Moorfields Eye Hospital NHS Foundation Trust

Patient safety incident response policy

Summary

This policy supports the requirements of the NHS England Patient Safety Incident Response Framework (PSIRF) and sets out how the Trust will approach the development and maintenance of effective systems and processes for responding to patient safety incidents and issues for the purpose of learning and improving patient safety.

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Contents

Executive summary

The Patient Safety Incident Response Framework (PSIRF) is a different and exciting approach to how we respond to patient safety incidents. Unlike the Serious Incident Framework (SIF), which we have operated under since 2013, PSIRF is **not** an investigation framework. It does not mandate investigation as the only method for learning from patient safety incidents (PSIs) and it does not prescribe which incidents we must investigate. It is a framework that supports development and maintenance of an effective patient safety incident response system with four key 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 PSIs.

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

This PSIR policy, and the associated PSIR plan (the Plan), describe how the trust responds to incidents under PSRIF to maximise learning and improvement (see flowchart in Appendix 1). With the exception of incidents that require a nationally mandated response to certain categories of events, such as Never Events, this policy supports how we will:

- Balance effort between learning from responding to incidents and/or exploring issues and our improvement work.

- Broaden the methodologies that we use to learn from PSIs, e.g., clinical audit, thematic analysis.

- Focus our attention on understanding events that we may not have previously had the resource to examine. Our chosen response will not be solely based on harm that has already occurred; we will be able to consider the risk of future harm occurring and then identify how that risk can be reduced across the organisation.

- Further develop our existing learning system and ensure that the output of the proportionate learning responses that we undertake are shared across the organisation and that local improvement opportunities, in areas other than that in which an event occurred, can be considered by teams.

  A glossary of terms used can be found at Appendix 2.

What is PSIRF?

Moorfields Eye Hospital NHS Foundation Trust

The **Patient Safety Incident Response Framework** (PSIRF) is a new, national approach to responding to patient safety incidents. It focuses on effective learning, continuous improvement, and compassionate engagement with patients and staff following an incident.

Previous framework	New framework
Organisations reacted to individual incidents in isolation, without always actively joining up learning across the organisation. A decision to investigate was often based on the occurrence of harm.	We have analysed our patient safety data and pre-selected incident types that will maximise our opportunities for proactive learning and improvement. Our responses will be proportionate and not always driven by the occurrence of harm.
Individual action plans were developed in response to investigation findings. Action plans could be implemented in isolation, and the effectiveness of actions was not always consistently measured.	To maximise improvement and efficiency across our organisation, we will focus our resources to ensure we monitor the impact of any changes we make. We will also have mechanisms in place to effectively share learning across our organisation.
Previous systems and processes did not always prioritise compassionate engagement with those affected by an incident (i.e., patients, families, carers, staff). Therefore, support provided following an incident could be variable.	The new framework prioritises compassionate engagement with all those involved in, or affected by an incident, not only when the duty of candour applies. We will involve those affected in our learning responses.
The limitations of previous investigation methods often resulted in a focus on the individual actions of staff rather than the reasons why they took those actions.	We will move further towards a just culture – a culture of fairness, openness, and learning – where staff feel confident to speak up if things go wrong, rather than fearing blame. We will seek to learn, rather than seek to establish liability.

Our patient safety incident response plan

1. Introduction

The Patient Safety Incident Response Framework (PSIRF) sets out the NHS's approach to developing and maintaining effective systems and processes for responding to patient safety incidents (PSIs)[1] for the purpose of learning and improving patient safety.

The PSIRF replaces the Serious Incident Framework (SIF) (2013) and makes no distinction between 'PSIs' and 'Serious Incidents'. As such, it removes the 'Serious Incidents' classification and the threshold for it. Instead, the PSIRF promotes a proportionate approach to responding to PSIs by ensuring resources allocated to learning are balanced with those needed to deliver improvement. Unlike SIF, it is **not** an investigation framework.

PSIRF supports organisations to respond to incidents in a way that maximises learning and improvement rather than basing responses on arbitrary and subjective definitions of harm. Therefore, organisations can explore PSIs relevant to their context and the populations they serve rather than exploring only those that meet a certain nationally defined threshold.

The PSIRF also advocates a co-ordinated and data-driven response to PSIs. It embeds PSIs within a wider system of improvement and prompts a significant cultural shift towards systematic patient safety management and provides the tools to support this shift.

2. Purpose

This policy supports the requirements of the NHS England PSIRF and sets out how Moorfields Eye Hospital NHS Foundation Trust (the trust) will approach the development and maintenance of effective systems and processes for responding to PSIs and issues for the purpose of learning and improving patient safety.

This policy also supports the development and maintenance of an effective PSI response system that integrates the four key aims of the PSIRF.

- Compassionate engagement and involvement of those affected by PSIs.
- Application of a range of system-based approaches to learning from PSIs.
- Considered and proportionate responses to PSIs and safety issues.

[1] Patient safety incidents (PSIs) are unintended or unexpected events (including omissions) in healthcare that could have or did harm one or more patients.

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

This policy should be read in conjunction with the documents listed in section 18, including the trust's patient safety incident response plan ('the Plan'), which is a separate document setting out how this policy will be implemented.

It should be noted that this policy will evolve as the organisation transitions to PSRIF, and the PSIRF is embedded in the trust.

Learning and improvement

The learning responses available under PSIRF provide a range of tools and approaches to elicit learning from PSIs. These tools and approaches enable us to understand any vulnerabilities in our systems which need to be addressed, to avoid repeat. The Plan that supports this policy outlines the trust learning responses against our identified incident priorities.

The incident review group (IRG) will determine, using the Plan as guidance, where a learning response to explore the contributory factors to a patient safety incident or cluster of incidents, is required to inform improvement.

Where the IRG determines that the contributory factors are known and determines there is already a robust workstream in place to support improvement (that is a learning response has already occurred), the PSI will be fed into the most appropriate improvement workstream as described in the Plan and Appendix 1 in this policy.

3. Scope

This policy is specific to PSI responses that are conducted solely for the purpose of learning and improvement, across all trust NHS and private services.

Those leading patient safety incident responses (learning response leads) and those involved in the oversight of learning and improvement emerging from patient safety incident response require specific knowledge and experience.

Responses under this policy will follow a systems-based approach. This recognises that patient safety is an emergent property of the healthcare system: that is, safety is provided by interactions between components (e.g., people, tasks, equipment, environment (internal and external) and organisation), and not from a single component.

Responses to PSIs **will not** take a 'person-focused' approach where the actions or inactions of people, or 'human error', are stated as the cause of an incident.

There is no remit to apportion blame or determine liability, preventability, or cause of death in responses to PSIs that are conducted for the purpose of learning and improvement. The processes listed below exist for that purpose and are outside the scope of this policy:

- Claims handling.
- Human resources investigations into employment concerns.
- Professional standards investigations.
- Coronial inquests.
- Criminal investigations.
- Information governance concerns.
- Financial investigations and audits.
- Fraudulent activity.
- Complaints (except where a patient safety concern is highlighted).

Information from a PSI learning or improvement response process can be shared with those leading other types of responses, but these processes should not influence the remit of the PSI responses described in this policy.

Some departments and services within the trust (e.g., eye bank, pathology, electro-physiology department, contact lens and prosthetics manufacturing) are subject to accreditation, certification, license or permit inspection by an Approved Body or a Regulatory Body. As such, there is a requirement to record non-conformities identified with work processes and systems against certain standards, so that improvement opportunities can be identified and considered as stipulated by these bodies. These non-conformities do not fall within the remit of this policy unless a patient is involved or affected, in which case a PSI will be reported on Safeguard (the trust electronic incident reporting system) via the trust incident reporting process and will then be within scope.

The process for the management of non-PSIs is described in the incident reporting policy and procedure[2].

[2] This policy will be updated to take account of the change from the SIF to the PSIRF and introduction of the NHS England Learning from Patient Safety Events (LFPSE) service.

4. Our patient safety culture

This policy supports the trust's commitment to improving the existing patient safety culture and recognises the direct correlation between the experiences of staff in relation to engagement and the impact on safety and clinical outcomes for patients. We are striving to be an employer that staff feel they can trust, and to create an environment in which staff feel valued, respected, and supported. This is being done in accordance with the Trust values of *Excellence*, *Equity*, and *Kindness* and the NHS People Promise themes.

The annual staff survey is recognised as a primary source of data to inform our priorities and processes, and the trust is committed to reviewing the results of the survey yearly and identifying mechanisms to improve the response rate. There is an expectation that improvement plans are developed in response to the survey findings. There will be executive oversight of the organisational improvement plans, as a minimum.

Our work to enhance our patient safety culture is evolutionary and the specific priorities within each workstream, not all of which are explicitly referenced below, will be refreshed based on the work that is completed and feedback we receive during the PSIRF implementation phase.

In respect of PSIs, and as a priority to support the development of a positive patient safety culture, we will strive to ensure we:

- Have effective processes that support open and transparent reporting, and that staff are aware of the importance and significance of engaging with these processes. To achieve this, alongside this policy, we will seek feedback from staff regarding the effectiveness of these processes (e.g., electronic incident reporting of PSIs via Safeguard (Ulysses)), and any barriers to engaging with them in order to drive improvements, where possible. We will continue our efforts to ensure that staff are aware of the importance of reporting near misses, and that they understand the ways in which this can proactively prevent future harm.
- Effectively engage and involve those affected by PSIs as described in our involving and supporting patients and staff following a patient safety incident policy[3].
- Prioritise our learning and improvement responses to PSIs, and provide staff with the information, instruction, and training that they need to be able to respond appropriately and in a timely manner.

[3] This policy is currently under development and will replace the existing 'being open and duty of candour policy'.

- Continue to seek to evaluate and improve the effectiveness of our freedom to speak up service (FTSU), to ensure that it is accessible by all staff, staff recognise it as a safe way in which to raise concerns so that timely and appropriate action can be taken.

- Continue to encourage completion of the level 1 National Patient Safety Syllabus (NPSS) training, so that staff recognise that safety is a key priority and to meet the national PSRIF standards requirement.

- Ensure that the barriers and facilitators to the conduct of an effective safety huddle are being identified, as safety huddles are recognised within the trust to:

    - Enhance teamwork through communication and co-operative problem-solving

    - Encourage shared understanding of the focus and priorities for the day

    - Improve situational awareness of safety concerns.

    - Further develop our learning system and create an environment in which there is both system level and organisational level shared learning, and that the ability to learn will be reinforced through the culture and behaviour of staff.

Supporting the development of a just culture

The trust recognises that effective learning can only take place in a non-threatening environment and that fear of disciplinary action may deter staff from reporting an incident. This message should be reiterated to staff and managers wherever possible. To this end, managers who are reviewing an incident will be supported to apply Just Culture principles where a potential concern regarding an individual action is identified. Application of Just Culture principles will support consistent, constructive, and fair evaluation of the actions of staff involved in PSIs.

5. Patient safety partners (PSPs)

PSPs are a new and evolving role that has been developed by NHS England to help improve patient safety across the NHS. The role recognises the important effect 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. Our PSPs are either a previous or existing trust patient and/or an individual who has experienced Moorfields as a close family member/carer. We are in the process of developing the role and recognise that it will take time and commitment from both the organisation and PSPs to shape the role to ensure that PSPs can fulfil our shared vision

that improving patient safety, experience and outcomes should be at the forefront of everything that we do.

The trust recognises that the involvement of patients in their care and in the development of services is an essential element of safety. The PSP role at Moorfields is central to ensuring that decisions made by the trust are considered from a patient/service user perspective. There are many ways in which this is achieved including, but not limited to, the involvement of our PSPs in:

- Key governance committees and groups focussing on safety, risk, quality, and experience.
- Range of inspection programmes, including those that are executive-led and national inspections such as the Patient-Led Assessments of the Care Environment (PLACE).
- The development of projects delivered by divisional teams, service improvement & sustainability, central quality & safety and patient experience teams ensuring that patient co-design is promoted
- The development of plans to deliver services from new locations, such as a new site
- Development of our quality priorities.

Specifically in relation to the PSIRF, our PSPs have been consulted regarding our initial and on-going delivery and implementation plans (see Appendix 3). We will continue to engage our PSPs in the development of PSIRF-related documents and materials, ensuring that we have an effective PSI response system that prioritises compassionate engagement with those affected by PSIs.

6. Addressing health inequalities

The trust recognises the importance of reducing the health inequalities of the populations we serve and under the Equality Act (2010), as a public authority, we have statutory obligations that we are committed to delivering on.

The trust supports the NHS National Patient Safety Strategy objective to understand populations with respect to demography, ethnicity, and social deprivation factors to improve safety and outcomes. We will aim to gain further evidence about disparities in the safety of the services that we provide, as experienced by different groups. As such, we will determine a methodology to analyse incident reporting by protected characteristics to give insight into any apparent inequalities in reporting. Once established, this will be included in our incident reporting and management policy and procedure.

The trust is committed to reducing health inequalities as described in our excellence portfolio, monitored by the Excellence Delivery Unit (XDU) working together board, including:

- Accessible Information Standard (AIS)

This work aims to support effective communication by improving our compliance with the AIS standard. The AIS principles will be applied to the use of supportive tools, such as easy read, translation, and interpretation services to ensure that we maximise the ability and potential for patients and staff to be involved in patient safety incident responses. This will be considered under the engaging staff and patients policy which is being developed as part of the PSIRF implementation phase.

- 'Make Every Contact Count' (MECC)[4]

In 2022/23 the trust identified a quality priority relating to the need to develop systems and processes to reduce health inequalities by working in partnership with staff. By utilising the principles of MECC, and our day to day interactions with patients to encourage changes in behaviour, there is an opportunity to have a positive effect on the health and well-being of our patients, the community, and the wider population. A quality priority for 2023/24, relating again to MECC, was developed, and the trust plans to develop a MECC evaluation framework to assist with implementation of the quality priority and measurement of the impact of MECC interventions.

- Making better use of routine health data

Making better use of routine health data' was included as a trust quality priority for 2023/24. The aim of the priority is to identify and quantify any health inequalities or disparities across our Network or within Clinical Services, as a means for addressing underlying predisposing factors and for taking necessary actions. This project has provided the trust with better understanding of our patient population and their experience with our services. It will also provide assurance and demonstrable accountability on our compliance with current requirements for actively monitoring and addressing unwarranted disparities. In addition, systems will be developed to triangulate the information with patient safety data.

[4] Many long-term diseases are closely linked to known behavioural risk factors such as tobacco, hypertension, alcohol, being overweight or being physically inactive. Making every contact count (MECC) is an approach to behaviour change that utilises day-to-day interactions with patients to encourage changes in behaviour that have a positive effect on the health and well-being of the individual, but also the wider population.

The arrangements for the following are specifically described in section 9 of this policy:

- How the tools the trust will use to respond to PSIs will prompt consideration of inequalities, including when developing safety actions.
- How the trust will engage and involve patients, families and staff following a PSI with consideration of their different needs.
- How the trust will uphold a system-based approach (not a 'person focused' approach) and ensure staff have the relevant training and skill development to support this approach.

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

The PSIRF recognises that learning and improvement following a PSI can only be achieved if supportive systems and processes are in place. It supports the development of an effective PSI response system that prioritises compassionate engagement and involvement of those affected by PSIs (including patients, families, and staff). This involves working with those affected[5] by PSIs to understand and answer any questions they have in relation to the incident and signpost them to support as required[6].

The post-PSI engagement arrangements the trust has in place are as described in the 'policy for engaging and involving patients, families, and staff following a PSI'[7]. The same policy will describe how we will meet our professional and regulatory requirements in relation to the statutory duty of candour, which requires that we are open and transparent with people who receive care from us.

Our PSPs will be integral to the continued development and implementation of this policy.

8. Patient safety incident response planning

The 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

[5] The term 'those affected' include staff and families in the broadest sense; that is: the person or patient (the individual) to whom the incident occurred, their family and close relations. Family and close relations may include parents, partners, siblings, children, guardians, carers, and others who have a direct and close relationship with the individual to whom the incident occurred.

[6] Until the engaging patient and staff following a patient safety incident policy has been developed staff and patients seeking support or information following an incident should contact the central quality team at moorfields.qands@nhs.net

[7] This policy is currently under development and will replace the existing 'being open and duty of candour policy'.

subjective definitions of harm. Beyond nationally set requirements, organisations can explore PSIs relevant to their context and the populations they serve rather than only those that meet a certain defined threshold.

8.1 Resources and training to support patient safety incident response

- **Resources**

Delivery of the PSIRF is accommodated within our existing trust staffing resource, however it is acknowledged that as we develop and improve our learning responses and our learning system, there may be a need to increase this. As such, the effectiveness of our implementation of the PSIRF will be subject to continuous review, using quality improvement methodology. The adequacy of the number of staff trained, along with their placement across the organisation, will be considered as part of this.

The PSIRF standards define the competencies required for individuals leading on the implementation of PSIRF. The following sections describe how the trust will resource PSI responses, including the training and competencies that staff undertaking the responses require.

To meet the PSIRF standards we must:

- Have in place sufficient governance arrangements to ensure that learning responses are not led by staff who were either involved in or affected by the PSI itself, or by those who directly manage those staff. The central quality and safety team will provide advice and support regarding cross-system and cross-divisional working, where required, and will support and record the allocation of learning response leads.
- Ensure that learning responses are only be led by staff who have completed the relevant training[8] and who have an appropriate level of seniority and influence within the organisation. The expectation is that a PSI investigation (PSII) will normally be led by a member of staff who is a band 8a or above[9].
- Ensure that learning responses are not undertaken by staff working in isolation.

[8] The NPSS is a system-wide, multi-professional syllabus that has been developed for all staff in the NHS. Completion of both level one (essentials of patient safety) and level two (access to practice) of the syllabus is an essential requirement for any staff member in an oversight role or those appointed as a learning response lead and/or an engagement lead. This is in addition to the PSIRF-specific role training.

[9] Exceptions to this may exist providing it has been agreed by the Incident Review Group (IRG).

- Maintain a list of involvement in a learning response, in order to ensure that:
    - There is equitable allocation across the organisation, and
    - Learning response leads can satisfy the national requirement to contribute to a minimum of two learning responses per year.
- Continuously review the sufficiency of the capacity that we have for co-ordinating and monitoring the effectiveness of our learning and improvement responses and for sharing learning. Identification of additional need will be included in the annual business planning process, where necessary.
- Strive to ensure that staff involved in understanding learning responses, or staff affected by a PSI who are contributing to a learning response, are provided with allocated time (as part of their normal working day) in which to participate. Arrangements to backfill staff who are participating in learning responses will be considered, where possible, and in agreement with the relevant management team.
- Seek to engage subject matter expert involvement, (e.g., peer support from another organisation), if appropriate. Such involvement must be notified to the central quality and safety team so that the correct application of information governance requirements can be ensured. This may also include the support of a healthcare provider learning response lead from within North Central London Integrated Care System NCL ICS.
    - **Training for specific PSIRF roles**

Learning response leads, those leading engagement and involvement and those in PSIRF oversight roles require specific knowledge and experience. Training for the PSIRF-specific roles must be delivered by a training provider that satisfies the requirements identified in the NHS England PSIRF standards[10].

Learning response lead training and competencies

In addition to the training previously described, learning response leads must:

- Undertake appropriate continuous professional development in incident response skills and knowledge.

[10] Training will only be conducted by those who have attended courses in learning from safety incidents amounting to more than 30 days, are up to date in learning response best practice and have both conducted and reviewed learning responses.

- Network with other leads at least annually to build and maintain expertise. An annual networking event will be arranged by the central quality & safety team in the event that an alternative activity has not occurred during the year.
- Be able to apply human factors and systems thinking principles to gather qualitative and quantitative information from a wide range of sources.
- Summarise and present complex information in a clear and logical manner and in report form.
- Manage conflicting information from different internal and external sources.
- Communicate highly complex matters and in difficult situations.

Engagement and involvement lead behaviour and competencies

Engagement and involvement with those affected by a PSI (e.g., staff, patients, families, carers) must be led by staff members who have had at least six hours of training in involving those affected by PSIs in the learning process.

- Engagement leads must:
  - Have completed levels one and two of the NPSS.
  - Undertake appropriate continuous professional development in engagement and communication skills and knowledge.
  - Network with other leads at least annually to build and maintain expertise.
  - Contribute to a minimum of two learning responses per year.
- As a trust we expect that all engagement leads will always:
  - Communicate and engage with patients, families, staff, and external agencies in a positive and compassionate way.
  - Listen and hear the distress of others in a measured and supportive way.
  - Maintain clear records of information gathered and contact with those affected.
  - Identify key risks and issues that may affect the involvement of patients, families, and staff.
  - Recognise when those affected by PSIs require onward signposting or referral to support services.

- Seek support from the central quality and safety team in relation to the above, where queries exist or if support is required.

Oversight roles training and competencies

- All PSI response oversight must be led/conducted by staff:
  - With at least two days formal training and development in learning from PSIs **and** one day training in oversight of learning from PSIs.
  - Who have completed either level 1 (essentials of patient safety) and level 1 (essentials of patient safety for boards and senior leadership teams) of the NPSS.
  - Who undertake continuous professional development in incident response skills and knowledge.
  - Who network with peers at least annually to build and maintain expertise.
- All staff with PSIRF oversight roles should:
  - Be inquisitive with sensitivity (that is, know how and when to ask the right questions to gain insight about patient safety improvement).
  - Apply human factors and systems thinking principles.
  - Obtain (e.g., through conversations) and assess both qualitative and quantitative information from a wide range of sources.
  - Constructively challenge the strength and feasibility of safety actions to improve underlying system issues.
  - Recognise when safety actions following a PSI response do not take a system-based approach (e.g., inappropriate focus on revising policies without understanding 'work as done' or self-reflection instead of reviewing wider system influences).
  - Summarise and present complex information in a clear and logical manner and in report form.

8.2 Our patient safety incident response plan

Our Plan sets out how the trust intends to respond to PSIs over a period of 18 months. The plan is not a permanent set of rules that cannot be changed. We will remain flexible and consider the specific circumstances in which each PSI occurred and the needs of

those affected, as well as the plan. The plan includes our PSI response arrangements for PSIs occurring during the provision of both NHS and privately funded healthcare services.

The plan has been developed following completion of an extensive stakeholder engagement exercise and review of available information (e.g., PSIs, risks, complaints, claims, NHS staff survey, junior doctor survey, FTSU data). A detailed account of the work that has been completed is described in sections 3 and 4 of our Plan.

A copy of our current plan can be found on the trust internet site (www.moorfields.nhs.uk).

8.3 Reviewing our patient safety incident response policy and plan

Our Plan is a 'living document' that will be amended and updated as we use it and learn how to respond to PSIs most effectively under the PSIRF. We will formally review the plan and policy after 18 months, following initial implementation, to ensure our focus remains up to date. We recognise that on-going improvement work means that our PSI profile is likely to change. Early review will also provide an opportunity to re-engage with stakeholders to discuss and agree any changes that have occurred in the previous 18 months.

Given the changes to mindset and trust processes that PSIRF introduces and encourages we acknowledge that there may be changes to our policy and plan that were unforeseen and which cannot be accommodated for 18 months. We will establish methods for monitoring and measurement, using quality improvement (QI) methodology and key performance indicators, in order to detect any unwarranted variation in our data or feedback from staff, PSPs, integrated care board (ICB) or our service users. Interim changes to our policy or plan will require approval from the clinical governance committee (CGC), and these will be reported to the quality & safety committee as a sub-committee of the trust board.

A rigorous planning exercise will be undertaken every three years and more frequently if appropriate (as agreed with our ICB) to ensure efforts continue to be balanced between learning and improvement. This more in-depth review will include reviewing our response capacity, mapping our services, a wide review of organisational data (e.g., PSI investigation reports, improvement plans, complaints, claims, staff survey results, inequalities data, and reporting data) and wider stakeholder engagement.

Updated plans will be published on our website, replacing the previous version.

9. Responding to patient safety incidents

9.1 Patient safety incident reporting arrangements

All staff, of all grades and disciplines, are responsible for reporting PSIs and near misses that they become aware of in accordance with the trust incident reporting policy[11]. All incidents, relating to patients receiving both NHS-funded and privately funded care and treatment must be reported via the trust e-reporting system (Safeguard) as soon as possible following discovery of the incident.

Reporting incidents and near misses via this mechanism will ensure that relevant managers and specialist advisers are notified either automatically or following review of the incident by the central quality & safety team. Clinical divisions/corporate teams have an equivalent checking process, to ensure that all incidents are reviewed and that additional relevant staff not already aware of the incident receive notification.

The harm impact of all incidents and near misses will be graded by the reporter in the first instance, at the point at which the incident is reported. It is not necessary for the reporter to be in possession of all facts at the time of initial grading. At the point of incident notification, clinical divisions and services are responsible for reviewing the harm grading ensuring that duty of candour processes[12] have been initiated or for taking action to ensure that this happens as a priority.

Incidents requiring notification to another provider organisation will ordinarily be identified following review by the clinical division/service and/or be identified by the central quality & safety team (see section 9.3).

9.2 Patient safety incident response decision-making

The trust has governance arrangements in place to allow it to meet the requirements associated with the review of incidents under the PSIRF. Our local governance arrangements (see Appendix 1) include a process by which we will use the Incident Review Group (IRG) to confirm:

- If a particular incident meets the requirements for completion of a learning response, in accordance with our Plan.

[11] Note, modification to this policy is required to remove reference to serious incidents (SIs) and the National Reporting and Learning Service (NRLS). Amendments will include reference to the new Learn from Patient Safety Events (LFPSE) and PSIRF.

[12] As described in the 'being open and duty of candour policy' that will be replaced by the policy for engaging and involving patients, families, and staff following a PSI'.

- The proportionate learning response(s) required.

Identification of our local incident priorities, as described in our Plan, has been informed through the analysis and identification of our patient safety profile. The proportionate learning response that is planned to be undertaken is also defined. The following rules apply to our selection of the appropriate learning response, where for our national and local priorities we will be seeking to learn from 'everyday work'[13] to inform improvement:

- **National PSI priority** - Patient safety incident investigation (PSII) is mandated. The PSII may be informed by another learning response (e.g., after action review (AAR)).

- **Local PSI priority** – PSII or application of another learning response tool, as described in the plan. Multiple learning responses may be conducted. Escalation to PSII as the preferred learning response may occur, even when not described in the plan as such.

- **Priority unconfirmed** – where it is unclear if a PSI fulfils the criteria for either a national or local priority, an assessment will be undertaken to determine whether there were any problems in care that require further exploration and potentially action.

- **PSIs that are not a national or local priority** – PSIs that do not fulfil the criteria as either a national or local priority will normally be managed locally, by the reporting team or divisional management team. The local reporting team/divisional management team will be responsible for selecting the proportionate learning response and/or improvement response.

  Exceptions to this are where a concern is identified, by any person (including patient/family), or if a PSI which signifies an unexpected level of risk and/or potential for learning and improvement is recorded. If a concern is raised, careful consideration will be given regarding whether a learning response is the best way to address concerns and questions. Any request for a learning response will be carefully considered and a decision regarding the appropriateness of conducting a learning response will be made by the Incident Review Group (IRG).

[13] 'Everyday work' describes the reality of how work is done and how people performing tasks routinely adjust what they do to match the ever-changing conditions and demands of work.

The IRG governance reporting arrangements are as shown in Figure 1, below. The role of IRG, and the reporting arrangements, are described in more detail in the incident reporting and management policy.

Figure 1 Governance structure

9.3 Responding to cross-system incidents/issues

The trust central quality & safety (risk & safety) team will securely (e.g., via an NHS.net to NHS.net e-mail account) forward those incidents identified as presenting potential for significant learning and improvement for another provider directly to that organisation's patient safety team or equivalent. Where required, summary reporting will be used to share insight with another provider about their patient safety profile. Incidents of this type will normally be identified in the PSI reports submitted by staff, or during review by the IRG.

We will work with partner providers (peer trusts) and the relevant ICBs to establish and maintain robust procedures to facilitate the free flow of information and minimise delays to joint working on cross-system incidents. The quality & safety team will act as the liaison point for such working and will have supportive operating procedures to ensure that this is effectively managed.

We will defer to the ICB for co-ordination where a cross-system incident is felt to be too complex to be managed as a single provider. It is anticipated that the ICB will give support with identifying a suitable reviewer in such circumstances and will agree how the learning response will be led and managed, how safety actions will be developed, and how the implemented actions will be monitored for sustainable change and improvement.

Providers wanting to engage with the trust regarding a cross-system incident/issue should e-mail moorfields.QANDS@nhs.net in the first instance.

9.4 Timeframes for learning responses

Patient safety incident investigations (PSIIs)

Where a PSII for learning is indicated, the investigation must be started as soon as possible after the PSI is identified and should ordinarily be completed within three months of the start date. No local PSII should take longer than six months.

The timeframe for completion of a PSII will be agreed with those affected by the incident, as part of the setting of terms of reference, provided they are willing and able to be involved in that decision. A balance must 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 they remain relevant.

In exceptional circumstances (e.g., when a partner organisation requests an investigation is paused, or the processes of an external body delays access to information) the trust can consider whether to progress the PSII and determine whether new information indicates the need for further investigative activity once this is received. This action would require authorisation from either the medical director or the chief nurse and director of allied health professionals, on behalf of the CGC.

In exceptional circumstances, a longer timeframe may be required for completion of the PSII. In this case, any extended timeframe should be agreed between the trust and those affected, including the patient.

The IRG will monitor timescales and progress of PSIIs.

Other forms of learning response

All learning responses must be started as soon as possible after the PSI is identified and ordinarily should be completed as soon as possible, but within no more than two months of the start date. No learning response should take longer than six months to complete.

9.5 Safety action development

A thorough understanding of the work system will only be gained where a learning response is conducted; led by an individual who has completed the relevant training and secured the associated competencies (see section 8.1). We will have an integrated process for developing, implementing, and monitoring safety actions to not limit our attempts to reduce risks and potential for harm.

Our process for development of safety actions will align with the NHS England Safety Action Development Guide 2022. This has been summarised for local use and can be found in Appendix 4. Use of the guide, which will include working through the following steps, will prompt consideration of health inequalities during the development of safety actions. A collaborative approach to the development of safety actions, involving those beyond our 'immediate and obvious' professional groups (e.g., doctors, nurses, optometrists) such as patients, PSPs, estates and facilities teams and administrative staff will be taken.

1. **Agree areas for improvement** (where improvement is needed, without defining how that improvement is to be achieved).
2. **Define context** (agree approach to developing safety actions by defining context).
3. **Define safety actions to address areas for improvement** (focus on the system, using a collaborative approach).
4. **Prioritise safety actions** (using the iFACES criteria – see Appendix 4, table 2).
5. **Define safety measures** (identify how we will know if the safety action is influencing what it intended, who, what, when and how).
6. **Write safety actions** (document in a learning response report or safety improvement plan, including details of measurement and monitoring).
7. **Monitor and review** (confirm that safety actions are impactful and sustainable).

9.6 Safety action monitoring

All safety actions will be added to the relevant PSI record on the trust local incident reporting system, Safeguard, so that implementation can be monitored. Monitoring reports will be generated from Safeguard and presented to the Incident Review Group (IRG) and the Clinical Governance Committee (CGC), in accordance with the relevant terms of reference. Local monitoring of the implementation and effectiveness of safety actions, to ensure that they continue to have an impact and are sustainable, will be overseen by the divisional head of nursing and quality partner for the location in which the PSI occurred. Updates will be provided at monthly quality forums and/or monthly executive performance meetings, as a minimum. Where safety actions have broader organisational or trust wide relevance, the specific ad-hoc monitoring plans will be as described in the safety action report (see template in Appendix 5).

9.7 Safety improvement plans

Safety improvement plans bring together findings from various responses to PSIs and issues. There are no thresholds for when a safety improvement plan should be developed

after completion of learning responses. The decision to do so will be based on knowledge gained through the learning response process and other relevant data.

Within the trust committee structure, the CGC is accountable for ensuring that there is continuous improvement of the quality of clinical services and for safeguarding high standards of care. There are numerous governance committees with reporting responsibility into CGC, including resuscitation, drugs and therapeutics, and infection prevention and control. Our local priorities and the national priorities, described in our Plan, were selected either because of the opportunity they offer for learning and improvement across areas where there is no existing plan, or where improvement efforts have not been accompanied by reduction in apparent risk or harm. Each priority has been allocated a committee, who will be responsible for overseeing implementation of the safety improvement plan(s).

We will use a variety of approaches to the development of safety improvement plans, as outlined below:

- We will develop safety improvement plans that focus on specific services, pathways, or issues. Examples of such safety improvement plans are those arising from trust wide safety summits. Safety summits are to be used where an organisation-wide, multi-disciplinary response is required to a particular patient safety issue or set of similar issues. Safety summit progress updates will be reported to the CGC.

- Where multiple learning responses (a minimum of two) associated with individual incidents generate sufficient understanding of any underlying, interlinked system issues, an overarching safety improvement plan may be developed.

- A review of the outcomes from our existing PSI reviews, such as investigations undertaken under the SIF, will be undertaken to identify whether it is possible to create safety improvement plans to help focus our improvement work, where this has not already happened.

- Where overarching issues are identified by learning responses, and there is already an existing improvement plan or review that is considering the specific issue (e.g., a quality priority) the findings from the learning response will be fed into the relevant workstream.

- Where overarching system issues are identified by a learning response, a safety improvement plan will be developed.

Monitoring of progress with safety improvement plan implementation will be overseen by the committee that has been identified alongside each of the national and local priorities.

Updates will be provided to IRG and the CGC, with escalation of concerns being made to the quality and safety committee.

10. Oversight roles and responsibilities

We will work with the NHS North Central London ICB and the Care Quality Commission (CQC), the independent regulator of health and social care in England, to ensure that the PSIRF mindset principles (see Appendix 6) underpin the oversight of our PSI response. Following these key principles will allow us to demonstrate improvement rather than compliance with prescriptive and centrally mandated measures.

Organisational responsibilities in relation to PSIRF oversight

The trust has designated the chief nurse and director of allied health professionals and the medical director as joint executive leads for PSIRF, as members of the trust board. The PSIRF executive leads, via the quality & safety committee (the sub-committee of the trust board to whom responsibility for PSIRF has been delegated) are responsible and accountable for effective PSI management in the trust.

The executive leads will maintain oversight by fulfilling the following responsibilities:

- **Ensure the organisation meets national patient safety incident response standards**

The joint executive leads will oversee the development, review and approval of the trust PSI response policy and plan. They will ensure that both documents meet the expectations set out in the PSIRF standards.

The trust executive leads will be supported by the director of quality & safety and the central quality & safety team in the preparation of the policy and the plan, the on-going review and development of which will be informed by our PSI profile and continued engagement with internal and external stakeholders. The trust approach to the initial development of both are as described in section 3 of our Plan.

- **Ensure PSIRF is central to overarching safety governance arrangements**

The trust board will receive assurance regarding the implementation of PSIRF via existing reporting mechanisms, including the quality & safety committee escalation summary and chief executive briefing to the board.

The quality & safety committee, which meets six times per year, will receive updates regarding PSIRF implementation, the development and monitoring of safety improvement plans and the learning system via the following mechanisms:

- Quarterly quality & safety report[14].
- Escalation and activity report from the CGC.

The quarterly report will provide assurance regarding implementation of the PSIRF and detail the positive impacts that the PSIRF is having on the organisation. Both documents will seek to highlight any specific risks that are known or emerging, either in relation to implementation of the PSIRF and the associated processes or arising directly from learning responses.

The CGC, which is jointly chaired by the executive PSIRF leads, will be responsible for the operational oversight of PSIRF. It will receive summary reports at each meeting in relation to learning responses initiated and completed, in line with our Plan, and the development and delivery of safety actions and improvement plans. The report will also detail the identification of incident(s) which signify an unexpected level of risk and/or potential for learning and improvement.

Divisional quality forums will receive quarterly reports, as a minimum, regarding the initiation and completion of learning and improvement responses in the division. This activity will be reviewed at executive performance meetings. Clinical divisions will be responsible for identifying any financial resources required to deliver safety actions and improvement plans, and for including resources required in the business planning process.

The effectiveness of the governance structure will be monitored, and changes will be made to the policy and plan where the need to do so is identified and approved by the CGC.

- **Quality assure learning response outputs**

A final report will be produced for all individual PSIIs, and this will be reviewed and signed off as complete by the PSIRF executive leads. This process will be supported by the central quality and safety team.

There is not a requirement for formal executive lead sign-off of other learning responses (e.g., AAR, thematic reviews). All learning responses will be reviewed by IRG.

[14] It is anticipated that the format in which learning and improvement activity associated with the PSIRF is reported will evolve over time (e.g., it may be more appropriate for the information to be presented in a standalone report). Over time the report will be developed to include an assessment of the balance of resources going into patient safety incident response versus improvement.

11. Complaints and appeals

The trust recognises that there will be occasions when patients, service users, and carers are dissatisfied with aspects of care and/or the services provided by the organisation. We have established processes for identifying PSIs arising from complaints and PALS enquiries/concerns and ensure either that an incident form has been completed or provide instruction where needs to be completed retrospectively.

Our PSPs are involved in scrutiny of the complaints system and processes to ensure that the complainant and their concerns remain at the forefront of our processes and individual responses.

Complaints and concerns will be handled respectfully, ensuring that all parties concerned feel involved in the process and assured that the issues raised have been comprehensively reviewed and the outcomes shared in an open and honest manner. Any complaints or appeals received specifically in relation to our response to PSIs will be managed in line with our normal complaint management process.

Patients, service users, and carers wishing to contact the trust in relation to a response to a PSI can do so via the PALS department in the first instance. The PALS team provides confidential advice and support to help service users with any concerns that they have about the service or care that the trust provides, including how a formal complaint can be made.

Any concerns or complaints made to the PALS/complaints team of the host trust from which the trust runs a service will be shared and the process described in our policy will then apply.

Complaints regarding NHS services

The team can be contacted via:

- Post: The complaints manager, Moorfields Eye Hospital NHS Foundation Trust, 162 City Road, London, EC1V 2PD
- Telephone: 020 7566 2324/2325
- E-mail: moorfields.pals@nhs.net (for queries or concerns) or moorfields.complaints@nhs.net (for formal complaints)

In person at: the PALS office (address as above, 9:30-16:00 on normal working days). Patients who are dissatisfied with the outcome of the local resolution process are entitled to go to the second stage of the NHS complaints procedure and request their complaint is considered by the Parliamentary and Health Service Ombudsman for England (PHSO).

The PHSO can be contacted as follows:

- In writing: Millbank Tower, Millbank, London, SW1P 4QP
- Email: phso.enquiries@ombudsman.org.uk
- Telephone: 0345 015 4033
- Website (for further information): www.ombudsman.org.uk

Complaints regarding private services

The team can be contacted via:

- Post: Moorfields Private Complaints Team, Moorfields Private, 9-11 Bath Street, London. EC1V 9LF
- Email: moorfields.privatecomplaints@nhs.net

Moorfields Private is a member of The Independent Sector Complaints Adjudication Service (ISCAS), the recognised independent adjudicator of complaints for the private healthcare sector. ISCAS can be contacted via:

- Post: ISCAS, CEDR, 3rd Floor, 100 St. Paul's Churchyard, London, EC4M 8BU
- Email: info@iscas.org.uk
- Telephone: 020 7536 6091

12. Stakeholder engagement and communication

The central quality and safety team has engaged with key stakeholders, over a 12-month period, to inform the policy. The engagement activities undertaken have been summarised below and described in more detail in Appendix 3 and have included:

- Communication with the organisation regarding the introduction and purpose of the PSIRF.
- Involvement of our Patient Safety Partners (PSPs).
- Presentation of the Plan and policy at governance meetings, including the trust's quality and safety committee and clinical governance committee.
- Safety culture focus groups.

- Attendance at networking events, in particular those attended by partnership organisations.
- Both the policy and the plan have been developed collaboratively and in consultation with key stakeholders, including patient safety partners. The policy has undergone consultation with clinical governance committee members.
- The draft policy and plan were shared with the ICB, and their feedback has been incorporated into the final version.

13. Approval and ratification

For completion following approval and ratification.

14. Dissemination and implementation

A PSIRF implementation group is in place to support the implementation of this policy.

A transition phase from the old system to the new system will commence following approval. The progress of this transition will be documented in a PSIRF implementation plan and monitored by the working together board.

15. Review and revision arrangements

The policy will be reviewed every 12-18 months in the first instance. It is anticipated that earlier review may be required as the PSIRF processes are tested and embedded in the trust.

16. Document control and archiving

The current and approved version of this document can be found on the trust's intranet site. Should this not be the case, please contact the quality and compliance team.

Previously approved versions of this document will be removed from the intranet by the quality and compliance team and archived in the policy repository. Any requests for retrieval of archived documents must be directed to the quality and compliance team.

This document will be available on the trust internet page (www.moorfields.nhs.uk). The document will be made available to the communications team, who will be responsible for updating the webpage, by the quality and compliance team.

17. Monitoring compliance with this policy

The trust will use a variety of methods to monitor compliance with the processes in this policy, including the following methods:

Measurable policy objective	Monitoring/ audit method	Frequency of monitoring	Responsibility for performing the monitoring	Monitoring reported to which groups/ committees, including responsibility for reviewing action plans
Compliance with Incident Review Group terms of reference	Audit	Annual	Quality & safety team	Clinical governance committee
Reports submitted to clinical governance committee	Audit	Continuous during implementation	Quality & safety team	Clinical governance committee

18. Supporting references/evidence base

For completion following approval and ratification.

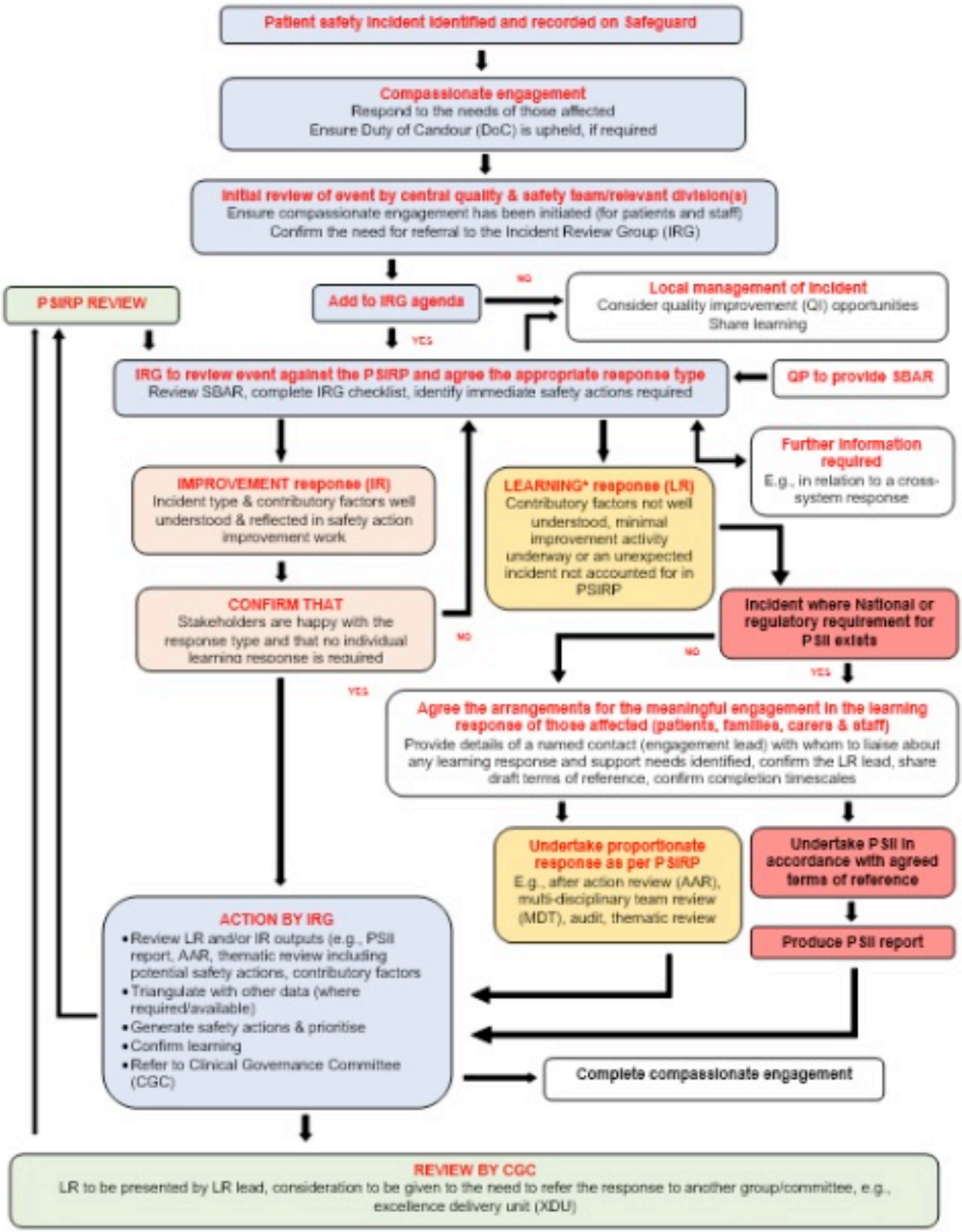
19. Supporting documents

Supporting documents/references	Owner
Patient safety incident response plan	Director of quality & safety
Incident reporting and management policy and procedure	Head of risk & safety
Policy for engaging and involving patients, families & staff following a patient safety incident[15] (formerly the being open and duty of candour policy)	Head of risk & safety
Risk management strategy and policy	Head of risk & safety

[15] Currently under development

Complaints policy	Head of patient experience and customer care
Policy & procedure for the management of clinical negligence, third party liability and property expenses claims (claims policy)	Director of quality & safety
Information governance policy	Director of quality & safety/senior information risk owner (SIRO)
Disciplinary policy & procedure	Deputy director of workforce and organisational development
Freedom to speak up policy	Director of quality & safety

Appendix 1: Patient safety incident management process



* ALL RESPONSES MUST
Understand everyday work, gather information, engage with staff affected, engage with patients and families (where agreed)

Appendix 2: Glossary of terms

Term	Definition/explanation
After Action Review (AAR)	AAR is a structured facilitated discussion of an event, the outcome of which gives individuals involved in the event understanding of why the outcome differed from that expected and the learning to assist improvement. AAR generates insight from the various perspectives of the MDT and can be used to discuss both positive outcomes as well as incidents. It is based around four questions: • What was the expected outcome/expected to happen? • What was the actual outcome/what actually happened? • What was the difference between the expected outcome and the event? • What is the learning? It aims to capture learning from these to identify the opportunities to improve and increase occasions where success occurs.
Compassionate engagement	An approach that prioritises and respects the needs of people who have been affected by a patient safety incident.
Duty of candour (DoC)	The duty of candour requires registered providers and registered managers (known as 'registered persons') to act in an open and transparent way with people receiving care or treatment from them. The regulation also defines 'notifiable safety incidents' and specifies how registered persons must apply the duty of candour if these incidents occur.
Engagement	Everything an organisation does to communicate with and involve people affected by a patient safety incident in a learning response. This may include the Duty of Candour notification or discussion, and actively engaging patients, families, and healthcare staff to seek their input to the response and develop a shared understanding of what happened.

Term	Definition/explanation
Everyday work	Everyday work describes the reality of how work is done and how people performing tasks routinely adjust what they do to match the ever-changing conditions and demands of work. Exploring everyday work shifts the focus from developing quick fixes to understanding wider system influences and is central to any learning response conducted to inform improvement. The following tools can be used to explore everyday work: • Observation guide Brief guide to conducting observations • Walkthrough guide Brief guide to walkthrough analysis • Link analysis guide Brief guide to link analysis • Interview guide Guidance on planning and conducting interviews as part of a patient safety incident learning response
Horizon scanning	The horizon scanning tool uses the Systems Engineering Initiative for Patient Safety (SEIPS) framework to structure conversations about work as done and emerging patient and staff safety risks Horizon scanning tool
Involvement	Part of wider engagement activity but specifically describes the process that enables patients, families, and healthcare staff to contribute to a learning response.
Multi-disciplinary team (MDT) review	An MDT review supports health and social care teams to learn from patient safety incidents that occurred in the significant past and/or where it is more difficult to collect staff recollections of events either because of the passage of time or staff availability. The aim is, through open discussion (and other approaches such as observations and walk throughs undertaken in advance of the review meeting(s)), to agree the key contributory factors and system gaps that impact on safe patient care.
Never Event (NE)	Patient safety incidents that are considered to be wholly preventable where guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and have been implemented by healthcare providers. A list of NEs can be found here: Never Event list February 2021

Term	Definition/explanation
Patient Safety Audit (PSA)	A review of a series of cases (of the same incident type) using clinical audit methodology to identify where there is an opportunity to improve and more consistently achieve the required standards (e.g., in a policy or guideline)
Patient Safety Incidents (PSIs)	Patient safety incidents are unintended or unexpected events (including omissions) in healthcare that could have or did harm one or more patients.
Patient Safety Incident Investigation (PSII)	PSIIs are conducted to identify underlying system factors that contributed to an incident. These findings are then used to identify effective, sustainable improvements by combining learning across multiple patient safety incident investigations and other responses into a similar incident type. Recommendations and improvement plans are then designed to effectively and sustainably address those system factors and help deliver safer care for our patients.
Patient Safety Incident Response Framework (PSIRF)	This is a national framework applicable to all NHS commissioned outside of primary care. Building on evidence gathered and wider industry best-practice, the PSIRF is designed to enable a risk-based approach to responding to patient safety incidents, prioritising support for those affected, effectively analysing incidents, and sustainably reducing future risk.
Patient Safety Incident Response Plan	Our local plan sets out how we will carry out the PSIRF locally including our list of local priorities. These have been developed through a coproduction approach with the divisions and specialist risk leads supported by analysis of local data.
Patient safety partners (PSPs)	PSPs are patients, carers, family members or other lay people (including NHS staff from another organisation working in a lay capacity) who are recruited to work in partnership with staff to influence and improve the governance and leadership of safety within an NHS organisation.

Term	Definition/explanation
Systems Engineering Initiative for Patient Safety (SEIPS)	SEIPS is a framework for understanding outcomes within complex socio-technical systems. Patient safety incidents result from multiple interactions between work system factors (i.e., external environment, organisation, internal environment, tools and technology, tasks and person(s). SEIPS prompts us to look for interactions rather than simple linear cause and effect relationships. SEIPS quick reference guide and work system explorer
Structured Judgement Review (SJR)	Originally developed by the Royal College of Physicians. The Trust follows the Royal College of Psychiatrists model for best practice in mortality review. The SJR blends traditional, clinical judgement based review methods with a standard format. This approach requires reviewers to make safety and quality judgements over phases of care, to make explicit written comments about care for each phase, and to score care for each phase. This allows the Trust to identify deaths assessed as more likely than not due to problems in care. This allows the Trust to identify those deaths which may need to progress to PSII according to the given national priorities.
Thematic review	A thematic review may be useful for understanding common links, themes or issues within a cluster of investigations, incidents or patient safety data. Themed reviews seek to understand key barriers or facilitators to safety. Top tips for completing a thematic review

Appendix 3: Background to the PSP role and a sample of activity relevant to PSIRF

Our PSIRF preparatory work has included the engagement of one of our PSPs in our PSIRF implementation and planning meetings, to help inform the development of our PSIRP and organisational readiness arrangements. Our PSP has had the opportunity to review and comment on our local priorities for inclusion in our PSIRP and support and challenge our assessment of our local improvement profile. A comprehensive review of our previous investigation reports, completed under the SIF, has been undertaken by the same PSP, to ensure that we improve the quality of our learning responses conducted under PSIRF. The review considered the following elements:

- Are contextual factors prioritised for investigation over behaviour and decision-making?
- Is blame avoided?
- Is 'local rationality' considered (that is, how and why did decisions make sense at the time)?
- Are safety actions system based?
- Appropriateness of terminology used in investigation reports.
- Compassionate engagement and involvement of those affected by patient safety incidents.
- Responding to patient safety incidents for the purpose of learning and improving patient safety.
- Identification of wording in investigation reports that does not align with wording in corresponding policies.
- Equity in engaging and involving patients, families and staff involved in a patient safety incident.
- Duty of Candour requirements.

We have reviewed, in detail, the findings of the PSP review of previous SI investigations and the improvement opportunities identified. We will continue to involve our PSPs in the development and review of our learning responses, in particular during the drafting of patient safety incident investigation reports, and the development of information resources to be shared with those affected by PSIs. We will specifically focus on improving the following, as priorities:

- The introduction of the Systems Engineering Initiative for Patient Safety (SEIPS) as a framework to guide the review of specified PSIs, as the mechanism to migrate from the linear root cause analysis investigation to the exploration of the interactions between the individual factors of a work system (i.e., external environment, organisation, internal environment, tools and technology, tasks, and person(s)).

- The application of Appendix 4 to support the development of safety actions, ensuring that there is a process for their development and subsequent monitoring.

- Ensuring that the language and terminology used within learning responses and patient information resources are both appropriate and easy to understand.

- The provision of support for staff and patients involved in a PSI.

Our PSPs have been attending some of our existing governance committees and will continue to attend when the new PSI response oversight arrangements are introduced. During transition from the SIF to the PSIRF, and following establishment of our new arrangements, there is an expectation that our PSPs will help us to scrutinise and improve our processes, particularly in relation to the:

- Ways in which we engage with and support patients and their families/carers following a PSI.

- Effectiveness of the mechanisms that we have in place for undertaking a learning response.

- Robustness of our on-going measuring and monitoring arrangements for our improvement responses.

- Arrangements that we have in place for supporting staff involved in or affected by a PSI, recognising that the services that our patients receive are directly impacted by the health and well-being of our staff.

Mechanisms that we have in place to identify and reduce health inequalities that exist within, or are exacerbated by, our services.

Appendix 4: Development of safety actions

Defining safety actions (SAs)

1. **Agree areas for improvement (AFI) - the problem(s) to be solved/risk(s) to be reduced**
   - Specify where improvement is needed, without defining how the improvement is to be achieved.
   - Involve the multi-disciplinary team, and patients, so that an informed decision can be made.
   - AFI must be linked to the outcome of a learning response or other review type.

2. **Define context (specific local OR wider organisation)**
   - Agree the approach to developing SAs by defining the context.
   - Where SAs will take time to develop and implement, record the area for improvement in a learning response report but note that the SAs will be developed as part of a wider improvement plan.

3. **Define safety actions to address AFIs**
   - Continue to involve the team - defining SAs should be a collaborative process.
   - The Human Factors Intervention Matrix (table 1) uses questions to prompt thinking about how each AFI identified might be translated in to possible safety actions to reduce risk.

4. **Prioritise safety actions**
   - Decide which SA, or set of SAs, to test for implementation. The iFACES tool (table 2) can help quantify, and prioritise, the potential value of each identified SA using six criteria.
   - Test the SAs (in 'real life' or under simulated conditions) that are being considered. During testing observe and discuss the SA, to identify any issues that people had (make the necessary safety improvements) and confirm that users behaved as expected (if not, update the SA).

5. **Define safety measures**
   - Before finalising a SA, plan how you will evaluate its effectiveness and progress towards specific goals. Identify meaningful measures, that can be monitored through normal work processes, to ensure that the benefits of change are sustained. Plan when to abandon a SA, if it isn't working. Seek the opportunity to invest in better alternatives.

6. **Write safety actions**
   - Safety actions must be SMART (specific, measurable, achievable, relevant, time-bound). They must **1)** be documented in a learning response report/safety improvement plan; **2)** start with the owner (e.g., head of risk & safety to.....); **3)** be directed at the people who have the levers to activate change; **4)** be succinct; **5)** standalone (readers should know what it means without reading the report); **6)** make it obvious why it is required. SAs, including measurement and monitoring arrangements, must be summarsied in a table at the end of the learning response.

7. **Monitor and review**
   - Monitor that SAs put in place remain impactful and are sustainable.
   - A review should be carried out periodically (typically annually) or if substantial changes are made.

Table 1: Human factors intervention matrix (HFIX) (with added questions)

Area for improvement		Set out where improvement is needed
Work system	**Person(s):** *Includes both characteristics of an individual and of a team*	How **can individual or team characteristics** be modified or changed to reduce risk or improve performance? – How could changes be made to the way individuals are recruited or selected for employment to ensure that they have the appropriate knowledge and skills necessary to perform their required tasks safely and efficiently? – How could the content of training programmes be developed or modified to improve individual's knowledge of procedures or tasks? – How could the method of training delivery be improved or modified to enhance its impact on individual's knowledge and skills (eg use of simulation)? – How could an individual's stress and fatigue be reduced or monitored to improve safety and performance? – How could verbal communication procedures be improved to reduce the likelihood of miscommunication among team members (eg standardisation, readback)? – How could the use of non-verbal communication (eg gestures or hand signals) be developed and standardised to improve communication? – How could team briefings/planning sessions be developed or improved to improve communication and co-ordination – Could procedures be developed to improve interactions between team members? – When individuals are working as a team, how could the responsibilities of each team member be more clearly defined? – How could changes be made to ensure that team leaders are identifiable and responsible? – How could handoffs/handovers be developed or improved to facilitate the communication between team members?
	Tasks: *Specific actions within larger work processes*	How can the **task or activity** be modified or redesigned to reduce risk or improve performance? – How can the task be restructured so that it requires less reliance on human memory (ie use checklists or technology that signals next step in task)? – If the task is done simultaneously with other tasks (divided attention), can it be done on its own? How can the mental workload/timesharing be reduced? – How could checklists be developed to guide the task or verify that the task has been performed properly? – How could immediate feedback be integrated into the task to allow operators to know when they have done things correctly or incorrectly? – How can procedures or checklist be redesigned to be clearer or more user-friendly? – If a task is repetitive, monotonous or boring, how could it be made more interesting? How could 'time on task' be changed to reduce vigilance decrements or mental lapses in attention? – How could procedures be rewritten so that they are less ambiguous or inapplicable to the safety critical tasks operators perform? – When operators switch tasks, what procedures could be developed to reduce negative transfer (habit interference)? – How could a task be modified to reduce the demands on the operator's physical or perceptual limitations?

Area for improvement		Set out where improvement is needed
Work system	**Tools and technology:** *Equipment, tools, software, and documents used to perform work*	How can **tools, equipment or technology** be modified or redesigned to reduce risk or improve performance? – How can warnings or alarms be improved to increase awareness of hazards or the presence of abnormal conditions? – How could tools, checklists, manuals or displays be redesigned to reduce confusion and errors? (eg highlight with bold text the items in a checklist that are the most important and/or should be memorised)? – Are better tools currently available but not purchased? What are these tools and how would they reduce errors on the job? – How could technologies be developed to reduce the task demands on the human decision-making processes, perceptual processes or physical limitations? – How could controls be more easily identified and/or better designed in terms of shape, size and other relevant considerations? – How could information sources be integrated or located in a more effective manner? – How could equipment be redesigned for more convenient maintenance? – How could inspection or troubleshooting aids be developed to ensure equipment is in proper working order? – How could maintenance procedures or schedules be improved to prevent equipment from failing during use?
	Internal environment: *Physical working environment in which individuals and teams perform their tasks*	How can the **physical environment** be modified or redesigned to reduce risk or improve performance? – How could the number of distractions in the environment be reduced to allow the operator to focus attention more fully on the task? – How could workspace arrangements or dimensions be modified to improve task performance? – How could the workspace be made better suited to the range of individuals who will use the facility? – How could lighting be changed to reduce shadows, glare or stark lighting changes (eg going from light to dark settings)? – How could the noise level be modified or reduced to reduce fatigue, improve concentration or enhance communication? – How could the temperature conditions be modified or improved to improve concentration, mood or performance? – How could physical/technological barriers to performance or communication be modified or rearranged? – How could the physical arrangement of workspaces/rooms be standardised to reduce confusion, delays or errors? – How could floor surfaces be modified or improved to allow for better movement or rearrangement of equipment when needed? – How could clutter be reduced or housekeeping improved to make the working environment more conducive to safe and productive work?
	Organisation: *Structures external to a person (but often put in place by people) that organise time, space, resources, and activity*	How can **organisational factors** be modified or redesigned to reduce risk or improve performance? – How could standard operating procedures (SOPs) be modified to reduce risks and improve safety? – How could the organisation ensure that SOPs are in place and that they are relevant and not out-of-date? – How could operational risk management procedures be implemented to reduce safety hazards? – How could tools that help supervisors plan activities and set goals be improved? – What tools or job aids could be developed to help supervisors create schedules, improve team composition or reduce operator fatigue? – How could the organisation improve its process for recruiting and hiring people who are better qualified or more experienced? – How could the organisation improve its process for evaluating and purchasing equipment that is user friendly and designed for safety?

Area for improvement		Set out where improvement is needed
		– How could leadership better communicate the importance and value of safety? – How could the organisation better disseminate and share safety information or lessons learned from safety events across units (ie become more transparent)? – How could the organisation better promote, reinforce or encourage safe practices? – How could the organisation's structure be redesigned to improve the co-ordination and integration of activities across divisions/departments?
	External environment: *Societal, economic, regulatory and policy factors outside an organisation*	How can **regulatory or societal factors** be modified or redesigned to reduce risk or improve performance? – How can manufacturers be influenced to improve the design of their products? – How can regulation be changed to improve safety? – How can external oversight/monitoring be improved to impact safety? – How can national safety programmes be redesigned to improve safety?

Table 2: iFACES tool (use to quantify and help prioritise safety actions)

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

Appendix 5: Safety action reporting template

Area for improvement: *(e.g., review of test results)*								
Ref.	**Safety action description** *(SMART)*	**Safety action owner**	**Target date for implementation**	**Date implemented**	**Tool/measure (e.g., audit)**	**Measurement frequency**	**Responsibility for monitoring oversight (i.e., specific group, individual)**	**Planned review date (e.g., annually)**
1.								
2.								
3.								
4.								
5.								

Appendix 6: PSIRF mindset principles

1. **Improvement is the focus**

PSIRF oversight should focus on enabling and monitoring improvement in the safety of care, not simply monitoring investigation quality.

2. **Blame restricts insight**

Oversight should ensure learning focuses on identifying the system factors that contribute to patient safety incidents, not finding individuals to blame.

3. **Learning from patient safety incidents is a proactive step towards improvement**

Responding to a patient safety incident for learning is an active strategy towards continuous improvement, not a reflection of an organisation having done something wrong.

4. **Collaboration is key**

A meaningful approach to oversight cannot be developed and maintained by individuals or organisations working in isolation – it must be done collaboratively.

5. **Psychological safety allows learning to occur**

Oversight requires a climate of openness to encourage consideration of different perspectives, discussion around weaknesses and a willingness to suggest solutions.

6. **Curiosity is powerful**

Leaders have a unique opportunity to do more than measure and monitor. They can and should use their position of power to influence improvement through curiosity. A valuable characteristic for oversight is asking questions to understand rather than to judge.

Appendix 7: Policy applicability to trust sites

This document applies to all premises occupied by trust staff/activities, unless explicitly stated otherwise.

For any sites that are excluded from the policy, the policy must list those sites together with a brief explanation as to why the site is excluded and name the local/host policy and any other documents that are used in its place.

Excluded sites	Reason for exclusion	Host policy and any other documents used in its place
UAE	The PSIRF applies to UK services only.	N/A

Where the list indicates that the policy does not apply, this implies that the trust will adhere to the policy of the host. Where a query exists then this must be referred, in the first instance, to either the:

- Divisional manager/head of nursing
- Policy owner
- Accountable director
- Service director

Moorfields Dubai will adhere to their own local policies and procedures and trust-wide documents will not apply, unless explicitly stated otherwise.

Appendix 8: Equality and health inequalities assessment

Initial EHIA Screening Tool

Title of Policy, Service or Project	Patient safety incident response framework (PSIRF)
Name and role of author of the assessment	[redacted], head of quality & safety [redacted], head of risk & safety
Department / Section	Quality & safety
Senior Responsible Officer	[redacted], director of quality & safety
Date of assessment	January 2024

Outline	
Give a brief summary of your policy or service • including partners, national or regional	The PSIRF sets out the NHS' approach to developing and maintaining effective systems and processes for responding to patient safety incidents (PSIs) for the purpose of learning and improving patient safety. It advocates a co-ordinated and data-driven response to PSIs. The PSIRF replaces the Serious Incident Framework (SIF) (2013) and makes no distinction between 'PSIs' and 'Serious Incidents'. It promotes a proportionate approach to responding to PSIs by ensuring resources allocated to learning are balanced with those needed to deliver improvement. Further, it supports organisations to respond to incidents in a way that maximises learning and improvement rather than basing responses on arbitrary and subjective definitions of harm. The PSIR policy supports the requirements of the NHS England PSIRF and sets out how Moorfields Eye Hospital NHS Foundation Trust (the Trust) will approach the development and maintenance of effective systems and processes for responding to PSIs and issues for the purpose of learning and improving patient safety.
What outcomes do you want to achieve?	Achievement of the four key aims of the PSIRF, namely: • Compassionate engagement and involvement of those affected by patient safety incidents (e.g., patients and their family members, carers, staff).

	• Application of a range of system-based approaches to learning from patient safety incidents. • Considered and proportionate responses to patient safety incidents. • Supportive oversight focused on strengthening response system functioning and improvement.
Give details of evidence, data or research used to inform the assessment of impact	• Completion of the diagnostic and discovery phase of PSIRF preparation, including a review of quality data (e.g., incidents, complaints, claims), high-level freedom to speak up (FTSU) data, and completion of a gap analysis of 'as is' processes. • The NHS Patient Safety Strategy: 2021 update (February 2021) was launched post the COVID 19 pandemic and recognises that there is increasing evidence of disparities in healthcare outcomes and interactions between different ethnic groups. The strategy update also acknowledges that socio-economic status and where in the country someone lives also impact on morbidity and mortality. This version of the strategy introduced a specific objective in relation to 'patient safety, equality, diversity and inclusion'. • Completion of the core PSIRF 5-day training by key staff groups.
Give details of all consultation and engagement activities used to inform the assessment of impact	• Engagement with peer trusts regarding implementation of the PSIRF via the University College London Partners (UCLP) health collaborative. • Participation in NHS England (NHSE) webinars and training events. • Engagement with early adopters, who have shared learning from their implementation of the PSIRF. • Focus groups with trust staff, undertaken during 2023. Departments/services were selected to participate in focus groups following review of the 2022 staff survey results. • Patient safety partner (PSP) oversight of PSIRF implementation activities conducted and planned, including the review of draft documents. • PSIRF implementation group established, including multi-disciplinary representatives from across the organisation.

	• Participation of multiple staff members in the 5-day mandatory PSIRF training.

SCREENING TEAM (Please enter below the names of the project team members who carried out this initial screening with you and their role in the screening (e.g., team colleague or critical friend).

Name	Department	Role
Implementation group team members	Multiple	Team colleague

1/ Identified Impact:

- **Positive Impact:** Will actively promote the standards and values of the Trust
- **Neutral Impact:** Where there are no notable consequences for any group;
- **Negative Impact:** If such an impact is identified, the EHIA should ensure, that as far as possible the risk, is eliminated, minimised or counter balanced by other measures. **This will require a 'Full EHIA" to be completed and submitted.**

Summarise impact & reasons

The PSIRF requires that we consider health inequalities when considering our learning and improvement responses following PSIs, and how we engage with those involved in PSIs.

In December 2018, NHS England and NHS Improvement analysed the National Patient Safety Strategy against the Equality Act 2010 (public sector equality duty) and concluded the strategy makes an overall positive contribution to advancing equality in relation to patient safety improvement across the NHS. They do not anticipate the implementation of the NPSS including PSIRF will have any negative impact on equality for people with protected characteristics.

The impact of the PSIRF on those with a protected characteristic is yet to be formally measured and the collection of data on protected characteristics is not currently mandatory for incident reporting. However, as part of the PSIRF implementation we will seek to capture data to inform our assessment and seek to confirm the existence of a positive impact on those involved in or affected by a PSI. In particular we will seek to collate data that can help identify any disproportionate risk to people with protected characteristics and consider how this information can be used to improve patient safety incident responses. Once this becomes known our EHIA will be updated to reflect these measures and impact data.

The development of safety actions, following completion of a learning response, will specifically consider whether any inequalities are associated with a particular improvement solution. The focus on proactive, preventative safety improvement action will directly benefit all patients and staff including all those with protected characteristics.

2/ Please state in the table below whether the policy/service/function etc. could have any potential impact on anyone from a "protected characteristic" group, whether service users, staff, or other stakeholders.

"Protected Characteristic Group"	Is there likely to be a Positive, Negative or Neutral impact	If the impact is positive or negative then please record your findings / concerns against the identified 'Protected Characteristics' group.
Human Rights	Neutral (currently not measured)	
Age	Neutral (currently not measured)	
Disability	Neutral (currently not measured)	
Gender Reassignment	Neutral (currently not measured)	
Marriage and Civil Partnership (duty only applies to elimination of discrimination)	Neutral (currently not measured)	
Pregnancy and Maternity	Neutral (currently not measured)	
Race	Neutral (currently not measured)	
Religion or Belief	Neutral (currently not measured)	
Sex	Neutral (currently not measured)	
Sexual Orientation	Neutral (currently not measured)	
Other relevant groups: N/A		

IMPORTANT NOTE: *If any of the above results in '**negative**' impact, a 'Full' EHIA which covers a more in-depth assessment on areas/groups impacted **must** be conducted.*

3/ Can the policy/service/function etc. be used to advance equality and foster good relations, including for example, participation in public life? If so, how?

One of the aims of PSIRF is compassionate engagement and involvement of those affected by patient safety incidents (e.g., patients and their family members, carers, staff).

4/ Please provide and summarise below any relevant evidence for your decision above, including any engagement activities – this could include for example the results of specific consultations, complaints or compliments, customer satisfaction or other surveys, service monitoring and take- up, comments from stakeholders and demographic data.

The central quality and safety team has engaged with key stakeholders, over a 12-month period, to inform the Plan. The engagement activities undertaken have been summarised below and described in more detail in Appendix 3 and have included:

- Activities undertaken to support delivery of the PSIRF as a quality priority.
- Communication with the organisation regarding the introduction and purpose of the PSIRF.
- Involvement of our Patient Safety Partners (PSPs).
- Presentation of the Plan and PSIRP at governance meetings, including the trust's Quality and Safety committee and Clinical governance committee.
- Sharing and development of resources made available by NHS England and other NHS organisations.
- Development of a PSIRF implementation group.
- Safety culture focus groups.
- Attendance at networking events, in particular those attended by partnership organisations.

5/ Are there any gaps in the evidence you have which make it difficult for you to determine whether there would be an adverse impact?

No ☐ Yes ☐

If yes, please state below how you intend to acquire this evidence and your timescales for doing so.

Equality and health inequality data is not routinely collated in relation to the occurrence of PSIs. Amendments required to the PSIR policy and plan will be considered throughout the implementation and embedding phase and formally 12-18 months following implementation. This will include the on-going consideration of metrics that need to be developed.

6/ You must compete a Full EHIA if you have identified a negative potential impact for any "protected characteristic" group, which is not legal or justifiable or if you have identified any gaps in evidence which make it difficult for you to determine whether there would be adverse impact.

Please insert below any issues you have identified/recommendations for the Full EHIA.

N/A

Appendix 9: Checklist for the review and approval of documents

To be completed (electronically) and attached to any document which guides practice when submitted to the appropriate committee for approval or ratification.

Title of the document: Patient Safety Incident Response Policy

Policy (document) author: Head of risk & safety and patient safety specialist
Head of quality & safety

Policy (document) owner: Director of quality & safety

	Title	Yes/no/ unsure/ NA	Comments
1	**Title**		
	Is the title clear and unambiguous?	Yes	
	Is it clear whether the document is a guideline, policy, protocol or standard?	Yes	
2	**Scope**		
	Is the target population clear and unambiguous?	Yes	
	Is the purpose of the document clear?	Yes	
	Are the intended outcomes described?	Yes	
	Are the statements clear and unambiguous?	Yes	
3	**Development process**		
	Is there evidence of engagement with stakeholders and users?	Yes	
	Who was engaged in a review of the document (list committees/individuals)?	• PSIRF implementation group • Risk & safety committee • Clinical governance committee • Divisional management teams • Service directors	
	Has the policy template been followed (i.e., is the format correct)?	Yes	
4	**Evidence base**		
	Is the type of evidence to support the document identified explicitly?	Yes	

	Are local/organisational supporting documents referenced?	Yes
5	**Approval**	
	Does the document identify which committee/group will approve/ratify it?	Yes
	If appropriate, have the joint human resources/staff side committee (or equivalent) approved the document?	N/A
6	**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
7	**Process for monitoring compliance**	
	Are there measurable standards or KPIs to support monitoring compliance of the document?	Yes
8	**Review date**	
	Is the review date identified and is this acceptable?	Yes
9	**Overall responsibility for the document**	
	Is it clear who will be responsible for coordinating the dissemination, implementation and review of the documentation?	Yes
10	**Equality impact assessment (EIA)**	
	Has a suitable EIA been completed?	Yes

Committee approval Policy and procedural review group (PPRG)			
Name of chair	Head of quality & safety	Date	27/03/2024
Ratification by quality & safety committee			
Date: 30/01/2024			