Lead	Approval	Complete by	Duration
	who could provide meaningful contribution to the review. Uses an open discussion to agree the key contributory factors and system gaps that impact on safe patient care. Can utilise a range of systems tools as relevant. A template will be available with prompts for capturing discussions.	lead/matron (or equivalent). Team of relevant stakeholders support the review	care groups, review and approval by specialist groups		
Patient Safety Incident Investigation (PSII) (individual PSII or thematic PSII systematic safety improvement project)	An in-depth systems analysis review of specific patient safety incidents which are defined in the Trust's Patient Safety Incident Response Plan. Patient Safety Incident Investigations (PSII) may be: • Individual patient safety incident investigation • Thematic PSII - focussed on systematic safety improvement project (regarding a theme or safety concern) Both investigation methodologies will involve a team approach.	**Individual PSIIs** – lead by Patient Safety Incident Investigator **Thematic PSII project** – lead by senior manager from Nursing, Quality & Professions Directorate, supported by Patient Safety	Chief Nurse/Director of Quality and Professions and Chief Medical Officer (or deputies) on behalf of Trust Board	As agreed in Patient Safety Support Team	**Individual PSII:** timescales agreed with the patient/family but take no longer than 6 months from the scope being agreed **Thematic PSII project:** timescales agreed with project group

Learning Response methods	Description	Lead	Approval	Complete by	Duration
		Incident Investigator			chair and are anticipated to have a duration of 6-9 months from the scope being agreed

Learning Responses for improvement based on learning

Where a safety issue or incident type is well understood (eg 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.

Retrospective thematic analysis	A retrospective thematic analysis of learning identified through our learning response methods for a patient safety priority. The analysis aims to help identify patterns in data, to help answer questions, show common links or identify issues or themes from a range of methods and data. Outcomes used to identify new system improvement to address key barriers to safety.	Specialist advisors / Patient Safety Support Team	Approved by the commissioning group for the patient safety priority or oversight group	As agreed by specialist group	Dependent upon the nature of the subject/learning responses

Learning Responses for assessing if a response is required

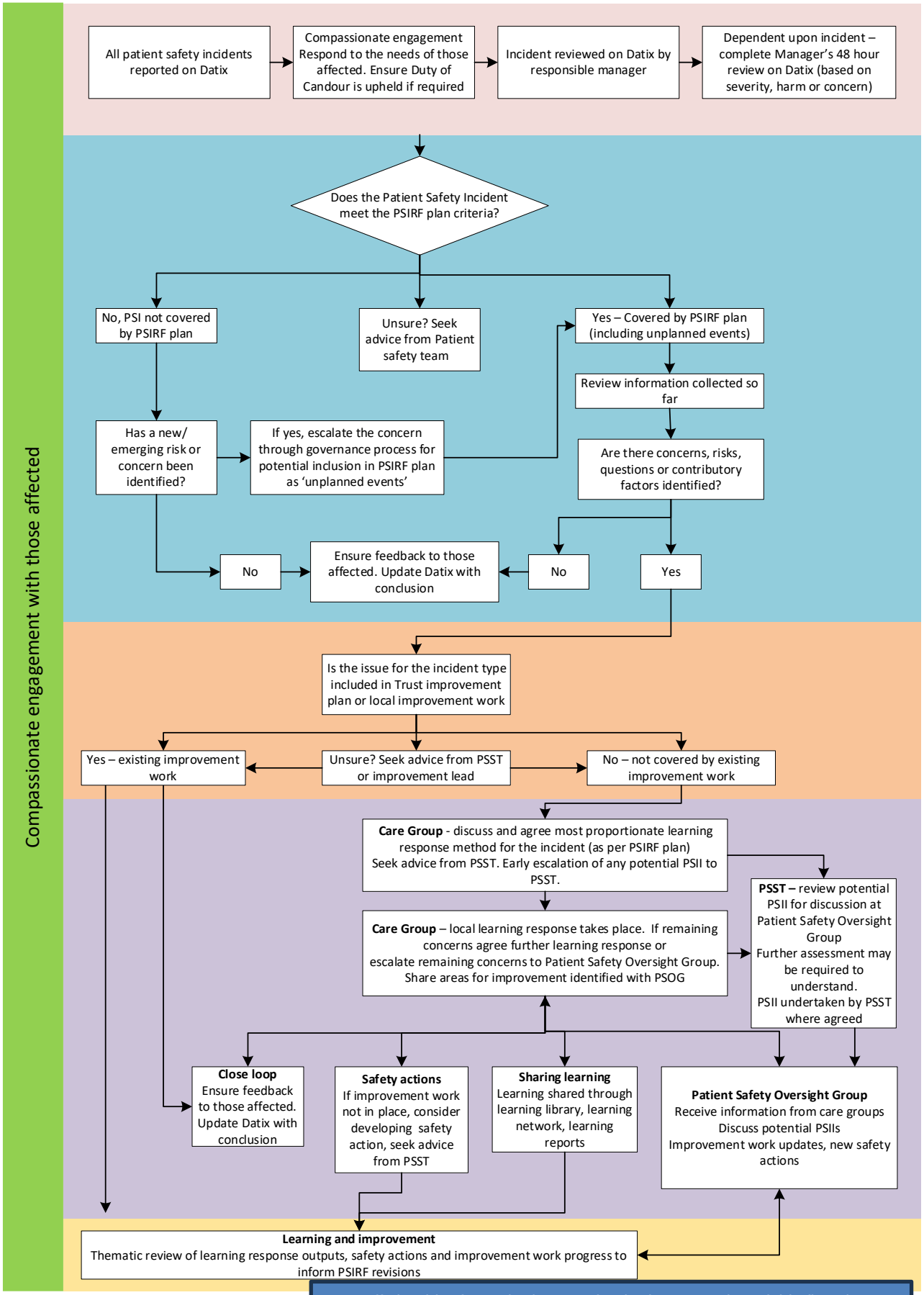
Learning Response methods	Description	Lead	Approval	Complete by	Duration
Where we cannot easily identify where an incident fits in relation to our plan (i.e. whether a learning response is required) we would need to perform an assessment. This is to determine whether there were any problems in care that require further exploration and potentially action.					
Manager's 48 hour review	Although not a learning response, our Manager's 48 hour review acts as a first stage case note review for a death under the Learning from Healthcare Deaths policy to help understand the care given and if there were any problems in the care provided. Manager's will review the clinical records to enable the review to be completed within the Datix record. Enables managers to make a safety statement about the care provided.	Completed by the team manager or deputy	Oversight within care group	Within 48 hours of the incident being reported	Dependent upon the nature of the incident
Case note review	Review of care records where the information already provided does not easily identify if there was any problem in care that led to the patient safety incident occurring. It will include a brief timeframe of relevant events and identify good practice and areas for improvement. The output for this review type will determine if a further learning response or action is required. Guidance and a template will be available.	Specialist advisor, patient safety investigator or any other who possesses the expertise to complete a meaningful review.	Approved by the commissioning group for the patient safety priority or oversight group.	As soon as possible after the incident	2-6 hours

Learning Response methods	Description	Lead	Approval	Complete by	Duration
Structured Judgement Review (SJR)	Structured Judgement Review is an assessment tool used where there is a death of a patient, where information already collected does not provide enough information to help determine if there was any problem in care or not that led to the death occurring. It is our second stage case note review under the Learning from Healthcare Deaths policy. This approach will continue under PSIRF. All cases will be allocated to an independent reviewer by the Patient Safety Support Team. The outcome of a Structured Judgement review may lead to a PSII or other learning response.	Led by trained SJR reviewer, independent of the service allocated by the patient safety support team.	Review and approval by care group governance leads and patient safety support team	Completed within 4-5 weeks of allocation	Allow around 7-10 hours

Concerns identified through any learning response method should be escalated through the governance structures as needed

DRAFT - UNDER DEVELOPMENT

Appendix E – PSIRF decision and oversight flowchart



Staff should refer to the intranet for the latest version of this flowchart

Glossary of terms / definitions

After action review	A reflective facilitated discussion used by teams when outcomes of an activity or event, have been particularly successful or unsuccessful. Provides individuals involved in an incident with the ability to reflect on and contribute to the understanding about what happened with the aim of learning and improvement.
Care Quality Commission (CQC)	The Care Quality Commission (CQC) regulates all health and adult social care services in England, including those provided by the NHS, local authorities, private companies or voluntary organisation. It also protects the interests of people detained under the Mental Health Act.
Case note review	Review of care records where the information already provided does not easily identify if there was any problem in care that led to the patient safety incident occurring. It will include a brief timeframe of relevant events dependent upon the incident and care pathway and gap analysis. The output for this review type will determine if a further learning response or action is required.
Debrief (immediate incident review)	A team debrief initiated as soon as possible after an incident whilst staff remain on site or as soon as reasonably practicable. Involves all disciplines/grades of staff present. Staff come together quickly to check how everyone is, gather immediate thoughts about what went to plan and what didn't, identify any immediate actions or changes that need to be made to ensure continued safety and support needs are met. Used where incidents are unexpected or unusual, resulting in patient harm.
Duty of Candour	Care Quality Commission Regulation 20 on Duty of Candour describes how providers should be open and transparent with people who use services and other 'relevant persons' (people acting lawfully on their behalf) in general in relation to care and treatment. It also sets out some specific requirements that providers must follow when things don't go to plan with care and treatment, including informing people about the incident, providing reasonable support, providing truthful information and an apology when things don't go to plan.
Freedom to Speak Up Guardian	Freedom to Speak Up Guardians support workers to speak up when they feel that they are unable to do so by other routes. They ensure that people who speak up are thanked, that the issues they raise are responded to, and make sure that the person speaking up receives feedback on the actions taken.
Healthcare	The preservation of mental and physical health by preventing or treating illness through services offered by the health professions, including those working in social care settings.
Integrated Care Board/System (ICB/ICS)	In broad terms, the aim of integrated care is to join up the health and care services required by individuals, to deliver care that meets their personal needs in an efficient way. Under PSIRF, our ICB/s have oversight responsibilities, summarised below: • ICB will collaborate with us in the development, maintenance and review of patient safety incident response policy and plans. • Agree our patient safety incident response policy and plan including agreeing a transition date with the Trust.

	• Oversee and support effectiveness of systems to achieve improvement following patient safety incidents. • Support co-ordination of cross-system learning responses. • Share insights and information across organisations/services to improve safety.
Just Culture / Safety Culture	The Trust aims to work within an open, honest and just culture in which staff can be assured that they will be treated fairly and with openness and honesty when they report incidents or mistakes. We want colleagues to feel confident to speak up when things don't go to plan, rather than fearing blame.
Learning from healthcare deaths	Learning from death in an NHS context refers to the process of examining patient deaths to identify areas where improvements can be made in healthcare practices and patient safety. It involves analysing the circumstances surrounding a death to learn valuable lessons and implement changes that can prevent similar incidents in the future.
Learning From Patient Safety Events (LFPSE)	LFPSE replaced the National Reporting and Learning System (NRLS) in Autumn 2023. Patient safety incidents reported locally are submitted to the national database to aid learning and improvement. It will also replace how we report PSIIs in the future.
Learning Response	Learning responses are different methods of patient safety incident response activity that aim to identify one of the three objectives below: 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 (eg 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 – used for issues or incidents where it is not clear whether a learning response is required
Manager's 48 hour review	Although not a learning response, our Manager's 48 hour review acts as a first stage case note review for a death under the Learning from Healthcare Deaths policy to help understand the care given and if there were any problems in the care provided. Manager's will review the clinical records to enable the review to be completed within the Datix record. Enables managers to make a safety statement about the care provided.
Medical Device	Any instrument, apparatus, appliance, software, material or other article (whether used alone or in combination) (including software intended by its manufacturer to be used for diagnostic and/or therapeutic purposes and necessary for its proper application), intended by the manufacturer to be used for: diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, alleviation of or compensation for an injury or disability; investigation, replacement or modification of the anatomy of a physiological process; control of conception

	and which does not achieve its physical intended action on the human body by pharmacological, immunological or metabolic means, but may be assisted in its function by such means.
Memory capture	A memory capture document is not a statement. Its purpose is as a tool to help staff preserve their memory about an incident that has occurred. It is a protective factor, and allows the widest appreciation of the situation at the time of the incident occurred.
NHS Funded Healthcare	Healthcare that is partially or fully funded by the NHS, regardless of the provider or location.
NHS Patient Safety Strategy	The strategy describes how the NHS will continuously improve patient safety, building on the foundations of a safer culture and safer systems.
Patient Safety	Patient safety is about maximising the things that go right and minimising the things that don't go to plan. It is integral to the NHS' definition of quality in healthcare, alongside effectiveness and patient experience. (NHS Patient Safety Strategy 2019)
Patient Safety Incident	Any unintended or unexpected incident that could have led or did lead to harm for one or more patients receiving NHS funded healthcare.
Patient Safety Incident Investigation	A system-based response to a patient safety incident for learning and improvement. Typically, a PSII includes four phases: planning, information gathering, synthesis, and interpreting and improving
Patient Safety Incident Response Framework	Sets out the NHS's approach to developing and maintaining effective systems and processes for responding to patient safety incidents for learning and improving patient safety.
Patient Safety Incident Response Plan	Trust specific - In response to the Patient Safety Incident Response Framework (PSIRF). It describes what is being done to prepare for "go live" with PSIRF and what comes next in how we will respond to patient safety priorities.
Patient Safety Partner	Relates to the role that patients, carers and other lay people can play in supporting and contributing to a healthcare organisation's governance and management processes for patient safety.
Retrospective thematic analysis	A retrospective thematic analysis of learning identified through our learning response methods for a patient safety priority. The analysis aims to help identify patterns in data, to help answer questions, show common links or identify issues or themes from a range of methods and data. Outcomes used to identify new system improvement to address key barriers to safety.
Serious Incident Framework	Previous framework to manage reporting and investigating of serious incidents. Replaced by PSIRF.
Specialist Advisor	Trust subject matter expert for a range of patient safety and health and safety subjects
Specialist learning review	A reflective facilitated discussion of an incident which gives individuals involved the ability to reflect on and contribute to the understanding about what happened with the aim of learning and improvement.
Specialist learning review	Supports teams to learn from multiple incidents or a safety theme (e.g. clusters in one team or a single incident that involved a number of teams) that occurred in the past and/or where it is more difficult to collect staff recollections of events either because of the passage of time or staff availability.

	Uses an open discussion to agree the key contributory factors and system gaps that impact on safe patient care. Can utilise a range of systems tools as relevant.
Structured Judgement Review (SJR)	Structured Judgement Review is an assessment tool used where there is a death of a patient, where information already collected does not provide enough information to help determine if there was any problem in care or not that led to the death occurring. It is our second stage case note review under the Learning from Healthcare Deaths policy. This approach will continue under PSIRF. All cases will be allocated to an independent reviewer by the Patient Safety Support Team. The outcome of a Structured Judgement review may lead to a PSII or other learning response.
Systems Based Approach	A system-based approach recognises that patient safety is an emergent property of the healthcare system: that is, safety arises from interactions and not from a single component, such as actions of people. A system-based approach therefore recognises that it is insufficient to look only at one component, such as only the people involved.
Systems Engineering Initiative for Patient Safety (SEIPS)	A framework for understanding outcomes within complex socio-technical systems.