Board of Directors' Meeting
12 October 2023

The Shrewsbury and Telford Hospital NHS Trust

Agenda item		124/23		
Report Title		Patient Safety Incident Response Framework (PSIRF) Policy and Plan		
Executive Lead		Hayley Flavell – Executive Director of Nursing		
Report Author		Peter Jeffries – Patient Safety Specialist		
CQC Domain:		**Link to Strategic Goal:**		**Link to BAF / risk:**
Safe	√	Our patients and community	√	BAF1, BAF2, BAF4, BAF7, BAF8, BAF9
Effective		Our people	√	
Caring		Our service delivery	√	**Trust Risk Register id:**
Responsive		Our governance	√	328/1353
Well Led		Our partners		
Consultation Communication		Quality Operational Committee, 19th September 2023 Quality and Safety Assurance Committee, 27th September 2023		
Executive summary:		PSIRF replaces the existing Serious Incident Framework and will fundamentally alter the way we respond to patient safety incidents based on four key principles: NHS organisations have until Autumn 2023 to prepare for and implement PSIRF. In order to proceed to go live, Board is asked to review and approve the: • Patient Safety Incident Response Plan – outlining how SaTH will respond to incidents under PSIRF. • Patient Safety Incident Response Policy – the overarching policy to which we will work as we move to PSIRF. The Board's attention is drawn to table 3 in the Patient Safety Incident Response Plan outlining our initial PSIRF safety priorities of: • The adult deteriorating patient • Falls • Missed radiology results • Omitted doses of time critical medication.		
Recommendations for the Board:		The Board is asked to: **Approve** the Patient Safety Incident Response Plan and Patient Safety Incident Response Policy in order to transition to the Patient Safety Incident Response Framework.		
Appendices:		Appendix 1: Patient Safety Incident Response Plan Appendix 2: Patient Safety Incident Response Policy		

APPENDIX 1

The Shrewsbury and Telford Hospital NHS Trust

Patient safety incident response plan

Effective date: November 2023

Estimated refresh date: November 2024

	NAME	TITLE	SIGNATURE	DATE
Author	**Peter Jeffries** **Sara Cormack**	**Patient Safety Specialist** **Deputy Patient Safety Specialist**		
Reviewer				
Authoriser				

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Introduction

This Patient Safety Incident Response Plan (PSIRP) sets out how The Shrewsbury and Telford Hospital NHS Trust (hereby referred to as SaTH or the Trust) intends to respond to patient safety incidents over a period of the first 12 months as we transfer to PSIRF and transition to new ways of working. The production of this plan is part of the introduction of the Patient Safety Incident Response Framework (PSIRF) which is a key component of the NHS patient safety strategy, which describes how the NHS will continuously improve patient safety, building on the foundations of a safer culture and safer systems.

PSIRF is based around four key principles which will inform and drive our approach to patient safety incidents as we go forward. These are:

1. Compassionate engagement and involvement of those affected by patient safety incidents.
2. Application of a range of system-based approaches to learning from patient safety incidents.
3. Considered and proportionate responses to patient safety incidents.
4. Supportive oversight focused on strengthening response system functioning and quality improvement.

The plan is not a permanent rule that cannot be changed. SaTH will remain flexible and consider the specific circumstances in which patient safety issues and incidents occurred and the needs of those affected. Our aim will be to maximise learning to inform improvements to our systems to reduce the risk of patient safety incidents occurring.

PSIRF is not just a small change to the current serious incident framework which guides how we respond to patient safety incidents but a radical shift and cultural change to how we approach safety. It will take time to embed and transition and will need to continually review what has worked (which we can build on) and where we must improve based on feedback from patients, families, and our staff. This PSIRF plan is underpinned by our Patient Safety Incident Response Policy.

As part of our policy, we will review and update our plan annually based on all we have learnt over the previous 12 months, so our PSIRF plan becomes part of an ongoing process of quality improvement supporting our overall patient safety plans and priorities.

A glossary of terms used in this plan can be found in Appendix 1.

Our services

SaTH is the main provider of district general hospital services for nearly half a million people in Shropshire, Telford & Wrekin, and mid Wales.

Our main service locations are the Princess Royal Hospital (PRH) in Telford and the Royal Shrewsbury Hospital (RSH) in Shrewsbury, which together provide 99% of our activity.

Both hospitals provide a wide range of acute hospital services including accident & emergency, outpatients, diagnostics, inpatient medical care, and critical care. Together the hospitals have just over 700 beds.

Alongside our services at the Princess Royal and Royal Shrewsbury, SaTH also provide community and outreach services such as:

- Consultant-led outreach clinics
- Midwife-led units
- Renal dialysis outreach services
- Community services including Midwifery, Audiology and Therapies.

Currently, SaTH is in the process of implementing plans to transform acute hospital services across the region under the Hospital Transformation Programme (HTP). HTP plan to implement the reconfiguration of acute services agreed as part of the Future Fit public consultation, which will see PRH specialise in planned care and the RSH specialise in emergency care.

This new model of care was designed, led, and supported by clinicians, and is designed to enable multiple patient benefits. These benefits include fewer cancellations and delays for planned procedures, a more streamlined and effective emergency care service, fewer ambulance handover delays and the provision of a dedicated, modern Emergency Department.

Further information about the organisation and HTP can be found on the SaTH website.

Defining our patient safety incident profile

The definition of SaTH's patient safety incident profile is a collaborative process. To define the priorities to include in our initial patient safety response plan under the PSIRF framework, a number of key stakeholders were engaged through a variety of engagement methods. These included:

- Key stakeholders- through meetings, discussions and engagement events with those staff members directly involved in patient safety investigations, for example, the patient safety team, quality governance teams, medications safety officer, quality managers, complaints managers, medical examiners, learning from deaths teams and specialist nurses.
- Staff- through the incidents reported on the SaTH Datix incident management system and information obtained on staff concerns via dedicated staff surveys.
- Senior leaders across divisions- through a series of stakeholder events, regular agenda items on various meetings and 1:1 discussion.
- Patient groups- through a review of the thematic contents of complaints and Patient advice and liaison service (PALS) contacts, involvement in stakeholder events and discussions at Patient and Carer Experience Panel (PaCE Panel).
- Commissioners/ICS partner organisations- through partnership working with the ICS patient safety and quality leads and inclusion at stakeholder events.

SaTH also aims to incorporate a wider patient perspective into future PSIRF planning through the introduction of Patient Safety Partners (PSPs).

Several data sources were also utilised to define SaTH's patient safety incident profile. These included:

- Thematic analysis of two years of Datix incident report data (November 2020-October 2022).
- Thematic analysis of two years of complaints and PALS data (November 2020-October 2022).
- Thematic analysis of two years of Serious Incident (SI) investigation data November 2020- October 2022), including thematic analysis of the recommendations and actions identified by these investigations.
- Key themes identified from specialist safety & quality committees (e.g., deteriorating patient, falls, pressure ulcers).
- Output of stakeholder event discussions and workshops.

As part of the PSIRF guidance, a number of national priorities have been defined by the national team at NHS England. Local patient safety incidents that relate to these national priorities will require a specific, defined response to be detailed in SaTH's current PSIRF plan. Table 1 in the "*Defining our patient safety improvement profile*"

section below details the full list of national priorities that require a response and defines the response that SaTH will undertake when these events occur.

SaTH's top local patient safety priorities (or Trust priorities) have been defined as the list of most significant patient safety risks identified through the data analysis and stakeholder engagement described above. Through this information gathering process, four initial Trust priorities have been identified as representing the most significant opportunities for learning and improvement in the SaTH healthcare system. Table 2 in the "*Defining our patient safety improvement profile*" section below details these Trust priorities.

The criteria SaTH have used to define our Trust Priorities for our initial PSIRP fall under two main categories: potential for harm that the incident type poses and the likelihood of reoccurrence of similar incidents. These were as follows:

- Potential for harm
    - People- physical, psychological, loss of trust (patients, family, caregivers, advocates)
    - 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 of incident occurrence.
    - Potential to escalate.

Defining our patient safety improvement profile

As outlined above SaTH has reviewed its current patient safety profile and has defined four initial key safety priorities. These priorities have been defined by:

In reviewing our safety profile, we have acknowledged a number of existing Trust programmes which are focused on, or have significant components relating to patient safety these include:

- Our 'Getting too Good' programme and existing quality priorities.
- The Emergency Care Transformation Programme
- The Maternity Transformation Programme
- The Paediatrics Transformation Programme
- The Hospital Transformation Programme
- Existing falls improvement programme
- Existing deteriorating patient programme
- Cultural improvement plans
- Infection Prevention and Control improvement plans

Our patient safety incident response plan: national requirements

Given that the Trust has finite resources for patient safety incident response, we intend to use those resources to maximise improvement. PSIRF allows us to use this resource to focus on improvement, rather than repeatedly responding to and investigating patient safety incidents based on thresholds and definitions of harm that can often be subjective. This is important as investigating numerous similar incidents will result in very limited new learning, whereas focusing on improving larger, often Trust wide systems, could yield much larger benefits for patients and staff.

Some patient safety events, such as Never Events and deaths thought more likely than not due to problems in care, will always require a specific type of response as defined by national policies or regulations, such as a Patient Safety Incident investigation (PSII), to learn and improve.

For other types of incidents which may affect certain groups of patients, for example children, a nationally defined response will also be required. These responses may include incidents being referred to, or reviewed by, a team or body outside of the organisation, depending on the nature of the event and the people involved. The Trust fully endorses this approach as it fits with our aim to learn and improve within a just and restorative culture.

Table 1 below outlines each defined national priority along with the nationally mandated responses to those incidents.

Table 1:

National Priority	Mandated response
Deaths clinically assessed as being more likely than not due to problems in care (incidents meeting the Learning from Deaths criteria)	Patient Safety Incident Investigation (PSII) led by SaTH
Deaths of patients detained under the Mental Health Act (1983), or where the Mental Capacity Act (2005) applies, where there is reason to think that the death may be linked to problems in care (incidents meeting the Learning from Deaths criteria)	PSII led by the provider. Where the event did not occur in SaTH but they had involvement, SaTH will participate in the investigation, if required.
Incidents that meet the criteria set in the Never Event list 2018	PSII led by SaTH
Mental health-related homicides	Refer to the NHS England Regional Independent Investigation Team (RIIT) for consideration for an independent PSII. A PSII led by SaTH may be required, dependent on circumstances.
Maternity and neonatal incidents meeting Healthcare Safety Investigation Branch (HSIB) criteria or Special Health Authority (SpHA) criteria when in place.	Refer to HSIB (or MSpHA when in place) for independent PSII if accepted.

Child deaths	Refer for Child Death Overview Panel (CDOP) review. SaTH led PSII (or other learning response) may be required alongside the panel review dependent on circumstances and decision of the panel.
Deaths of persons with learning disabilities	Refer for Learning Disability Mortality Review (LeDeR) including Structured Judgement Review (SJR). SaTH led PSII (or other learning response) may be required alongside LeDeR review dependent on circumstances.
Safeguarding incidents in which: Babies, children, and young people are on a child protection plan, looked after plan or are a victim of wilful neglect, domestic abuse, or violence. Adults (over 18 years old) in receipt of care and support needs by their Local Authority. The incident relates to FGM, Prevent (radicalisation to terrorism), modern slavery, human trafficking, or domestic abuse/violence.	Refer to local authority safeguarding lead. Healthcare providers must contribute towards domestic independent inquiries, joint targeted area inspections, child safeguarding practice reviews, domestic homicide reviews and any safeguarding reviews (and enquiries) as required to do so by the Local Safeguarding Partnership (for children) and local Safeguarding Adults Boards.
Incidents in NHS screening programmes.	Refer to local Screening Quality Assurance Service for consideration of locally led learning response.
Deaths in custody (e.g., police custody, in prison,	In prison and police custody, any death will be referred (by the relevant organisation) to the Prison and Probation Ombudsman (PPO) or the

etc.) where health provision is delivered by the NHS	Independent Office for Police Conduct (IOPC) to carry out the relevant investigations. Healthcare providers must fully support these investigations where required to do so.
Domestic homicide	A domestic homicide is identified by the police, usually in partnership with the Community Safety Partnership (CSP) with whom the overall responsibility lies for establishing a review of the case. Where the CSP considers that the criteria for a domestic homicide review (DHR) are met, it uses local contacts and requests the establishment of a DHR panel. The Domestic Violence, Crime and Victims Act 2004 sets out the statutory obligations and requirements of organisations and commissioners of health services in relation to DHRs.

Our patient safety incident response plan: local focus

In line with PSIRF guidance local responses will conform broadly with the plan outlined below. We will maintain the flexibility to adjust our approach. The key decision-making assumptions that have informed both our plan and will inform our ongoing decision making are:

- The views of those affected, including patients and their families.
- Capacity available to undertake a learning response.
- What is known about the factors that lead to the incident(s)
- Whether improvement work is underway to address the identified contributory factors
- Whether there is evidence that improvement work is having the intended effect/benefit
- If an organisation and its ICB are satisfied risks are being appropriately managed.

SaTH considers that all of the incident types detailed in Table 2 and 3 have relevance across a number of our inpatient, outpatient, and community services.

Because of this, this document is an organisation wide PSIRF plan and there are no separate plans for individual services.

An outline of potential incident learning responses we will utilise is outlined under appendix 2.

Table 2:

Patient safety incident type or issue	Planned response	Anticipated improvement route
Hospital acquired pressure ulcers	Below grade 3 – local review in line with current process for responding to local level datix incident reports. Grade 3 or above – After Actions System Review	Create local safety actions and feed these into the overarching quality improvement strategy
Hospital acquired infections	MRSA bacteraemia/C-Diff and nosocomial Outbreaks- After Actions System Review	Co-production of safety improvement actions managed through the IPC (Infection Prevention and Control) improvement plan.
Transfusion incidents meeting SHOT (Serious Hazards of Transfusion) criteria	SHOT reportable incident- After Actions System Review	Review at RALIG and Hospital Transfusion Committee (HTC)– develop local safety actions and feed these into the overarching quality improvement strategy
IRMER reportable incidents – Radiology incidents	IRMER reportable incident- After Actions System Review	Review at RALIG and Radiology governance– develop local safety actions and feed these into the overarching quality improvement strategy
Assessment of incidents outside of the identified priorities (above and in table 3)	Proportionate response dependent upon the circumstances surrounding the patient safety event	Co-production of safety improvement actions managed on a local/organisational safety improvement plan.

Initial PSRIF safety priorities and responses:

Table 3:

	Incident Type	Description	Response type
1	Adult Deteriorating patient. (Paediatric and maternity deterioration are subject to actions in the paediatric and maternity transformation programmes. Learning will be shared across these workstreams)	Actual or potential for patient harm due to delayed or non-recognition of deterioration despite clinical indicators, or incidents where deterioration is identified, but treatment is absent or significantly delayed.	For incidents falling under national priorities – PSII with learning incorporated into improvement plan. Dependent on capacity and if high likelihood of new learning for improvement plan – After Action System Review The main priority for deteriorating patient priority is to use thematic systems work already undertaken to define a longer-term strategy and improvement plan (work already underway).
2	Falls	Adult, inpatient falls	For incidents falling under national priorities – PSII with learning incorporated into improvement plan. Low/No harm -Hot Debrief Major, significant fractures or internal head injuries – Hot debrief. If high likelihood of new learning to inform improvement plan, an After Action System Review will be considered. Many of the key causal factors behind falls are well understood. The key

			focus of this improvement stream will be to review our understanding of known acts or omissions that lead to harm and review current improvement strategies.
3	Missed radiology results (alerts and availability)	Potential for patient harm as a consequence of non-communication or action of diagnostic radiology results.	For incidents falling under national priorities – PSII with learning incorporated into improvement plan. The current systems issues leading to missed radiology results has been explored. The focus of this improvement stream will be twofold: • Short term risk reduction pending new electronic systems. • Safety review of procured IT systems to ensure risk mitigation and any new risks are understood to reduce the chances of harm.
4	Omitted doses of time critical medication	Time critical medicine is delayed leading to patient harm	For incidents falling under national priorities – PSII with learning incorporated into improvement plan. Incidents not falling under national definitions will be subject to hot debriefs or after actions systems reviews based on potential for learning. The systems issues underlying missed doses are currently not well

			understood. An overall thematic system review will be undertaken (modelled on work already undertaken for adult deterioration.

Local methods such as the national PMRT and SJR tools and/or structured local proformas may be used. The completion of a narrative response on the Datix incident module is also appropriate.

Appendix 1: Glossary

- **PSIRP** - Patient Safety Incident Response Plan

Our local plan details how we will achieve the PSIRF locally, including our list of current local priorities. These have been developed through a coproduction approach with the divisions and specialist risk leads supported by analysis of local data and engagement with staff.

- **PSIRF** - Patient Safety Incident Response Framework

Building on years of evidence from previous investigations as well as the wider industry best-practice, the PSIRF is designed to enable a risk-based approach to responding to patient safety incidents. This framework prioritises support for those affected by incidents (including patients, families, advocates, and staff), effectively analysing incidents, and sustainably reducing future risk. This is the first year that SaTH will have implemented and be working under the PSIRF framework.

- **PSA** – Patient Safety Audit

A review of a series of cases of the same incident type using clinical audit methodology to identify opportunities to improve and more consistently achieve the required standards (e.g., in a policy or guideline) and/or outcomes.

- **PMRT** - Perinatal Mortality Review Tool

Developed through a collaboration led by MBRRACE-UK with user and parent involvement, the PMRT ensures systematic, multidisciplinary, high-quality reviews of the circumstances and care leading up to and surrounding each stillbirth and neonatal death, and the deaths of babies who die in the post-neonatal period having received neonatal care.

- **SJR** - Structured Judgement Review

SJR is a systematic, evidence-based mortality review programme that can help drive improvement in the quality and safety of patient care. SJR was developed by the Royal College of Physicians as part of the National quality board national guidance on learning from deaths and 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, and score, care for each phase.

- **Never Event**

Never Events are defined as incidents that are considered wholly preventable. This is because of the presence of guidance or safety recommendations that provide

strong systemic protective barriers, available at a national level that should have been implemented by all healthcare providers.

- **Deaths thought more likely than not due to problems in care**

Incidents that meet the 'Learning from Deaths' (LfD) criteria. These are deaths that have been clinically assessed as more likely than not due to problems in care using a recognised method of case note review. These reviews must have been 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.

Appendix 2: Learning Response types

- **PSII** - Patient Safety Incident Investigation

PSIIs are undertaken to identify underlying system factors that contributed to an incident meeting the national criteria. These findings are then used to identify effective, sustainable improvements by combining learning across multiple PSIIs and other learning responses into incidents involving a similar incident type. Recommendations and improvement plans are then designed to effectively and sustainably address the system factors identified by the investigation and help deliver safer care for our patients.

- **AASR** – After Action Systems Review

A method of evaluation that is used when outcomes of an activity or event have been particularly successful or unsuccessful. It aims to capture learning from these events to identify opportunities to improve and increase the instances where success occurs.

- **MDT (multi-disciplinary team) review**

Where an incident has been identified a period of time after it occurred (for instance via an audit or complaint) an MDT review approach may be used. It will follow a similar format to the After Action Systems Review but will acknowledge that there may be limits to the available information for learning given the time that has passed.

- **Hot Debrief**

Interactive, structured team dialogues that take place either immediately or very shortly after an incident. They can be used to capture immediate learning and inform further learning responses.

- **Thematic systems review**

Based on work undertaken to review the systems around the adult deteriorating patient we have developed a methodology for reviewing clinical systems to identify areas for improvement to reduce safety. We will build on this approach and continue to develop it. The key components of this approach are described below:

    - Review of key literature
    - Review of existing insights from incidents
    - Structured observations and discussions with staff of work systems based around the SEIPS framework

- **Learning Teams**

Learning teams allow staff who are involved in an incident to develop solutions to it. The process runs in parallel to the investigation and, rather than looking at the specific events that occurred, examines the process as a whole and identifies potential as well as actual hazards.

The learning team process consists of two facilitated group workshops attended by staff involved in the incident or others who undertake the same role. The first session maps out the process and identifies what could go wrong. This is followed by soak time – a period of reflection.

The second workshop brings the team back to explore solutions and develop a plan for fixing the process.

In line with the philosophy of PSIRF we will flexibly use the approaches outlined above in line with the nature of the incident which is being investigated and how it aligns with our PSIRP. Hybrid approaches mixing learning responses will be used as appropriate.

APPENDIX 2	The Shrewsbury and Telford Hospital NHS Trust

Patient safety incident response policy

Effective date: November 2023

Estimated refresh date: November 2024

	NAME	TITLE	SIGNATURE	DATE
Author	**Peter Jeffries** **Sara Cormack**	**Patient Safety Specialist** **Deputy Patient Safety Specialist**		
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Contents

Purpose

This policy supports the requirements of the Patient Safety Incident Response Framework (PSIRF) and sets out the approach Shrewsbury and Telford Hospital NHS Trust (hereby referred to as SaTH or the Trust) will take to developing and maintaining effective systems and processes for responding to patient safety incidents and issues for the purpose of learning and improving patient safety.

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

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

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

Scope

This policy is specific to patient safety incident responses conducted solely for the purpose of learning and improvement across SaTHs two acute hospital sites, The Royal Shrewsbury Hospital (RSH) and The Princess Royal Hospital Telford (PRH), as well as a number of offsite and subcontracted services including, but not limited to:

- Community maternity services based at Bridgnorth, Ludlow, Market Drayton, Oswestry, Shrewsbury, Telford, and Whitchurch.
- Renal units at Ludlow Community Hospital and Hollinswood House Telford (due to open November 2023)
- Home haemodialysis service
- Fertility services at Severn Fields
- Health harmony dermatology services
- Everlight radiology
- Virtual wards
- SaTH at home

Responses under this policy 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 and not from a single component. Responses do not take a 'person-focused' approach where the actions or inactions of people, or 'human error', are stated as the cause of an incident.

There is no remit to apportion blame or determine liability, preventability, or cause of death in a response conducted for the purpose of learning and improvement. Other processes, such as claims handling, human resources investigations into employment concerns, professional standards investigations, coronial inquests, and criminal investigations, exist for that purpose. The principle aims of each of these responses differ from those of a patient safety response and are outside the scope of this policy.

Response types that are outside the scope of this policy include:

- Complaints
- Human Resources (HR) investigations
- Professional standards investigations
- Coronial inquests
- Criminal investigations
- Claims management
- Financial investigations and audits
- Safeguarding concerns
- Information governance concerns
- Estates and facilities issues which do not impact on patient safety

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

Our patient safety culture

SaTH is on a journey to promote an environment that fosters a positive safety and just culture and PSIRF forms a key component.

During the implementation of PSIRF phase two of the programme focused on diagnostic and discovery, an opportunity to review current systems and processes and through them how the Trust already responds to patient safety incidents for the purpose of learning and improvement.

Through this process, several strengths as well as areas of improvement were identified that will support the requirements and transition to PSIRF.

- The Trust template for formal investigations reflected the human factors system model of Systems Engineering Initiative for Patient Safety (SEIPS), to ensure all contributing factors are explored.
- Ongoing development of the Trusts Executive led incident review group to focus on systems learning and improvement and support.

Areas for improvement that were identified included:

- Development of Datix system to ensure a systems-based approach to patient safety events at all levels of the organisation.
- More robust feedback to staff who submit Datix incidents.
- Effective ways to communicate shared learning from patient safety events, capturing all levels between Ward to Board.
- Engagement of staff when a patient safety event occurs, promoting a Just and Learning Culture and ensuring
- Development of HR systems and processes to support Just Culture.

Acting on this learning a separate but linked annual patient safety systems improvement plan will be developed to support the implementation of PSIRF and development of a proactive safety culture.

Patient safety partners

The NHS Patient Safety Strategy (July 2019) recognises the importance of involving patients, families, carers, advocates, and other lay people in improving the safety of NHS care, as well as the role that patients and carers can have as partners in their own safety.

This framework sets out how NHS organisations should involve patients in patient safety.

The framework is split into two parts:

- Involving patients in their own safety
- Patient Safety Partner (PSP) involvement in organisational safety

The Patient Safety Partner (PSP) is a new and evolving role developed by NHS England to help improve patient safety across healthcare in the UK. It is a vital part of the new PSIRF that aims to allows members of the general public to advocate for the local population to influence and improve safety across our services. PSPs can be patients, carers, family members or other lay people, including NHS and Social Care staff from another organisations.

PSPs will each bring their own unique perspective and insight on patient safety as users of services across different parts of the NHS. They may also have experience

of avoidable harm or healthcare related incidents and can therefore help inform the development of safety solutions that cross organisational boundaries. PSPs will also be pivotal in the development and continuous improvement of our policies and procedures relating to the involvement of patients, families, carers, and advocates who have been involved in patient safety incidents.

The recruitment process for our Trust PSPs is currently underway.

At SaTH we will use the insight of our Patient Safety Partners to:

- Support us in reviewing incidents, investigations and action plans by be a committee member at our Executive incident review group (RALIG)
- Forming part of the teams reviewing our four initial patient safety priorities (as outlined in our Patient Safety Response Plan) ensuring the patient and family perspective is at the heart of our improvement work and providing critical challenge to our improvement plans.
- With the patient safety investigation team support review of patient and family feedback to inform continuous improvement of our investigation processes.
- Be involved with the ongoing annual review of our patient safety incident response as outlined in this policy.

Addressing health inequalities

The Trust recognises that the NHS has a core role to play in reducing inequalities in health by improving access to services and tailoring those services around the needs of the local population in an inclusive way.

The Trust as a public authority is committed to delivering on its statutory obligations under the Equality Act (2010) and will use data intelligently to assess for any disproportionate patient safety risk to patients from across the range of protected characteristics.

Within our patient safety response toolkit, we will directly address if there are any particular features of an incident which indicate health inequalities may have contributed to harm or demonstrate a risk to a particular population group, including all protected characteristics. When constructing our safety actions in response to any incident we will consider inequalities, and this will be inbuilt into our documentation and governance processes.

Our systems and processes underlying our patient safety incident response will support us to understand health inequalities in relation to patient safety by:

- A new monthly safety and quality intelligence group will review safety information to identify themes and trends, including information on health inequalities.

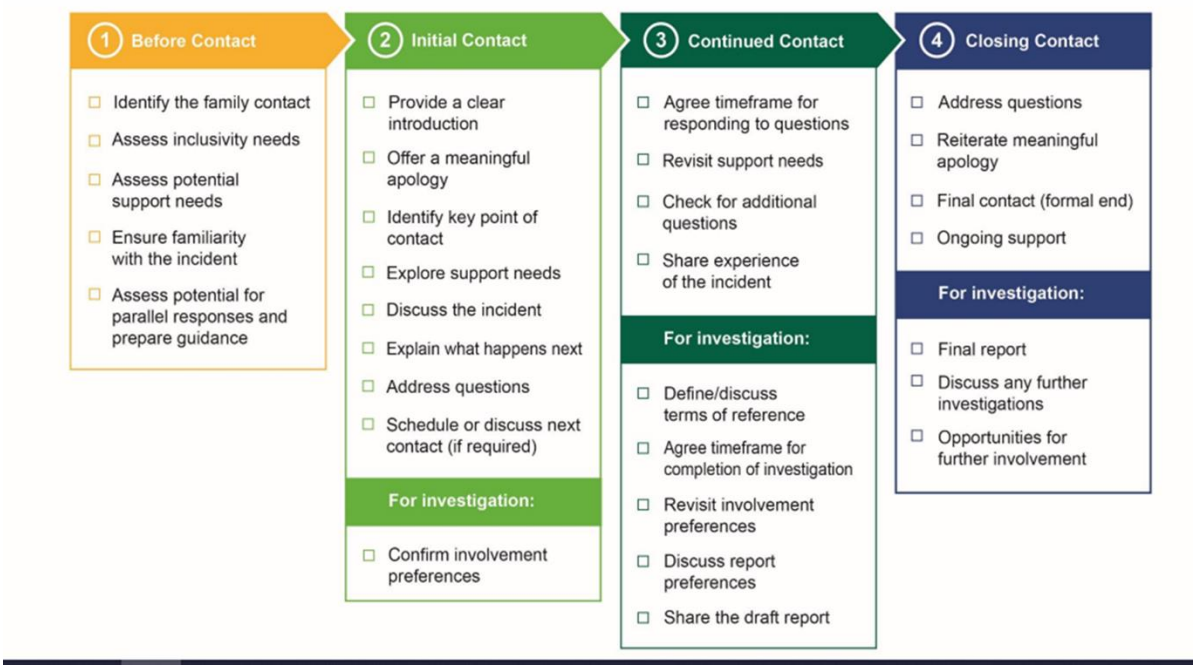
- Ongoing review and feedback from patient and families relating to incident responses will be assessed in terms of health inequalities.
- Our Patient Safety Partners and ongoing discussion of patient safety issues with our PACE panel will act as further sources of insight into disproportionate safety risk for any population group.
- Insight on health inequalities will inform our annual review of our patient safety incident response.

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

SaTH recognises that patient safety incidents can have a significant impact on all those involved in them, including the patient, their families, advocates, and staff. Getting involvement with all parties right as part of our incident response is crucial, not only to provide answers to questions all involved may have in relation to the incident, but to support learning and continuous improvement of the services we provide. Learning and improvement following a patient safety incident can only be achieved if supportive systems and processes are in place.

The voices of all those involved in an incident are an integral part of our PSIRF policy. We have developed procedures and guidance to support staff in how to discuss incidents with patients, families, advocates, and staff, as well as identifying any immediate support needs and signposting them to available support as required.

The overall framework for compassionate engagement of patients and families following and incident is outlined below, this forms the basis of the guidance we have produced for staff:



Duty of Candour is a general duty to be open and transparent with people using the services provided by the Trust, their family, carers, and advocates. It sets out specific requirements providers must follow when things go wrong with care and treatment, including informing people about the incident, providing reasonable support, providing truthful information and an apology when things go wrong.

Legal Duty of Candour regulations will still apply for “notifiable safety incidents”.

Patient safety incident response planning

PSIRF supports organisations to respond to incidents and safety issues in a way that maximises learning and improvement, rather than basing responses on arbitrary and subjective definitions of harm. Beyond nationally set requirements, organisations can explore patient safety incidents relevant to their context and the populations they serve rather than only those that meet a certain defined threshold. There are no further national rules or thresholds to determine what method of response should be used to support learning and improvement for each type of incident.

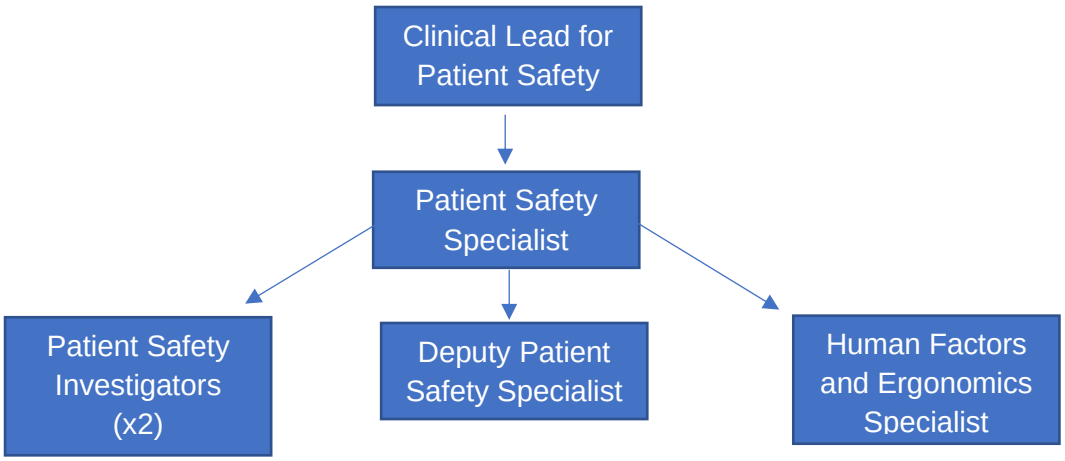
This change will result in some moderate harm and greater incidents receiving less review than they would previously. Conversely, some low and no harm incidents will receive more review due to the fact they will represent greater opportunity for learning and improvement in systems where the issues are not well understood.

With the implementation of the new PSIRF framework, SaTH are now able to balance effort and resources between learning through responding to incidents or exploring issues and improvement work. Responding proportionately to balance learning and

improvement efforts requires a thorough understanding of the local patient safety incident profile and ongoing improvement work.

Resources and training to support patient safety incident response

The central patient safety team will take responsibility for investigating PSII's under the national priorities as outlined in our Patient Safety Incident Response plan working closely with Divisional and clinical teams. The structure of the team is outlined below:



The central patient safety team will also take oversight of thematic work undertaken related to our PSIRF safety priorities.

Other safety learning responses (such as After Actions Systems Reviews) will be supported and facilitated by the Quality Governance Teams in each Division with further support from the central patient safety team.

Initial training support will be as below:

- Central patient safety team, quality governance teams and Corporate Nursing Quality team and quality leads from support services – *3 days training on systems investigations, compassionate engagement and oversight.*
- Divisional Leadership Teams – *two half days training on compassionate engagement and oversight.*
- Executive Director safety leads (Director of Nursing and Medical Director) - *two half days training on compassionate engagement and oversight and in line with PSIRF guidance level 1 for Boards National Patient Safety Syllabus training.*
- Non-Executive members of Quality and Safety Assurance Committee – *half day oversight training and in line with PSIRF guidance level 1 for Boards National Patient Safety Syllabus training.*

- Other members of Trust Board - *in line with PSIRF guidance level 1 for Boards National Patient Safety Syllabus training.*

The initial training packages will be delivered by an external human factors and ergonomics professional in conjunction with the patient safety team.

Ongoing safety needs will be assessed as part of the annual cycle of PSIRF review and further training delivered based on that assessment.

Our patient safety incident response plan

Our Patient Safety Incident Response Plan (PSIRP) sets out how SaTH intends to respond to patient safety incidents over a period of 12 months from November 2023. 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 patient safety incident occurred, including the needs of those affected, the level of organisational knowledge of the risks involved in the incident, the learning potential of the incident, and the Trusts PSIRF plan to determine the most proportionate response to each incident.

Reviewing our patient safety incident response policy and plan

Our Patient Safety Incident Response Plan is a 'living document' that will be appropriately amended and updated as we use it to respond to patient safety incidents. We will review the plan every 12 to months to ensure our focus remains up to date.

This review will be formed of three key components:

- Review of our ongoing patient safety profile informed by incidents, risks, complaints, learning from deaths information, external reports and patient, family and staff feedback.
- Review of improvement plans related to out Trust safety priorities.
- Feedback of ongoing review of both the positive and negative aspects of our PSIRF processes to inform ongoing improvement of our PSRIF implementation. This will be sourced from patient, family, and staff feedback.

These sources of information will be fed into annual workshops including external and internal stakeholders and used to report to Quality Operational Committee onto Quality and Safety Assurance Group and to our Trust Board with recommendations for the refreshing of our Patient Safety Incident Response Plan and Patient Safety Incident Response Policy.

This is an important feature of PSIRF as with ongoing improvement work progressing in the Trust, our patient safety incident profile is likely to change and evolve.

This regular review process will also provide an opportunity to re-engage with stakeholders to discuss and agree any changes made in the previous 12 to months. Updated plans will be published on our website, replacing the previous version.

Responding to patient safety incidents

Patient safety incident reporting arrangements

The main method for staff to report patient safety incidents is via the Trust Datix incident reporting system. This is a central Trust database of incidents and the learning and actions that have been implemented as a result of their review. This system allows managers and senior staff members in departments to have oversight of all incidents in their area and enables them to log how they have reviewed and responded to the incident as well as how they have provided feedback to the staff who have raised their concerns. Datix also allows senior managers and executives oversight of patient safety incidents and is a vital source of data to identify areas of concern as well as good practice to help inform the Trusts overall safety profile.

Patient Safety Incidents can also be identified via a number of different routes including Learning from Deaths (Medical Examiner (ME) reviews, Structured Judgment Reviews (SJR), complaints, Multi-Disciplinary Team (MDT) discussions, Freedom to Speak Up (FTSU) concerns and audits. Once identified via these alternative routes, the incident is added to the Datix incident reporting system for full and transparent review, investigation, and learning.

The Trust is also required to fulfil a number of requirements to report or notify various organisations or regulatory bodies external to the Trust of specific incidents and adverse events. These include:

- **UKHSA**- UK Health Security Agency- all laboratories in England performing a primary diagnostic role must notify UKHSA on the confirmation of a notifiable organism.
- **SHOT**- Serious Hazards of Transfusion- must report adverse events of transfusion of blood and blood components.
- **SABRE**- Serious Adverse Blood Reactions and Events- MHRA system for reporting adverse reactions and events related to blood or blood products.
- **HTARI-** Human Tissue Authority Reportable Incident- must report serious incidents and near-miss incidents that may affect the dignity of the deceased and damage public confidence.
- **HFEA-** Human Fertilisation and Embryology Authority- must report all incidents involving fertility treatment, including near misses to HFEA.
- **IRMER**- Ionising Radiation (Medical Exposure) Regulations- must report incidents involving accidental or unintended exposure to ionising radiation that the provider knows, or thinks are significant or clinically significant.

- **NRLS**- National Reporting and Learning System is a central database of all patient safety incident reports.
- **STEIS**- Strategic Executive Information system- system for reporting Serious Incidents (SI) to the appropriate Integrated Care System (ICS).
- **LFPSE-** Learning from Patient Safety Events- new national NHS service for the recording and analysis of patient safety events that occur in healthcare.
  NOTE: NRLS and STEIS will be replaced by LFPSE during the time period covered by this policy. Once PSIRF is implemented and SI investigations cease to exist, it is currently anticipated that all Patient Safety Incident Investigations (PSIIs) will be reported on STEIS in the short term.
- **RIDDOR-** Reporting of Injuries, Diseases and Dangerous Occurrences Regulations- reporting of deaths and specified injuries to the Health & Safety Executive (HSE).
- **MHRA-** Medicines and Healthcare Products Regulatory Agency- must report suspected problems and adverse incidents with a medicine or medical device to the MHRA using the Yellow Card Scheme
- **CDOP-** Child Death Overview Panel– must be notified of all child deaths by the Head of Safeguarding Children.
- **Coroner**- deaths where no doctor is available to provide a cause of death, or other specific circumstances including deaths linked to medical treatment, surgery or anaesthetic, suspected suicides and deaths linked to drugs or medications (prescribed or illicit).
- **NHS screening programs** – any incidents in screening programmes must be reported to Public Health England (PHE) via a Screening Incident Assessment Form (SIAF) to allow them to assess and respond to each incident. The NHS Screening Programmes covered are:
  - NHS Breast Screening Programme
  - NHS Cervical Screening Programme
  - NHS Bowel Cancer Screening Programme
  - NHS Diabetic Eye Screening Programme
  - NHS Abdominal Aortic Aneurysm Screening Programme
  - NHS Foetal Anomaly Screening Programme
  - NHS Infectious Diseases in Pregnancy Programme
  - NHS Sickle Cell and Thalassaemia programme
  - NHS Newborn Blood Spot Programme

Patient safety incident response decision-making

Because of the change of focus of which incidents need more detailed review under the new PSIRF, the Trust will be introducing a new approach to the initial review of incidents. This new approach will involve the introduction of a daily triage of incidents by a senior member of the Patient Safety Team with admin support.

This process is outlined in appendix A.

This new approach will have a number of benefits, including:

- Enabling early corporate oversight of incidents that are likely to meet the criteria of national or Trust priorities to ensure the appropriate procedures are promptly initiated, including compassionate engagement of all those involved.
- Allowing incident reports that represent organisational risks rather than specific incidents, to be immediately closed with appropriate comments and retained for the purpose of data analysis an informing our safety profile and risk register.
- Ensuring all incidents with likely only local learning are directed to the most appropriate staff and clinical area to review, learn, and respond.
- Enabling the early identification of incidents that are most likely to require a learning response, and those that require Duty of Candour (DoC) to be completed. These incidents can then be escalated to the appropriate Quality Governance Team, clinical area, and divisional leadership team for compassionate engagement of those involved, completion of DoC if applicable and information gathering for discussion at the next Trust Rapid Review.
- Better oversight of all Trust Patient Safety incidents is likely to allow emerging issues and themes to be identified more quickly by the Patient Safety Team.
- Quality control of the coding of incident reports including the locations and incident types will improve the quality of the data on Datix, and therefore improve the quality of the analysis performed on that data.
- Using a small pool of experienced, highly trained Patient Safety and Investigation Specialists to provide the initial review of incidents will likely improve standardisation of decision making, especially in conjunction with a clear process and implementation of a “Decision Tree” for decision making (appendix B)

Once incidents have been identified by the triage team as likely requiring a PSII or learning response, these will be reviewed by the appropriate Quality Governance Team in conjunction with the clinical area involved and all will require discussion at the Trusts Corporate Rapid Review meeting.

Any incidents that were triaged for immediate closure or local learning by the triage team but on review by the Quality Governance Team and clinical area have revealed additional concerns can also be escalated to Rapid Review for discussion. Significant incidents identified via routes other than Datix described previously can also be bought to Rapid Review for discussion by a representative of the team who identified the incident as requiring escalation.

The purpose of Rapid Review will be to recommend the most appropriate investigation or learning response method based on the Trust PSIRF plan and the assessed learning potential of each incident being reviewed (in line with the incident decision

tree). They will also consider appropriate target timescales for completion of reviews and suggest an Investigators or Learning Response Lead for each incident where possible.

Suggested Investigators and Response Leads should have received the appropriate level of training and be independent from the areas and staff involved in the incident, ideally being from outside of the care group involved, as detailed in the national PSIRF guidance. Any differences of opinion regarding the response quired to incidents, target timescales, or Investigator/Response Lead will be discussed at RALIG and a final decision ratified.

Rapid Review will be chaired by the Assistant Director of Nursing, Quality Governance and membership of the group will include a wide range of staff members and specialists which may include Safeguarding, Complaints, LfDs, the Improvement team, Specialist Nurses, Ward Managers, Matrons, Quality Governance Teams and Governance Leads and the Patient Safety Team.

The recommendations agreed by Rapid Review will then be discussed at the Trusts Review and Learning from Incidents Group (RALIG), chaired by the Trust Medical Director and Director or Nursing. At RALIG, the recommendations of Rapid Review will be discussed, challenged where appropriate and agreed before a final decision on the Trusts response to each incident is confirmed.

Membership of RALIG will include Deputy Medical Directors, Directors of Nursing for the divisions, Clinical Directors of care groups and specialties, Clinical Governance Leads, the Patient Safety Team, and representatives from the care groups and specialities whose cases are being discussed. Cases will be presented to RALIG by the senior leadership team for the area in which the incident occurred.

To ensure that there are sufficient resources to allocate to support responses to emergent issues that are not included in the initial PSIRF plan, one Trust priority has been left unallocated for this purpose. This will allow the Trust greater flexibility to react more promptly to newly identified system issues to ensure learning and improvement is completed more promptly.

Timeframes for learning responses

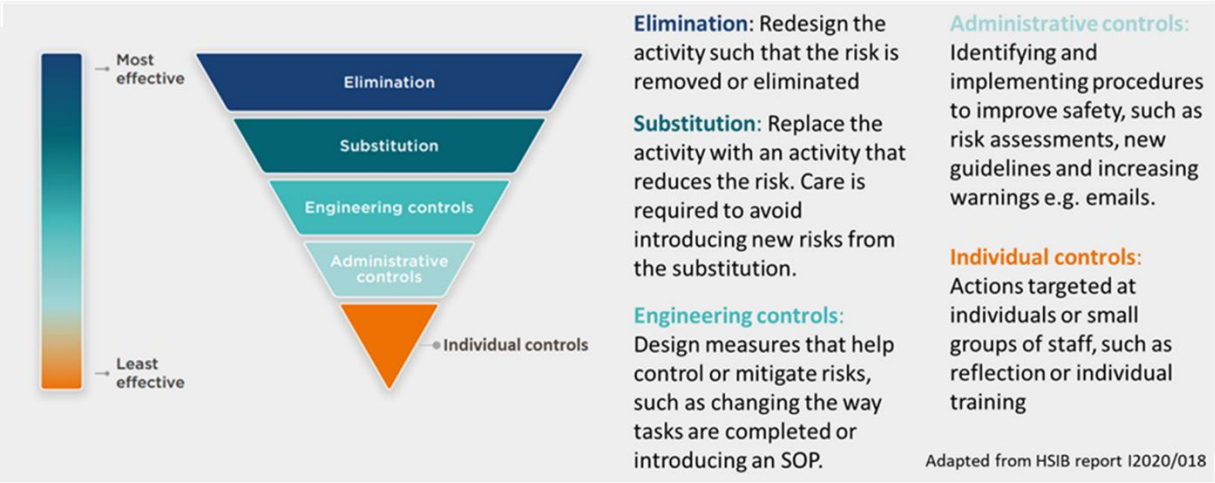
Under the new PSIRF framework there are no national target timeframes for completion of PSIIs or other learning responses. Instead, realistic, achievable timescales should be discussed and agreed by all those involved in the incident and its review, including the patient, their families, carers, and advocates where appropriate. These discussions should consider the complexity of the incident being reviewed, if it is an individual incident being reviewed or a cluster of similar incidents, the availability of those that need to be involved, and the current workload of the team that will be completing the review.

In some circumstances, particularly where demand for incident investigations and learning responses exceeds the Patient Safety Teams capacity, it may be appropriate to pause some PSIIs that are being completed for reasons other than those associated with national priorities. These incidents can then be restarted when capacity allows, but this approach and the delayed timescales must be discussed and agreed with all those involved in the incident and its review.

Target timescales for each PSII and learning response will be discussed at the Trust Corporate Rapid Review meeting, the conclusion of which will be put forward as a recommendation to RALIG. At RALIG, these timescales will be discussed, challenged where appropriate, and agreed before being communicated to all those involved. Any differences of opinion regarding these timescales will be discussed at RALIG and a final decision ratified.

Safety action development

Recommendations from Patient Safety Incident Investigations or other learning responses will be assessed against the hierarchy of risk controls to understand the likely impact in terms of reducing risk of harm. The hierarchy of interventions is outlined below:



Safety recommendations from PSII's and other learning responses will be reviewed as part of the ongoing annual review of PSIRF to understand how recommendations are being targeted and how recommendation making can be improved.

All safety actions identified for any level of learning response will expected to:

- Have been developed in collaboration with the teams who undertake the clinical/non-clinical work to be impacted with a focus on the 'work as done' and the ability to effectively implement.
- Are SMART (**S**pecific, **M**easurable, **A**chievable, **R**ealistic and **T**imed).

- In line with ‘measurable’ have a defined measure of improvement (qualitative or quantative) that can be tracked.

Safety improvement plans and monitoring improvement

Improvement plans will be reported and monitored at different level depending on the nature of the scale, significance of learning and cross Divisional nature of the improvement plan.

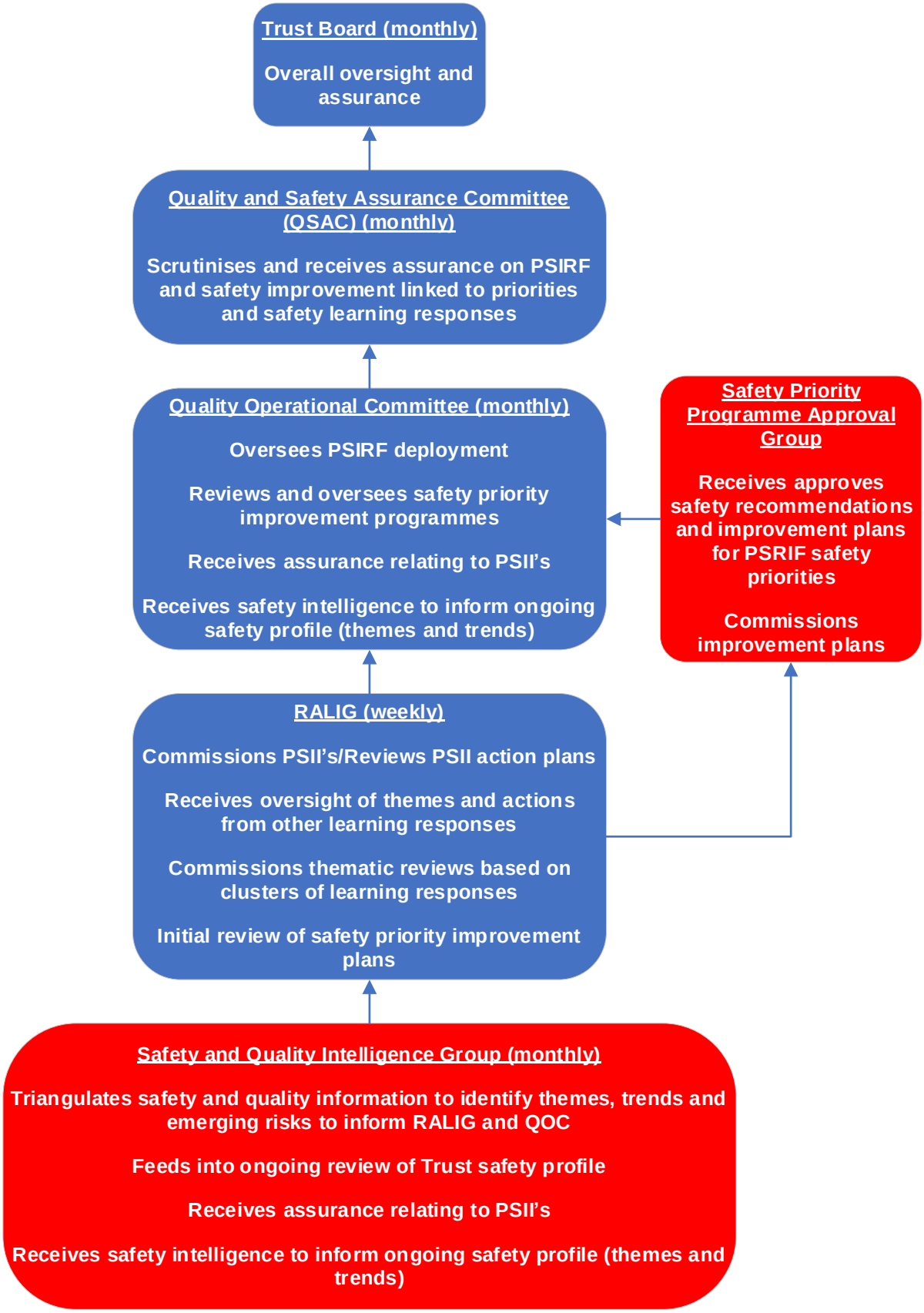
- Existing Corporate improvement plans that have a significant safety focus such as Maternity Transformation, Paediatric Transformation and the Emergency Care Transformation programme will continue to report to their respective steering committees to Quality Operational Committee, Quality and Safety Assurance Committee and for assurance to Trust Board.
- Specific PSIRF safety priority improvement plans will be scrutinised and approved by a dedicated Executive led Safety Programme Approval Group and then reported and monitored via Quality Operational Committee, Quality and Safety Assurance Committee and for assurance to Trust Board.
- Individual Patient Safety Incident Investigation improvement plans will be signed off at RALIG and will return for review based on a timescale agreed at RALIG. Reporting in summary and by exception will be undertaken via Quality Operational Committee, Quality and Safety Assurance Committee and for assurance to Trust Board.
- Other learning responses (such as After-Action System Reviews) improvement plans will be reported and monitored Divisionally via local specialty/department governance meetings. If learning and associated recommendations and actions span Divisions actions plans will be brought to RALIG for discussion and scrutiny and agreement of arrangements for ongoing monitoring.

The role of key Trust committees and their oversight role for PSIRF is outlined in the oversight section below.

Oversight roles and responsibilities

Principles and structure for oversight

Working under PSIRF, organisations are advised to design oversight systems to allow an organisation to demonstrate improvement rather than compliance with centrally mandated measures. The high-level structure for oversight of PSIRF at SaTH is outlined in the diagram below:


Trust Board (monthly)
Overall oversight and assurance
Quality and Safety Assurance Committee (QSAC) (monthly)
Scrutinises and receives assurance on PSIRF and safety improvement linked to priorities and safety learning responses
Quality Operational Committee (monthly)
Oversees PSIRF deployment
Reviews and oversees safety priority improvement programmes
Receives assurance relating to PSII's
Receives safety intelligence to inform ongoing safety profile (themes and trends)
Safety Priority Programme Approval Group
Receives approves safety recommendations and improvement plans for PSRIF safety priorities
Commissions improvement plans
RALIG (weekly)
Commissions PSII's/Reviews PSII action plans
Receives oversight of themes and actions from other learning responses
Commissions thematic reviews based on clusters of learning responses
Initial review of safety priority improvement plans
Safety and Quality Intelligence Group (monthly)
Triangulates safety and quality information to identify themes, trends and emerging risks to inform RALIG and QOC
Feeds into ongoing review of Trust safety profile
Receives assurance relating to PSII's
Receives safety intelligence to inform ongoing safety profile (themes and trends)

Responsibilities

Alongside our NHS regional and local ICB structures and our regulator, the Care Quality Commission, we have specific organisational responsibilities with the Framework.

In order to meet these responsibilities, the Trust has designated the Director of Nursing and Medical Director to support PSIRF as the executive leads.

1. Ensuring that the organisation meets the national patient safety standards

The Executive Medical Directors will oversee the development, review and approval of the Trust's policy and plan ensuring that they meet the expectations set out in the patient safety incident response standards. The policy and plan will promote the restorative just working culture that the Trust aspires to.

To achieve the development of the plan and policy the Trust will supported by internal resources within the Patient Safety team led by the Assistant Director of Nursing, Quality Governance and Clinical Lead for Patient Safety.

2. Ensuring that PSIRF is central to overarching safety governance arrangements

The Trust Board will receive assurance regarding the implementation of PSIRF, associated standards and implementation of improvement programmes linked to patient safety priorities via existing reporting mechanisms from the Quality Operational Committee and Quality and Safety Assurance Committee.

Divisions will have arrangements in place to manage the local response to patient safety incidents and ensure that escalation procedures as described in the patient safety incident response section of this policy are effective.

The Trust will source necessary training such as the Health Education England patient safety syllabus and other patient safety training across the organisation as appropriate to the roles and responsibilities of its staff in supporting an effective organisational response to incidents.

Updates will be made to this policy and associated plan as part of regular oversight.

3. Quality assuring learning response outputs

The Patient Safety Team will implement a central Patient Safety Incident panel to ensure that PSIIs are conducted to the highest standards and to support the executive sign off process and ensure that learning is shared, and safety improvement work is adequately directed. This process will also support review of the quality of other safety learning responses and ensure ongoing development and training needs are identified to support learning responses.

Complaints and appeals

If a patient or family has the need to complain or appeal relating to the learning response that has been undertaken relating to an incident, in the first instance we will look to resolve these issues at a local level via the learning response lead (such as a Patient Safety Investigation Specialist for a Patient Safety Incident Investigation).

If the issue cannot be resolved at a local level patients and families will be directed to the Trusts complaints procedures and process with signposting towards PALS and advocacy services for support.

References

NHS England (2021) Core20PLUS5: An Approach to Reducing Health Inequalities

core20plus5-online-engage-survey-supporting-document-v1.pdf (england.nhs.uk)

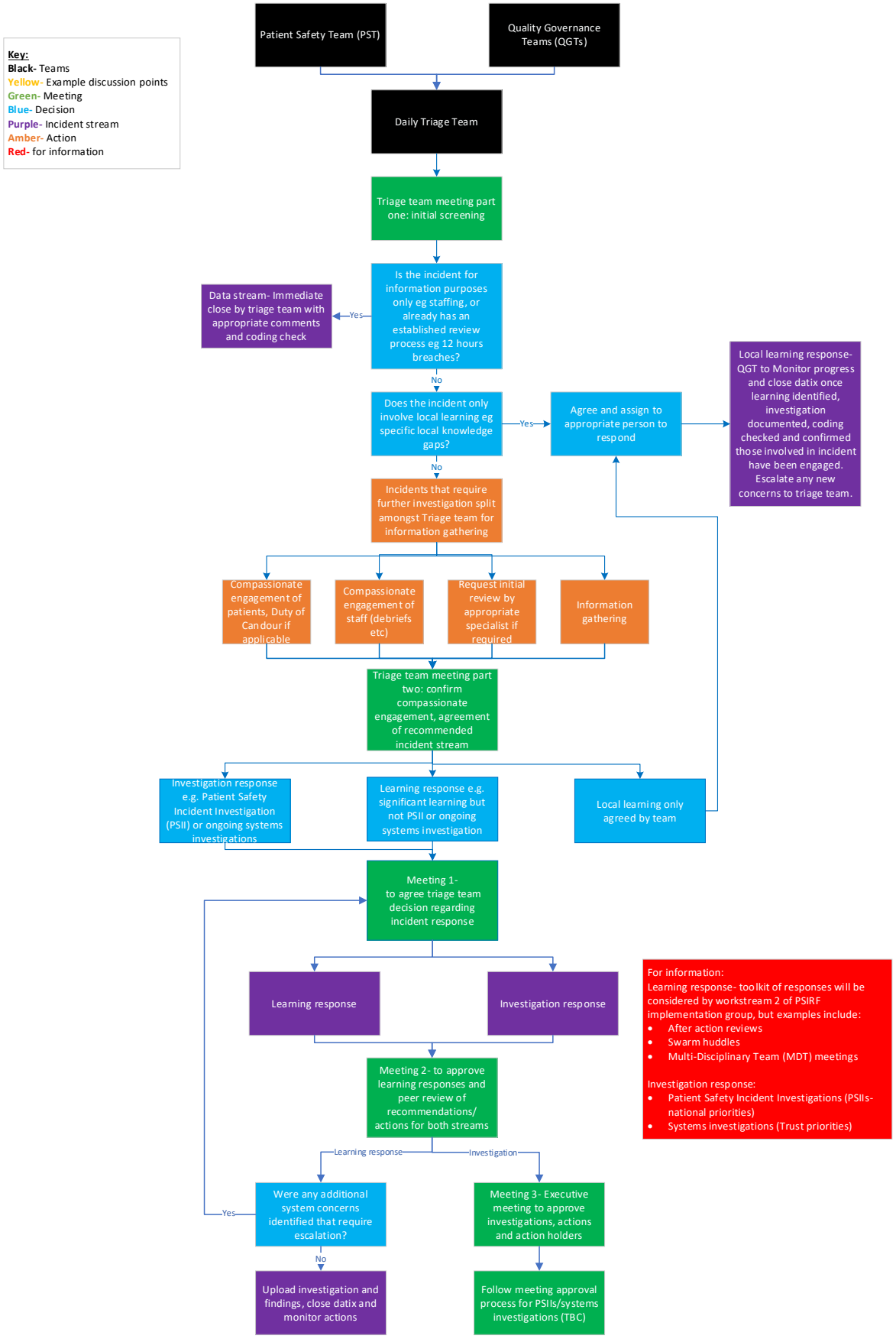
NHS England (2022) Patient safety incident response standards

B1465-5.-Patient-Safety-Incident-Response-standards-v1-FINAL.pdf (england.nhs.uk)

NHS England (2022) Safety action development guide

https://www.england.nhs.uk/wp-content/uploads/2022/08/B1465-Safety-action-development-v1.1.pdf

Appendix 1 – Draft Incident Triage Process



Appendix 2 – Incident response decision tree