The Queen Elizabeth Hospital King's Lynn
NHS Foundation Trust

Patient Safety Incident Response Plan (PSIRP)

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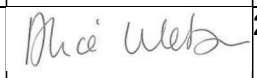
Reviewer	**Alice Webster**	**CEO**		**21 August 2023**
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1. Introduction

1.1. Forward

The NHS Patient Safety Strategy was published in 2019 and describes the Patient Safety Incident Response Framework (PSIRF), a replacement for the NHS Serious Incident Framework 2015 (SIF). This document is the Patient Safety Incident Response Plan (PSIRP) and describes what we have done at The Queen Elizabeth Hospital NHS Foundation Trust to prepare for "go live" with PSIRF.

The SIF provided structure and guidance on how to identify, report and investigate an incident resulting in severe harm or death. PSIRF is best considered as a learning and improvement framework with the emphasis placed on the system and culture that support continuous improvement in patient safety through how we respond to patient safety incidents.

The NHS Patient Safety Strategy 2019 describes the Patient Safety Incident Response Framework (PSIRF) as "a foundation for change" and as such, it challenges us to think and respond differently when a patient safety incident occurs. Unlike previous frameworks, PSIRF is not a small change or adaptation of what came before. PSIRF is a whole system and ethos change, to how we think and respond when an incident happens. Previous frameworks have described when and how to investigate a serious incident, PSIRF focusses on learning and improvement. With PSIRF, we are responsible for the entire process, including deciding what patient safety incidents to investigate and how. There are no set timescales or external organisations to approve what we do, and these decisions will be made internally within the trust.

Since the introduction of the Patient Safety Strategy the trust has been on a journey to redefine and strengthen how it classifies and governs patient safety including: -

2019/20

- Improvement to quality of incident investigations through commissioning RCA and Human Factors training
- Improvement to Datix capability to support Divisions to monitor incidents
- Development of Quarterly Patient Safety reports

2020/21

- Restructure of corporate risk and safety structure to create Patient Safety Directorate
- Deputy Medical Director and Head of Patient Safety & Clinical Effectiveness designated as Patient Safety Specialists to ensure implementation of Patient Safety Strategy

2022/23

- Patient Safety comes under Chief Nurse portfolio
- Interim Associate Director appointed
- Appointment of Patient Safety Specialists

- First Patient Safety Partner appointed with plans for a second
- Joint Just and Restorative Culture Training across ICS for key patient safety staff

1.2. Purpose

This Patient Safety Incident Response Plan (PSIRP) sets out how The Queen Elizabeth Hospital King's Lynn NHS Foundation Trust (QEHKL) intends to respond to patient safety incidents reported by staff and patients, their families, and carers as part of our work to continually improve the quality and safety of the care we provide.

The Serious Incident Framework 2015 (SIF) provided structure and guidance on how to identify, report and investigate an incident resulting in severe harm or death. PSIRF is best considered as a Learning and Improvement Framework with the emphasis placed on the system and culture that support continuous improvement in patient safety, through how we respond to patient safety incidents.

One of the underpinning principles of PSIRF is to do fewer "investigations" but to do them better. Better means taking the time to conduct systems-based investigations by people that have been trained to do them. This PSIRP, as well as associated policies and guidelines will describe how it all works. Carrying out investigations for the right reasons can and does identify learning. Removal of the SIF does not mean "do nothing", rather it means respond in the right (most effective) way depending on the type of incidents and associated factors.

This PSIRP sets out how QEHKL will respond to patient safety incidents reported by staff and patients, their families and carers as part of work to continually improve Patient Safety Incident Investigations (PSIIs) by:

- Refocusing PSII towards a system analysis approach and the rigorous identification of interconnected causal factors and system issues.

- Focusing on addressing these causal factors and the use of improvement science to prevent or continuously and measurably reduce repeat patient safety risks and incidents.

- Transferring the emphasis from the quantity to the quality of PSIIs such that it increases stakeholder (notably patients, families, carers and staff) confidence in the improvement of patient safety through learning from incidents.

- Demonstrating the added value from the above approach.

A risk to successfully implementing PSIRF is continuing to investigate and review incidents as we did before, but simply giving the process a new label. The challenge is to embed an approach to investigating that forms part of the wider response to patient safety incidents whilst allowing time to learn thematically from other patient safety insights, e.g., patient experience, audit, outcome measures and staff "speaking up".

PSIRF recognises the need to ensure we have support structures for staff and patients involved in patient safety incidents. Part of which is the fostering of a

psychologically safe culture shown in our leaders, our trust-wide strategy, and our reporting systems.

1.3. Scope

In line with the NHS Patient Safety Strategy 2019, a PSIRP is now an annual requirement of each provider delivering NHS-funded care. This first PSIRP will be in place from 1st September 2023. This document should be read alongside the introductory Patient Safety Incident Response Framework 2022, which sets out the requirement for this plan to be developed. We will develop the planning aspects of this PSIRP with assistance and cooperation of partner organisations across the ICS.

It is important to note that the PSIRP is not a permanent rule that cannot be changed. The Trust will remain flexible and consider the specific circumstances in which patient safety issues and incidents occurred and the needs of those affected. As such this document will be reviewed quarterly for the first year and annually thereafter.

There are many ways to respond to an incident. This document covers responses conducted solely for the purpose of system learning and improvement.

There is no remit within this plan or PSIRF to apportion blame or determine liability, preventability or cause of death in a response conducted for the purpose of learning and improvement.

This plan explains the scope for a systems-based approach to learning from Patient Safety Incidents (PSIs). We will identify PSIs to review through nationally and locally defined patient safety priorities. An analysis of which is explained later within this document.

Responses covered in this plan include:

- Patient Safety Reviews (PSRs)
- Patient Safety Incident Investigations (PSIIs)

Other types of response exist to deal with specific issues or concerns. Examples of such responses include complaints management, claims handling, human resources investigations into employment concerns, professional standards investigations, coroners' inquests, or criminal investigations. The principal aims of each of these responses differ from the aims of a patient safety response and are outside the scope of this plan.

To be effective in meeting their specific intended purposes, responses that are not conducted for patient safety learning and improvement are separate entities and will be appropriately referred as follows:

- Human resource (employee relations) teams for professional conduct/competence issues and if appropriate, for referral to professional regulators
- Legal teams for clinical negligence claims
- Medical examiners and, if appropriate, local coroners for issues related to the cause of a death
- The police for concerns about criminal activity.

1.4. Strategic Aims and Objectives

The strategic aims and objectives of PSIRF are as follows:

Overarching aims	Specific objectives
1. Improve the safety of the care we provide to our patients	• Develop a climate that supports a just culture and an effective learning response to PSIs • Respond to PSIs purely from a patient safety perspective • Reduce the number of duplicate PSIIs into the same type of incident to reduce waste, enable more resource to be focused on effective learning and so enable more rigorous investigations that identify systemic contributory factors • Aggregate and confirm validity of learning and improvements by basing PSIIs on a small number of similar repeat incidents • Consider the safety issues that contribute to similar types of incidents • Develop system improvement plans across aggregated incident response data to produce systems-based improvements • Better measurement of improvement initiatives based on learning from incident response
2. Improve the experience for patients, their families and carers wherever a patient safety incident or the need for a PSII is identified	• Act on feedback from patients, families, carers and staff about their concerns with patient safety incident responses in the NHS. • Support and involve patients, families and carers in incident response, for better understanding of the issues and contributory factors
3. Improve the use of valuable healthcare resources	• Transfer the emphasis from quantity of investigations completed with an arbitrary deadline to a higher quality response to patient safety incidents, and the implementation of meaningful actions that lead to demonstrable change and improvement • Develop a local board-led, commissioner and integrated care system (ICS)/sustainability and transformation partnership (STP) assured architecture around response to patient safety incidents, which promotes ownership, accountability, rigour, expertise and efficacy

4. Improve the working environment for staff in relation to their experiences of patient safety incidents and investigations	• Act on feedback from staff about their concerns with patient safety incident responses in the NHS. • Support and involve staff in patient safety incident response, for better understanding of the issues and contributory factors

2. Our services

The Queen Elizabeth Hospital King's Lynn is in West Norfolk. QEHKL provide a comprehensive range of specialist, acute, obstetrics and community-based healthcare services to around 331,000 people across West and North Norfolk, in addition to parts of Breckland, Cambridgeshire and South Lincolnshire.

QEHKL has more than 4,000 staff and volunteers, approximately 530 beds, and a helipad for air ambulances. We work with neighbouring hospitals for the provision of tertiary services, including as part of regional partnership and network models of care, such as the trauma network. Some specialist services and clinics are provided in community facilities, such as the North Cambridgeshire hospital in Wisbech.

In February 2022, the significant progress that has been made at QEHKL in just three years since 2019 was recognised by the Care Quality Commission who rated the Trust as 'Good' in all of the core services they inspected, and recommended the Trust moves out of the recovery support system (formerly special measures). The Trust has an absolute determination to continuously improve care and services for our patients and their families.

2021/22 was year two of the five-year Corporate Strategy and was an exceptional year for QEHKL and the wider NHS with a continued response to the impact of the COVID-19 pandemic and unprecedented pressures on urgent and emergency care services.

There was a relentless focus on the top four priorities across the region in response to the challenges the health service has faced: (1) addressing the waiting lists that have built up for our planned (elective) patients, (2) the ongoing COVID vaccination programme, (3) providing timely urgent and emergency care and (4) staff health and wellbeing. Alongside this, QEHKL sustained a clear focus on continuous improvement journey and delivery of our Integrated Quality Improvement Plan, against which the Trust has evidenced further considerable progress for patients, their families, and staff.

3. PSIRF Transition

The following is a summary of the full transition project plan and tracker.

Time scale	Changes
Q1 23/24	• Engagement and benchmarking meetings with colleagues across the ICS • Alignment of PSIRP with other organisations across the ICS • Change of Serious Incident Review Forum chair

	• SIRF Terms of Reference updated • "Moderate" incidents reviewed prior to SIRF • Workshops for all key stakeholders to help define and shape changes • Identification of PSII investigators • PSII training (three modules) procured and delivered • Thematic reviews for the 3 priority areas (based on risk profile) commenced • Associate Director of Patient Safety attends Divisional Governance meetings to support decision making of learning responses • Training/coaching for Patient Safety Team and Risk and Governance Leads in other types of learning responses • Pilot of a PSII, including using PSII template • Evaluation the changes required on the Datix system • Evaluation the changes required to policies • Define the requirement of the "learning response tool kit" of documents • Initial meeting with Organisational Development team to discuss development of Restorative Just Culture and Psychological Safety • Joint engagement meetings with coroner's office, Trust legal team and ICB • Trust wide communications regarding PSIRF • Patient Safety Syllabus Levels 1&2 go live on ESR • Liaison with communication and IT teams for Patient Safety area to be developed on Trust's new intranet and website to include learning response "toolkit"
Q2 23/24	• Thematic reviews completed and reports shared – actions agreed, Quality Improvement commences • Policies updated or new ones written as required (Including PSIRF policy) • PSII and "learning response tool kit" developed • Templates and content of upwards reporting of PSII to Patient Safety and Experience Executive Group agreed and piloted • Templates and content of upwards reporting of other learning responses to Patient Safety and Experience Executive Group agreed and piloted • Trust wide communication regarding PSIRF • Meeting with Organisational Development team to discuss development of Restorative Just Culture and Psychological Safety • Transition to new framework on 1st September 2023 • Divisions leading on their own learning responses with support from the patient safety team • ICB support and monitoring of transition
Q3 23/24	• Final changes to Datix made • Upward reporting evaluated and refined • ICB support and monitoring of transition • Evaluation of "learning response tool kit"

	• Analysis of additional training requirements • Evaluation of Quality Improvement work • Development of Patient Safety area on Trust intranet site to include publication of "tool kits", "lessons learned", Just Culture, Being Open and Duty of Candour guidance
Q4 23/24	• Annual review of risk profile to inform PSIRP 24/25 • Review of PSIRP for the next financial year • Patient Safety Priorities agreed for PSIRP 24/25
Q1 24/25	• New PSIRP

4. Situation Analysis – National

Many millions of people are treated safely and successfully each year by the NHS in England, but evidence tells us that in a highly complex and adaptive healthcare system things will and do go wrong, no matter how dedicated and professional the staff.

When things go wrong, patients are at risk of harm and many others may be affected. The emotional and physical consequences for patients and their families can be devastating. For the staff involved, incidents can be distressing and members of the clinical teams to which they belong can become demoralised and disaffected. Safety incidents also incur costs through lost time, additional treatment, and litigation. Overwhelmingly these incidents are caused by system design issues, not mistakes by individuals.

Historically, the NHS via the SIF has required organisations to investigate each incident report that meets a certain outcome threshold or 'trigger list'. When this approach was developed it was not clear that:

a) Luck often determines whether an undesired circumstance translate into a near miss or a severe harm incident. As a result, focusing most patient safety investigation efforts on incidents with the most severe outcome does not necessarily provide the most effective route to 'organisational learning'.

b) There is no clear need to investigate every incident report to identify the common causes and improvement actions required to reduce the risk of similar incidents occurring. To emphasise this point, it has been highlighted that in-depth analysis of a small number of incidents brings greater dividends than a cursory examination of large number.

An increased openness to report patient safety issues has also led to an ever-growing number of incidents being referred for investigation. NHS organisations are now struggling to meet the number of requests for investigation into similar types of incidents with the level of rigour and quality required. Available resources have become inundated by the investigation process itself – leaving little capacity to carry out the safety improvement work the NHS originally set out to achieve.

In addition, the remit for serious incident investigation has become unhelpfully broad and mixed over time. This originates from an attempt to be more efficient by addressing the many and varied needs of different types of investigation in a single approach. Sadly, the very nature and needs of some types of investigation (e.g., professional conduct or fitness to practise; establishing liability or avoid ability; or establishing cause of death) have frustrated the original patient safety aim and blocked the system learning the NHS set out to achieve.

Many other high-profile organisations now identify and describe their rationale for deciding which incidents to investigate from a learning and improvement perspective. While some industry leaders describe taking a risk-based approach to safety investigation (e.g., The Rail Accident Investigation Branch and Air Transport Safety Board), others list the parameters that help their decision-making processes (Police, Parliamentary Health Service Ombudsman and Healthcare Safety Investigation Branch).

We need to remove the barriers in healthcare that have frustrated the success of learning and improvement following a PSII (e.g., mixed investigation remits, lack of dedicated time, limited investigation skills). We also need to increase the opportunity for continuous improvement by:

a) Improving the quality of future PSIIs
b) Conducting PSIIs purely from a patient safety perspective
c) Reducing the numbers of PSIIs into the same types of incidents
d) Aggregating and confirming the validity of learning and improvements by basing PSIIs on a small number of similar repeat incidents

This approach will allow NHS organisations to consider the safety issues that are common to similar types of incidents, and, based on the risk and learning opportunities they present, demonstrate that these are:

a) Being explored and addressed as a priority in current PSII work or
b) the subject of current improvement work that can be shown to result in progress or
c) listed for PSII work to be scheduled in the future

In some cases where a PSII for system learning is not indicated, another response may be required. This will depend on the intended aim and required outcome and might include a case note review, timeline, or chronology, learning review meeting or sharing of an anonymised incident report. All information relating to PSIs, and the insight generated from all responses must be recorded within Datix, our local risk management systems and shared with the National Reporting and Learning Systems or its successor. PSIIs will also be recorded on the Strategic Executive Information System (StEIS) or its successor to allow organisations to monitor progress of PSIIs.

As part of this approach, incidents requiring other types of investigation and decision-making, which lie outside the scope of this work, will be appropriately referred as follows:

a) Professional conduct/competence – referred to human resource teams
b) Establishing liability/avoid ability – referred to claims or legal teams
c) Cause of death – referred to the coroner's office
d) Criminal – referred to the police

5. Situation Analysis – Local

5.1. Results of a review of activity and resources

A review of the patient safety resource and activity (associated with serious incident investigations) for the period April 2018 to March 2022 has been undertaken to determine how many PSIIs can be supported from September 2023 through to September 2024. This review has been undertaken by applying the Patient Safety Incident Standards to previous Serious Incident Investigations to assess how many would be commissioned under PSIRF.

The total number of SIIs commissioned by QEHKL 2018-2022 is 264. Those investigations undertaken by independent/external bodies have been excluded from the analysis as this will still be a requirement for this under PSIRF. The analysis below shows how many of the past SIIs would meet the requirements of PSIRF for a PSII. Those incidents requiring PSII due to regulatory requirements have been included in the PSII numbers.

Of these 158 SIIs, 5 were not related to patient safety and therefore would not be PSIIs under PSIRF. These would have been more suitable for professional conduct/competence investigations, criminal investigations (alleged assault). In addition, 3 were purely related to administration processes or information security breaches (establishing liability/avoid ability).

Nationally, Patient Safety Specialists have estimated that on average each PSII takes 60 hours to complete (this time is reflective of all staff involvement rather than just the investigation lead). The number of incidents that would meet the PSII standards is 62. Therefore 62 PSII x 60 hours each = 3720 hours over 5 years. Or 744 hours (per year average). Meaning that 14.3 hours per week (not including Family Liaison role) would be needed for PSIIs. In conclusion, it is estimated that QEHKL would be able to support 12-13 PSIIs per year within existing staffing numbers.

Division	SIs completed 2018-2022	Number which would meet new PSII standards	Comments
W&C	38	3	PPHs would be better reviewed by After Action Review or thematic review
UEC	39	20	Many 12-hour breeches and transfer delays
Surgery	32	11	Healthcare Acquired Infections should be reviewed by After Action Review
Medicine	37	27	Pressure Ulcers and falls could be reviewed by AAR
CSS	12	1	Missed diagnosis in radiology, many triage of referral issues
Total	158	**62**	

Figure 1. Table of SIs and future PSII analysis

In summary, QEHKL has identified that within the current Patient Safety Team and Divisional Risk and Governance Leads there is enough resource to manage this workload. The structure for each PSII is a lead investigator, who will be supported centrally by a PSII investigator and subject matter experts as appropriate.

Further support in terms of administrative support and patient/family/staff liaison will also be provided by the patient safety team/investigation coordinator or division. Lead investigators will not be expected to manage any more than two full PSIIs at any time. The remainder of safety incidents should be managed with other types of patient safety responses. This analysis should be repeated for subsequent PSIRPs to manage resources.

To improve the Trusts ability to deliver against PSII standards the plan is to:

- Assign an appropriately trained executive to oversee delivery of the PSII standards and support the sign off of all PSIIs (this will be an updated version of the current Serious Incident Review Forum)
- Train up to 30 staff in systems-based training to support either leading or reviewing and investigation.
- Develop an incident review toolkit to support the review of patient safety incidents where a PSII is not indicated.

5.2 Types or categories of patient safety response (PSR)

There are many ways an organisation can respond to a PSI to learn and improve. PSRs include several techniques to identify areas for improvement, immediate safety actions and to respond to any concerns raised by the affected patient, family member or carer. Different PSR techniques can be adopted depending on the intended aim and required outcome. All PSRs are conducted locally by the Trust. There are four broad categories of PSRs (see Annex A for full details).

Incident recovery

Immediate measures taken to:

- Address serious discomfort, injury, or threat to life
- Respond to concerns raised by the affected patient, family member, or carer
- Determine the likelihood and severity of an identified risk

Team Reviews

Post-incident review as a team to:

- Identify areas for improvement
- Celebrate success
- Understand the expectations and perspectives of all those involved
- Agree actions
  Enhance teamwork through communication and collaborative problem solving

Systematic review

To determine:

• The circumstances and care leading up to and surrounding the incident

• Whether there were any problems with the care provided to the patient

Patient Safety Incident Investigation (PSII)

Comprehensive, in depth, systems-based investigations lead by a suitably trained investigator of at least band 8a (see Annex B for training needs analysis).

Where a PSII is required (as defined in this plan for both local and national priorities), the investigation will start as soon as possible after the PSI is identified. PSIIs will ordinarily be completed within one to three months of their start date. In exceptional circumstances, a longer timeframe may be required for completion of a PSII. In which case, any extended timeframe will be agreed between the Lead Investigator, Executive Sponsor and patient/family/carer. No PSII should take longer than six months. A balance will be drawn between conducting a thorough PSII, the impact that extended timescales can have on those involved in the incident, and the risk that delayed findings may adversely affect safety or require further checks to ensure they remain relevant. Where the processes of external bodies delay access to some information for longer than six months, a completed PSII can be reviewed to determine whether new information indicates the need for further investigative activity.

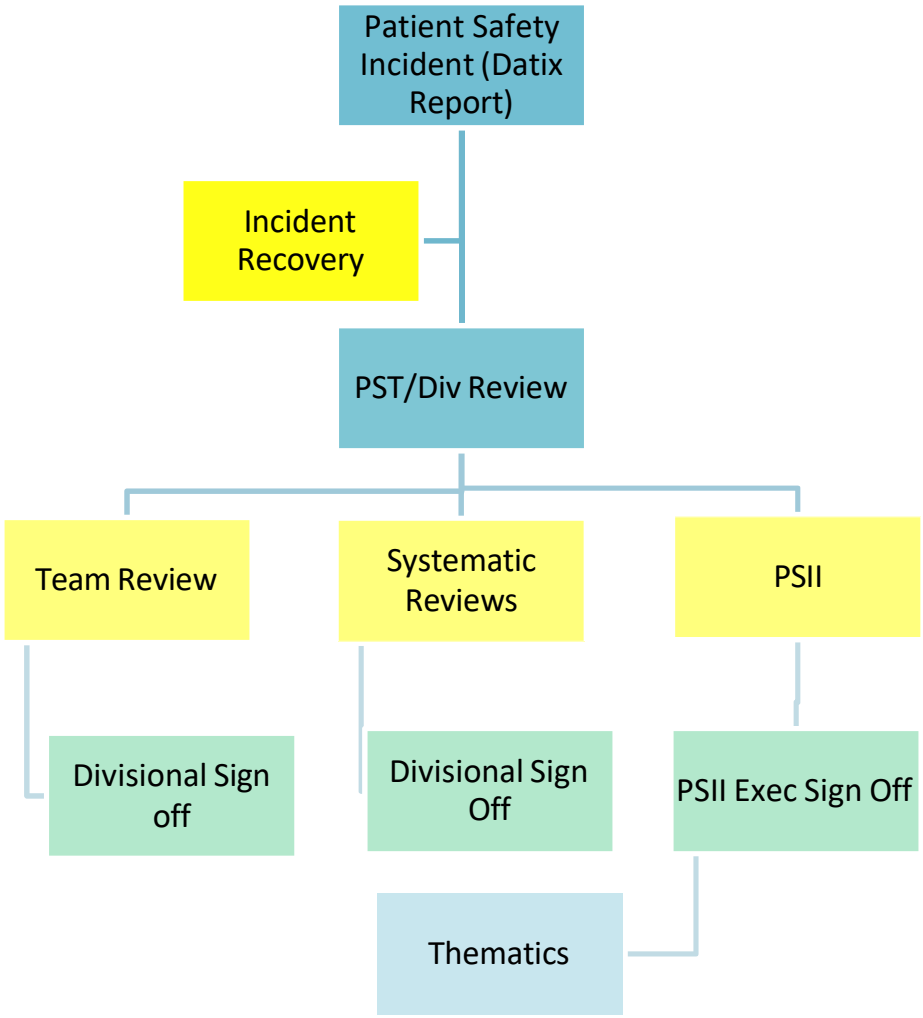

Figure 3. High level process flow chart of patient safety reviews including PSII.

5.3 Review of Patient Safety Incident Risks

The patient safety incident risks for this organisation have been profiled using organisational data from recent patient safety incident reports, including: -

- Audit
- Complaints and PALS
- External reviews
- Incidents
- Inquests and Claims
- Patient Surveys
- SJRs and learning from deaths
- Staff Surveys and FTSU

To support the assessment of risk and to agree patient safety incident priorities an in-depth thematic analysis of patient safety data (2018-2022) was undertaken and discussed at

workshops with both internal and external stakeholders. By this analysis it was possible to identify and agree local priorities for investigation.

- Key stakeholders included:
    - Senior Managers within the Trust
    - Patient Safety Specialists
    - Risk and Governance Leads
    - Legal Team
    - Medical Examiner
    - ICB representatives
    - Patient Participation Groups and Health Watch
    - Patient Safety Partner

5.4 Conclusions from review of the local patient safety incident profile

Criteria for defining top local patient safety risks

Criteria	Considerations
Potential for harm	• People: physical, psychological, loss of trust (patients, families, caregivers) • Service delivery: impact on quality and delivery of healthcare services; impact on capacity • Public confidence: including political attention and media coverage
Likelihood of occurrence	• Persistence of the risk • Frequency • Potential to escalate

Top local Patient safety risks

The overall top 3 themes from 2018-2022 were

1. Falls
2. Medication omissions / errors
3. Unplanned admissions

Other themes identified through soft intelligence which would not have pulled through onto the themed slides are:

- Nutrition and hydration
- Delays in chemotherapy treatment
- Delays to identify and escalate deteriorating patients
- Treatment delays
- Diagnostic incidents

Average annual response activity for 2018 – 2022

This table shows the highest occurring patient safety responses, including the high number of moderate reviews undertaken.

Response Type	Category	Average Number of Responses
Patient safety incident investigations conducted locally (SIIs)	(Top 3) • Treatment delays • Slips/Trips and falls • Diagnostic incidents	 92 56 27
Patient safety reviews	SJR	20.8
	Moderate reviews	387.6

This data produced the overall risk profile for the Trust. From this, further analysis was undertaken to review current patient safety work currently being undertaken and the progress of this work, to further inform the identification of priorities for the first PSIRP.

The current top 3 local priorities/risk for PSII are therefore:

Incident Type / Theme	Description	Speciality
• **Identification and Escalation of the Deteriorating Patients**	Monitoring, escalation and communication	Trust wide
• **Nutrition and Hydration**	Vulnerable adults, nil by mouth, NG and parental feeding	Trust wide
• **Hospital Acquired Thrombosis**	Assessment, diagnosis and treatment of HAT	Trust wide

6. Selection of incidents for patient safety incident investigation

6.1. Aim of a patient safety incident investigation (PSII)

PSIIs are conducted for systems learning and safety improvement. This is achieved by identifying the circumstances surrounding incidents and the systems-focused, interconnected casual factors that may appear to be precursors to patient safety incidents. These factors must then be targeted using strong (effective) improvements to prevent or continuously and measurably reduce repeat patient safety risks and incidents.

6.2. Nationally defined priorities to be referred for PSII or review by another team

The national priorities for referral to other bodies or teams for review or PSII (described in the PSIRF) are:

a) Maternity and neonatal incidents:

- Incidents which meet the 'Each Baby Counts' and maternal deaths criteria detailed in Appendix 4 of the PSIRF must be referred to the Healthcare Safety Investigation Branch (HSIB) for investigation
- All cases of severe brain injury (in line with the criteria used by the Each Baby Counts programme) must also be referred to NHS Resolution's Early Notification Scheme
- All perinatal and maternal deaths must be referred to MBRRACE

b) Mental health-related homicides by persons in receipt of mental health services or within six months of their discharge must be discussed with the relevant NHS England and NHS Improvement regional independent investigation team (RIIT)

c) Child deaths:
- Incidents must be referred to child death panels for investigation

d) Deaths of persons with learning disabilities:
- Incidents must be reported and reviewed in line with the Learning Disabilities Mortality Review (LeDeR) programme

e) Safeguarding incidents:
- Incidents must be reported to the local organisations named professional/safeguarding lead manager and director of nursing for review/multi-professional investigation

f) Incidents in screening programmes:
- Incidents must be reported to Public Health England (PHE) in the first instance for advice on reporting and investigation (PHE's regional Screening Quality Assurance Service (SQAS) and commissioners of the service)

g) Death of patients in custody, in prison or on probation where healthcare is/was NHS funded and delivered through an NHS contract:
- Incidents must be reported to the Prison and Probation Ombudsman (PPO), and services required to be registered by the Care Quality Commission (CQC) must also notify CQC of the death. Organisations should contribute to PPO investigations when approached.

6.3. Nationally defined incidents requiring local PSII

Nationally defined incidents for local PSII are set by the PSIRF and other national initiatives . These are:

a) Incidents that meet the criteria set in the Never Event List 2018

b) Incidents that meet the 'Learning from Deaths' criteria; that is, deaths clinically assessed as more likely than not due to problems in care (more than 50% probability) – using a recognised method of case note review, conducted by a clinical specialist not involved in the patient's care, and conducted either as part of a local LfD plan, or following reported concerns about care or service delivery. Further, specific examples of deaths where a PSII must take place include:
- **Deaths of persons with mental illness whose care required case record review as per the Royal College of Psychiatrist's** mortality review tool and which have been determined by case record review to be more likely than not due to problems in care

- **Deaths of persons with learning disabilities** where there is reason to believe that the death could have been contributed to by one or more patient safety incidents/problems in the healthcare provided by the NHS. In these circumstances a PSII must be conducted in addition to the LeDeR review
- **Deaths of patient in custody, in prison or on probation** where there is reason to believe that the death could have been contributed to by one or more patient safety incidents/problems in the healthcare provided by the NHS

c) Suicide, self-harm or assault resulting in the death or long-term severe injury of a person in state care of detained under the Mental Health Act

6.4. Locally defined incidents requiring local PSII

Through our analysis of patient safety insights, potential for learning and improvement, systemic risk and resources available to complete PSII investigations, the Trust will investigate each local priority until learning and recommendations have been made and improvement work commenced. Based on the local situational analysis and review of the local incident reporting, local priorities for PSII have been set by this organisation for the period September 2023- September 2024.

All other patient safety incidents/risks will be triaged and allocated a PSR response. For further details on PSRs (see Appendix A).

a) Locally defined emergent patient safety incidents requiring PSII.
An unexpected patient safety incident which signifies an extreme level of risk for patients, families and carers, staff or organisations, and where the potential for new learning and improvement is so great (within or across a healthcare service/pathway) that it warrants the use of extra resources to undertake a comprehensive PSII response.

b) Locally predefined patient safety incidents requiring investigation.
Key patient safety incidents for PSII have been identified by this organisation (through analysis of local data and intelligence from the past five years), and agreed with the commissioning organisation(s) as a local priority in line with the following guidance:

- Criteria for selection of incidents for PSII:
  - Actual and potential impact of outcome of the incident (harm to people, service quality, public confidence, products, funds, etc)
  - Likelihood of recurrence (including scale, scope and spread)
  - Potential for learning in terms of:
    - enhanced knowledge and understanding
    - improved efficiency and effectiveness (control potential)
    - opportunity for influence on wider systems improvement
- Based on our analysis of patient safety risks and previous incidents we have identified that **we can support 12 PSIIs per year** in total within current resources.
- To support the identification of common causal factors, incident types are narrowly defined. This means from a large group of incidents, a

smaller subset of incidents (which may be specific to an area, process, and/or presentation of a patient or other characteristic) will be identified.

- Not all PSIs require PSII but may benefit from a different type of examination to gain further insight or address queries from the patient, family, carers or staff. Where this is the case, we will adopt relevant techniques.

A number of incident types such as development/deterioration of pressure ulcers and medication-related incidents have been excluded from the priority categories as they have active improvement delivery plans in place based on learning identified from previous patient safety incident investigations. Delivery of these improvement plans will be monitored by the central patient safety team and via their respective specialist subgroup. A combination of both process and outcome metrics will be utilised to measure their effectiveness once fully complete.

All incidents will be reported in line with existing patient safety incident reporting guidance and principles described in the PSIRF.

In some cases, incidents may need to be reported to other bodies as described in the Incident Management Policy.

Any incident resulting in moderate harm or above will continue to be managed in accordance with Being Open and Duty of Candour regulations.

Any request for information about a PSI – by the patient, families and/or staff – will be responded to openly and as much information as possible will be provided regardless of severity of outcome or the type of response required under this plan.

6.5. Completing PSII

Each comprehensive PSII will be:

a) Conducted separately, in full and to a high standard, by a team whose lead investigator is an experienced Band 8 and has received a minimum of two days' training.
b) Undertaken as per the PSIRP and will adhere to the national PSII standards and with national good practice for PSII.
c) Use the national standard template to report the findings of the PSIIs.
d) Identify common, interconnected, deep-seated causal factors (not high-level themes or problems)

For each group of PSIIs dedicated to a similar/narrow focus incident type we will:

e) Design strong/effective improvements to sustainably address common interconnected causal factors.
f) Develop an action plan for implementation of the planned improvements. NB: while some actions may be needed after only one investigation, where possible, we will wait until all investigations for each incident type are completed, and common causal factors identified so that solutions/action plans can be developed to address them
g) Monitor implementation of the improvements.
h) Monitor effectiveness of the improvements over time.

To monitor the quality of PSII findings and progress against this PSIRP we will seek answers to the follow:

i) Are the actions likely to achieve improvement?
j) Is there evidence of improvement

6.6. Timescales for patient safety PSII

Where a PSII for learning is indicated, the investigation must be started as soon as possible after the patient safety incident is identified. PSIIs should ordinarily be completed within one to three months of their start date.

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 healthcare organisation with the patient/family/carer.

No local PSII should take longer than six months. 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. (Where the processes of external bodies delay access to some information for longer than six months, a completed PSII can be reviewed to determine whether new information indicates the need for further investigative activity.)

6.7. Thematic analysis following the completion of a small number of individual investigations of similar patient safety incidents

A valuable and thorough way of accomplishing thematic analysis of PSII findings is to select a few (three to five) recent and very similar incidents and investigate each individually with skill and rigour to determine the interconnected contributory and causal factors.

The findings from each individual investigation are then collated, compared and contrasted to identify common causal factors and any common interconnections or associations upon which effective improvements can be designed.

Importantly, investigation of recent incidents allows more accurate information gathering from properly specified, good quality PSIIs, and detailed analysis of the system as it currently stands.

7. Roles and Responsibilities

This organisation describes clear roles and responsibilities in relation to its response to patient safety incidents, including investigator responsibilities and upholding national standards relating to patient safety incidents.

Chief executive

- Overall responsibility for the effective management of all patient safety incidents, including contribution to cross-system/multi-agency reviewed and/or investigations where required.
- With the executive and non-executive team, models behaviours that support the development of patient safety reporting, learning and improvement system.
- Ensure that systems and processes are adequately resourced including funding, management time, equipment and training.

The **Chief Nurse**, supported by the **Medical Director**, is the executive lead responsible for supporting and overseeing implementation of the Patient Safety Incident Response Framework (PSIRF) and includes.

- Ensuring processes are in place to support an appropriate response to PSIs (including contribution to cross-system/multi-agency reviews and/or investigation where required).
- Oversee development and review of the organisations PSIRP.
- Agrees sufficient resources to support the delivery of the PSIRP (including support for those affected, such as named contacts for staff, patients, families and carers where required.
- Ensures the organisation complies with the national patient safety investigation standards.
- Establishes procedures for agreeing patient safety investigation reports in line with the national patient safety investigation standards.
- Develops professional development plans to ensure that staff have the training, skills and experience relevant to their roles in patient safety incident management.

Patient Safety Team

- Ensure that patient safety investigations are undertaken for all incidents that require this level of response (as directed by the organisation's PSIRP)
- Develop and maintain local risk management systems and relevant incident reporting systems to support the recording and sharing of PSIs and monitoring of incident response processes.
- Ensure the organisation has procedures that support the management of PSI in line with the organisation's PSIRP (including convening review and investigation teams as required and appointing trained named contacts to support those affected).
- Established procedures to monitor/ review investigation progress and the delivery of improvements.
- Work with executive lead to address identified weaknesses/areas for improvement in the organisations response to patient safety incidents including gaps in resource including skills and training.
- Support and advise staff involved in the patient safety incident response

Investigation leads

- Ensure that investigations are undertaken in line with the patient safety investigation standards.
- Ensure they are competent to undertake the investigation assigned to them and if not request it is reassigned.
- Undertake patient safety investigations and related duties in line with latest national guidance and training.

Investigators

- Under the direction of investigation lead undertake investigations in line with the patient safety investigation standards.
- Ensure they are competent to undertake the investigation assigned to them and if not request it is reassigned.
- Undertake patient safety investigations and related duties in line with latest national guidance and training.

Named contact for patients, families and carers

- Identify those patients, families and carers affected by PSIs and provide them with timely and accessible information and advice
- Ensure they are provided with an opportunity to access relevant support services
- Act as liaison between patients, families and carers and investigation teams to help manage expectations.

All named contacts for patients, families and carers must have.

- Received appropriate training in communication of including 'being open' and Duty of Candour.
- Sufficient time to undertake their role; that is, they should be staff dedicated to the role or with dedicated time for this role.

Named contacts for staff

- Provide advice and support throughout the investigation process to staff affected by a PSI.
- Facilitate access to additional support services as required.
- Act as liaison between these staff and investigation team as required.

Department Leads/managers

- Encourage reporting of all PSI including near misses and ensure all staff in their area are competent in using the Datix reporting system and are provided sufficient time to record incidents and share information.
- Provide protected time for training in patient safety disciplines to support skill development across the wider staff group.
- Provide protected time for participation in investigations as required.
- Liaise with the patient safety team and others to ensure those affected by patient safety incidents have access to the support they need.
- Support development and delivery of actions in response to PSI that relate to their area of responsibility (including taking corrective action to achieve the desired outcome)

All Staff

- Understand their responsibilities in relation to the organisations PSIRP.
- Know how to access help and support in relation to patient safety incident response process

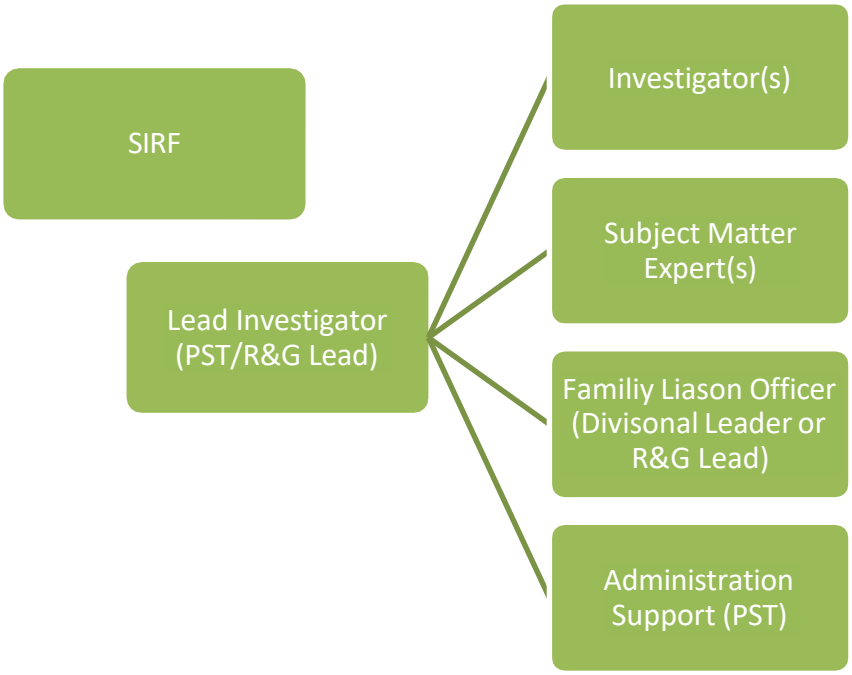

Figure 2. Overview of an investigation team

8. Patient Safety Incident reporting arrangements

The process of complying with both internal and external notification requirements for the reporting of patient safety-related incidents can be found within the Trust's Incident Management Policy.

9. Procedures to support patients, families and carers affected by PSIIs

Local arrangements for supporting patients, families and carers are detailed within the Trust's Being Open (Duty of Candour) Policy. A "tool kit" to support and provide guidance will be developed and made available on the trust's new intranet site for all staff. A limited view will be available to the public on the new website. Procedures to support staff affected by PSIs. The local arrangements for supporting staff affected by patient safety incidents are detailed within the Supporting Staff affected by an Incident, Complaint, Claim or Inquest "toolkit": This will be developed during the implementation phase and the toolkit will be made accessible to all staff on the trust's new intranet site. A limited view of this will be made available to the public on the new website. General arrangements for supporting staff health and wellbeing will be detailed on the Trust's intranet and include occupational health support and employee assistance programme.

National sources of support are given in Appendix 3 of the PSIRF.

10. Mechanisms to develop and support improvements following PSIIs

The Trust utilises the Quality, Service, Improvement and Redesign (QSIR) quality programme through their Royal Academy of Improvement. The Academy provides training, education and support for a wide variety of improvement projects. There is a cohort of improvement ambassadors and educators who have undergone training to support teams throughout the Trust with implementing improvements/solutions arising from patient safety incident investigations.

11. Evaluating and monitoring outcomes of PSIIs, Reviews etc

Robust findings from PSIIs and reviews provide key insights and learning opportunities, but they are not the end of the story.

Findings must be translated into effective improvement design and implementation. This work can often require a different set of skills from those required to gain effective insight or learning from patient safety reviews and PSIIs.

Improvement work should only be shared once it has been monitored and demonstrated that it can be successfully and sustainably adopted, and that the changes have measurably reduced risk of repeat incidents.

Reports to the Patient Safety and Experience Group will be monthly and will include aggregated data on:

- patient safety incident reporting
- audit and review findings
- findings from PSIIs
- progress against the PSIRP
- results from monitoring of improvement plans from an implementation and an efficacy point of view
- results of surveys and/or feedback from patients/families/carers on their experiences of the organisation's response to PSIIs
- results of surveys and/or feedback from staff on their experiences of the organisation's response to patient safety incidents

12. Complaints and Appeals

Local arrangements for complaints and appeals relating to the organisation's response to PSIs are detailed within the Trust's Patient Safety Incident Response Policy.

Patient experience and feedback offer learning opportunities that allows us to understand whether our services are meeting the standards we set and addressing patients' expectations and concerns. With these objectives very much

in mind, we take all patient and stakeholder feedback very seriously, clearly identifying any lessons and using these to improve our service.

We report trends and emerging themes through the Trust's governance processes and to widen the learning, we publish anonymised case examples on the Trust website. With the implementation of PSIRP we will continue to manage complaints in the usual way in accordance with Trust Policy and the NHS Complaint Regulations, with close liaison with the Patient Experience and Quality Improvement and Teams in relation to any complaints about incidents that are also the subject of a thematic review.

ANNEX A Patient Safety Response (examples)

PSIRF – PATIENT SAFETY RESPONSE TYPES (PSR)			
PSR TYPE	**METHODS & OBJECTIVES**	**WHO**	**TIME FRAME**
Incident Recovery Immediate measures **taken to**: Address serious discomfort, injury or threat to life Respond to concerns raised by the affected patient, family, or carer Determine the likelihood and severity of an identified risk e.g., medication delay, missing equipment, documentation absent	**Immediate actions** To take urgent measures to address serious and imminent: • Discomfort, injury or threat to life. • Damage to equipment or the environment	All staff	Immediate
	Risk assessment To assess the likelihood and severity of identified hazards in order that risks can be determined, prioritised, and control measures applied	All staff	Immediate
	Open discussion (Duty of Candour) To provide the opportunity for a verbal discussion with patient/family/carer about what is known and to make an apology	Most appropriate clinical /medical staff member	This should be done as soon as possible but most must be completed within 10 days
Team Reviews Post-incident review as a team to: • Identify areas for improvement • Celebrate success • Understand the expectations and perspectives of all those involved • Agree actions Enhance teamwork through communication and collaborative problem solving, Treatment delay, missed diagnosis	**Rapid review** To gain a greater understanding of the incident and identify any immediate actions / learning required to keep patient(s) safe.	Nominated Divisional lead	2 working days
	Debrief (hot) An unstructured, moderated discussion. The simplest and most informal method to gain understanding and insight soon after an incident (debriefs held immediately after an incident are known as 'hot' debriefs).	All staff involved in the incident	Within 48hrs
	Safety huddle **Proactive:** a planned team gathering to regroup, seek collective advice, or talk about the day, shift, next few hours. Allows for on the-spot assessment, reassessment, and consideration of whether there is a need to adjust plans. **Reactive:** triggered by an event to assess what can be learned or done differently. Focused on process-oriented reflection to find actionable solutions	All staff	Daily As and when required
	Round Table A 'cold' structured debrief facilitated by a senior manager. Based around four overarching questions: 1. What is expected to happen? 2. What happened?	All staff Involved in the incident	Within 5 working days or as soon as possible

	3. Why was there a difference between what was expected and what happened? 4. What are the lessons that can be learnt? Minutes are required of meeting with safety issues identified, lessons learnt, and any safety improvement plans		
Systematic Reviews To determine: • The circumstances and care leading up to and surrounding the incident • Whether there were any problems with the care provided to the patient e.g., Pressure ulcers, return to theatre, medication error	**Case record/note review (e.g., SJR, LeDeR, safeguarding)** To determine whether there were any problems with the care provided to a patient by a service. (To routinely identify the prevalence of issues; or when bereaved families/carers or staff raise concerns about care.)	Trained reviewer	As per national guidance for each type of review
	Specialised reviews For example, falls, pressure ulcers, IPC reviews, return to theatre, pharmacy. To review the clinical documentation against an agreed checklist of questions / statements to identify any areas of learning i.e., Pressure Ulcers, Falls, VTE	Appointed staff member	4 weeks
	Concise report To conduct a clinical review of documentation and a review of staff testimony in line with Trust policy and national guidance	Nominated Divisional Lead	2 months
Patient Safety Incident Investigation In depth Investigation e.g., Required by regulations, Never Events, national and local priorities	**PSII** Systems based approach using investigatory science Extract system wide learning to inform improvement	Led by Band 8 and above who has completed the nationally accredited training (minimum of 2 days)	Usually with 1-3 months