Royal Berkshire NHS Foundation Trust

Patient Safety Incident Response Framework Policy (CG819)

Approval

Approval Group	Job Title, Chair of Committee	Date
ICB SQG	ICB Chief Nurse	March 2024
Quality Governance Committee	Chief Medical Officer & Chief Nursing Officer	March 2024

Change History

Version	Date	Author, job title	Reason
1.0	March 2024	Sharon Andrews- Associate Director of Safety and Risk Sarah Brown- Head of Patient Safety Hannah Spencer, Deputy Chief Nurse	New Policy

Contents

Other relevant corporate or procedural documents:

This document must be read in conjunction with:

- Patient safety Incident Response Plan

1.0 Purpose

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

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

This policy integrates the four key aims of the PSIRF and which also align to our existing Trust values:

- Compassionate engagement and involvement of those affected by patient safety incidents (Accountability, Respect and Support).
- Application of a range of system-based approaches to learning from patient safety incidents (Continuous Improvement and Accountability).
- Considered and proportionate responses to patient safety incidents and safety issues (Continuous Improvement and Accountability).
- Supportive oversight focused on strengthening response system functioning and improvement. (Continuous Improvement, Support, Respect and Enthusiasm).

This policy should read in conjunction with our current patient safety incident response plan, which is a separate document setting out how this policy will be implemented.

2.0 Scope

This policy applies to all people working for the Trust including substantive staff, temporary or agency staff locums, apprentices, students, and volunteers.
This policy is specific to patient safety incident responses conducted solely for the purpose of learning and improvement across the Trust.

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.

Where other processes exist with a remit of determining liability or to apportion blame, or cause of death, their principal aims differ from a patient safety response. Such processes as those listed below and are therefore outside of the scope this policy.

- claims handling,
- human resources investigations into employment concerns,
- professional standards investigations,
- information governance concerns,
- estates and facilities concerns,
- financial investigations and audits,
- safeguarding concerns,
- coronial inquests and criminal investigations,
- Complaints (except where a significant patient safety concern is highlighted, in which the complaint process would be suspended until the patient safety process is complete. Where possible the complainants concerns would be address in the patient safety investigation, if not follow up afterwards).

For clarity, the Trust considers these processes as separate from any patient safety investigation. 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.

3.0 Roles and Responsibilities

Chief Executive Officer

The Chief Executive Officer, so far as it is within their control to do so, has responsibility on behalf of the Trust Board for ensuring there is a robust patient safety incident response framework in place across the Trust.

Chief Medical Officer

The Chief Medical Officer, so far as it is within their control to do so, is responsible for ensuring there are effective patient safety structures in place across the Trust.

Specifically, the Chief Medical Officer has responsibility for providing assurance around

clinical effectiveness of care delivered. The Chief Medical Officer chairs the Quality Governance Committee (QGC) jointly with the Chief Nursing Officer.

Chief Nursing Officer

The Chief Nursing Officer, so far as it is within their control to do so, has responsibility for ensuring there are effective structures and processes in place for patient safety, clinical risk, and patient experience across the Trust. The Chief Nursing Officer chairs the Quality Governance committee jointly with the Chief Medical Officer.

Deputy Chief Nurse

The Deputy Chief Nurse, so far as it is within their control to do so, is responsible for monitoring, assessing and reviewing the processes and procedures in place for patient safety, risk, and clinical effectiveness. The Deputy Chief Nurse chairs the Patient Safety committee, which reports directly into the Quality Governance committee.

Associate Director of Safety & Risk

The Associate Director of Safety & Risk, so far as it is within their control to do so, is responsible for the implementation of patient safety processes and initiatives Trust-wide including overseeing the incident reporting and management systems. They are also responsible for the implementation and compliance with the PSIRF within the Trust. They hold a dual role of patient safety specialist. They will be responsible for the ongoing monitoring and review of PSIRP and the policy and the learning outcomes.

Head of Patient Safety

The Head of Patient Safety, so far as it is within their control to do so, is responsible for supporting the Associate Director of Safety & Risk with the development, embedding and monitoring of the PSIRF within the Trust and overseeing the patient safety team. The also hold the role of patient safety specialist. They will assist with the ongoing PSIRF reviews and thematic analysis Trustwide including reporting.

Patient Safety Leads

The Patient Safety Leads, so far as it is within their control to do so, are responsible for overseeing and facilitating the implementation of PSIRF processes, including providing care group guidance on the new framework and tools for investigation.

Patient Safety Partners

The Patient Safety Partner (PSP) is a new and evolving role developed by NHS England / Improvement to help improve patient safety across the NHS in the UK.

PSPs will offer support alongside our staff, patients, families /carers to influence and improve safety across our range of services. PSPs can be patients, carers, family members or other lay people (including NHS staff from another organisation). It is expected this role will evolve over time and in RBFT the main purpose of the role is to be a voice for the patients and community who utilise our services and ensure that patient safety is at the forefront of all that we do.

Patient Safety Specialists

As so far as it is within their control to do so, should have an overview of and ability to influence and interact with all patient safety processes within the organisation. This includes managing teams that lead on patient safety processes, such as patient safety incident reporting, risk management and investigation.

Patient Safety Incident Investigators

Patient Safety Investigators (PSI) will lead patient safety incident investigations (PSIIs) and other learning responses as appropriate, for incidents that fall within the Trust patient safety priority areas. They have all received appropriate PSII training.

A senior member of the Patient Safety Team will lead the completion of PSIIs and work with the PSI, services and Care Group/s to encourage a shift towards PSIRP principles of the whole system approach, psychological safety and compassionate engagement of staff, patient and families.

All Staff

All staff have a responsibility to contribute to and comply with systems and processes to keep patients safe, to treat patients with dignity and respect, and to ensure they deliver high quality care as per their professional codes of practice. Including, and not exclusive to engaging with the PSIRF model and its new ways of learning.

4.0 Definitions

PSIRF- Patient safety incident response framework
PSIRG- Patient safety incident review group
PSIRP- Patient safety incident response plan
PSII- Patient safety incident investigation
PSP- Patient safety partners
QGC- Quality governance committee
Level 1 incident
Level 2 incident

5.0 PSIRF process

A flowchart summary of the PSIRF process can be found in appendix 3.

5.1 Reporting

All staff are responsible for reporting any safety events on our Trust incident reporting system (Datix) in accordance with Datix operational procedures (available via workvivo). New definitions of harm will apply in accordance with the new NHS England (2023) National Policy available here: https://www.england.nhs.uk/long-read/policy-guidance-on-recording-patient-safety-events-and-levels-of-harm/

The PSIRF process is triggered by the submission of a datix incident. The patient safety team will triage the datix and all those of level 2 and above will be automatically considered for the PSIRF process (see appendix 3 on how this applies to level 1 incidents).
In order to provide a timely review, the patient safety team and operational areas within Care Groups will have daily incident review mechanisms in place. Patient safety will

perform daily reviews of incidents submitted, ensuring correct handlers are in place, therefore care groups should receive appropriate notification for the submission of new datix requiring review.

Levels are automatically generated by the datix system depending on the answer to the 3 LSFSE questions posed to the submitter. These will take in to consideration the Trusts chosen Patient Safety Priorities, more information for which can be found in the PSIRP document:

Theme	Description	Key Risks
1.	**Treatment delay within the two week wait pathway**	Safety and clinical stability of patients in pathway
2.	**Communication and/or handover between departments**	An issue where significant concerns about communication and/or handover, between staff, teams and/ or departments have affected the patient journey and subsequent treatment/diagnosis.
3.	**Recognition of the deteriorating patient**	Recognition of the deteriorating patient, escalation of deterioration, and subsequent treatment/ diagnosis,
4.	**Patient flow from ED**	Delays in patient admission, transfer and discharged from ED, leading to delays in subsequent specialist treatment
5.	**Medication errors- prescribing and administering**	Medication errors resulting in patient harm

5.2 Reviewing

A joint initial safety review with the care group team representative and patient safety will then occur within 72 hours; a rapid review panel (RR) to determine the recommended path of action (see appendix 2) This will be facilitated within the datix system reviewing a series of questions to determine the options for next steps. If a Swarm or de-escalation is recommended, this will be actioned by the rapid review panel. If the recommendation is for any of the alternative methodologies, this will then be ratified at PSIRG and the agreed pathway will commence. The options include:

- De-escalation
- MDT roundtable review
- After Action review
- Swarm Huddle
- Thematic Analysis
- Patient Safety Incident Investigation

These learning methodologies are defined as below:

LEARNING RESPONSE METHODOLOGY	WHAT IS IT AND WHEN CAN IT BE USED?
Patient Safety Incident Investigation (PSII)	A PSII is a patient safety incident 'review methodology' adopting an 'investigative approach' for the incident response. This leads to an in-depth review of a single patient safety incident with the formulation of a comprehensive report A PSII is undertaken when an incident or near-miss indicates significant patient safety risks and potential for new learning.
Swarm Huddle	Swarm-based huddles are used to identify learning from patient safety incidents. Immediately after an incident, staff 'swarm' to the site to quickly analyse what happened and how it happened and decide what needs to be done to reduce risk.
After Action Review (AAR)	An AAR is 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 tasks to avoid failure and promote success for the future.
Multidisciplinary (MDT) roundtable review	The MDT roundtable review supports health and social care teams to identify learning from multiple patient safety incidents; agree the key contributory factors and system gaps in patient safety incidents; explore a safety theme, pathway, or process; and gain insight into 'work as done' in a health and social care system.
Thematic Analysis	This can identify patterns in data to help answer questions, show links or identify issues, typically using qualitative data to identify safety themes and issues
• De-escalation	No further learning or risk has need. Incident to be closed locally via datix.

PSIRG will continue to review decisions for thresholds for investigation and appropriate methodologies and review learning and action quality post investigation to allow for appropriate executive oversight and input.

5.3 Timeframes

In order to provide timely and supportive outcomes, the following timelines will be applicable for the varying methodologies:

Where a PSII for learning is indicated, the investigation must be started as soon as possible after the patient safety incident is identified. No local PSII should take longer than six months and the time frame for completion of a PSII will be agreed with those affected by the incident, as part of the setting of terms of reference, provided they are willing and able to be involved in that decision. A balance must be drawn between conducting a thorough PSII, the impact that extended timescales can have on those involved in the incident, and the risk that delayed findings may adversely affect safety or require further checks to ensure they remain relevant. In exceptional circumstances (e.g., when a partner organisation requests an investigation is paused, or the processes of an external body delays access to information) the Trust can consider whether to progress the PSII and determine whether new information indicates the need for further investigative activity once this is received. This would require a decision by the Trust PSIRG and open and clear communication to everyone involved should be achieved. PSII expected meeting flow can be found in appendix 10.

5.4 Templates

Templates for these methodologies can be found in appendix 1-6. Further information regarding the methodologies can be found in the appendix 12. Appendix 11 outlines

where there are national requirements for particular learning methodology choices.

5.5 Initial Facilitation

It is expected that initially the patient safety team and safety investigators will provide more input in to supporting and facilitating the new methodologies, however as this embeds within organisational culture and the teams are trained, it is expected the balance of facilitation will shift and that teams will be able to chair the agreed learning methodology with lighter facilitation and oversight from the patient safety team. It is anticipated that learning responses led by care groups will be by members of the team suitable trained at band 8a and above or equivalent.

5.6 Sharing lessons learnt

PSIRF provides the ability to look at the lessons generated from learning methodologies. In order to share these wider than the individual team, following completion of the learning response a standardised template will be generated and available on the intranet (workvivo) patient safety page for sharing trust wide and dissemination across the care groups (appendix 9). These will be shared in speciality and care group governance and via the patient safety newsletter.

5.7 Safety Actions

Learning responses enable understanding and immediate mitigation, but it is key that areas identified for improvement are coupled with safety actions to reduce the risk of future incidents. Safety actions must continue to be centrally recorded and monitored within the care group governance arrangements, with appropriate support and oversight from the Patient Safety Team, to ensure that any actions put in place remain impactful and sustainable. Care Group reporting on the progress with safety actions, including the outcomes of any measurements will continue to be made via the care group governance and PRMs escalations from care groups will occur via quality governance committee exception reports. There will be an agreed time limit for completion in order to ensure optimum learning is achieved. It is expected that no safety action should be outstanding for more than 6 months from the point of generation. These will be logged in datix so there is a central record and effective oversight of potential closure delays.

5.8 Safety Improvement Plans

Safety improvement plans collate findings across multiple safety incidents and issues. The PSIRP has outlined the initial local priorities for focus of investigation under PSIRF. These were developed due to the opportunity they offer for learning and improvement across areas where there is no existing plan or where improvement efforts have not yet been accompanied by reduction in apparent risk or harm.

Ongoing monitoring will identify overarching system issues outside of the trust local priorities. Where these are identified a safety improvement plan will also be developed (or may be enhanced/reviewed if pre-existing). The care groups will work collaboratively with the patient safety team to ensure there is an aligned approach to the development of plans across the various working/steering groups and committees. Measurement and monitoring of the progress of the safety improvement plans will be overseen by reporting by the designated committee on a scheduled basis. There will be a schedule of reporting from subcommittees to the patient safety committee annually to provide an overview of progress. Where incidents fall in to existing work streams, no further investigation should be required and the incident will be referred to the relevant subcommittee

6.0 Safety Culture

Positive safety culture is fundamental in the implementation of PSIRF. As a Trust, RBFT has an ongoing commitment to fostering a culture of psychological safety and continuous quality improvement. The Trust senior leadership have strongly embraced this work there are regular Executive-led safety huddles as well as the daily operational safety huddles that are undertaken across the organisation. Our executive led Patient Safety Incident Review Group (PSIRG) was reviewed in early 2020 to have additional oversight of the Trust's patient safety responses and improvement activity. These multidisciplinary meetings are held at least twice a week and give the opportunity to share learning widely, as well as consider emerging risks and insights from incidents. More details on how the Trust supports continuing development of psychologically safe environments and just culture can be found in the PSIRP.

7.0 Staff and Patient/ Family involvement

The four strategic aims of PSIRF are aligned with the Trust vision, strategic objectives and CARE values. The implementation of PSIRF will provide a clear sense of direction for how all of these can be embodied in our work:

- Compassionate engagement and involvement of those affected
- Application of a range of system based approaches
- Considered and proportionate responses
- Supportive oversight

PSIRF will support the Trust to achieve stronger links between a patient and/or staff safety incident, and learning and improvement. We will work in collaboration with those affected – patients, staff, families and carers – and this will support us in increasing the transparency and openness amongst our staff in reporting of incidents, as well as in the engagement in developing and implementing the learning and improvements that follow. This will include insight from when things have gone well and where things have not gone as planned.

Patient, Family, Carer involvement

Getting involvement right with patients and families/carers in how we respond to incidents is crucial, particularly to support improvement and transformation of the services we provide.

Duty of Candour

There will be incidents that meet the threshold for both statutory and professional duty of Candour as outlined in the Trust Duty of Candour Policy (CG605). However, a strategic aim of PSIRF is to compassionately engage and involve those affected by patient and staff safety incidents. As well as meeting our regulatory and professional requirements for Duty of Candour, we want to be open and transparent with our patients, families, carers and staff because it is the right thing to do. This is regardless of the level of harm caused by an incident.

Our patient safety team will be the main point of contact for our patients and families involved in incidents. Depending on the method of investigation used, where appropriate, patients/families will be invited to incorporate their questions into terms of reference, participate in feedback meetings, and have facilitative meetings with the patient safety teams and relevant clinicians to discuss the learning outcomes relating to the incident. It is pivotal that the voice of our patient, family/carer forms a key foundation within the investigative process. Our Patient Safety Leads will guide patients, families, carers, and support their expectations, through any investigation or learning review process.

For issues of concern that do not sit within the remit of patient safety, patients and families will be supported to utilise our PALS and Complaints services.

There are varying other forms of support that can help those affected by a patient safety incident and the safety leads will work with patients, families, and carers to signpost to their preferred source for this. The following is a best practice guide to supporting patients and families after a patient safety event, produced by Berkshire Healthcare NHS Foundation Trust, it gives advice and guidance on compassionate communication and meaningful engagement:

Compassionate Communication Meaningful Engagement (berkshirehealthcare.nhs.uk)

Staff Involvement

Those staff affected by patient safety incidents will be afforded the necessary managerial support and be given time to participate in learning responses and any supportive interventions. All Trust managers will work within our safety culture principles and utilise support systems such as TRIM (Trauma Incident Management) to ensure that there is a dedicated staff resource to support such engagement and involvement. Managers will work with the Trust staff wellbeing resources to assure psychological safety is paramount.

The Patient Safety Team will continue supporting Care Groups to ensure all incidents reviews (whether PSII or other methodology) meet PSIRF standards and to promote a cultural progression towards whole system approach and compassionate engagement of staff, patients and families.

The Trust will have in place governance arrangements to ensure that a level of objectivity is brought to all learning responses. This will mean that some learning responses (i.e. PSII) will not be led by staff who were involved in the patient safety incident itself, or by those who directly manage those staff.

A senior member of the relevant Care Group will be responsible in identifying a designated individual to lead on a learning response. The individual should have an appropriate level of seniority, expertise and influence within the Trust; should be a Band 8A or above in line with PSIRF best practice guidance. This of course will depend on the nature and complexity of the incident and response required, but it is anticipated that learning responses are led by staff at Band 8a and above where resource allows, or alternatively, a staff member who is deemed competent and capable.

Where possible a member of the Patient Safety Team should attend learning responses to support the implementation of PSIRF values and ensure ongoing support and learning of the new review methodologies being implemented. They will also ensure a degree of objectivity is brought to the group especially where the review methodology may involve staff that provided direct care to the patient.

The Patient Safety team will support learning responses wherever possible and can provide advice on cross-system and cross-divisional working where this is required.

The Trust will also utilise both internal and, if required, external subject matter experts with relevant knowledge and skills, where necessary, throughout the learning response process to provide expertise (e.g., clinical, or human factors review), consultation and advice.

8.0 Consultation Undertaken

ICB Senior Patient Safety Manager
Chief Nursing Officer
Chief Medical Officer
Deputy Chief Nursing Officer
Associate Medical Director for Patient Safety
Care Group representatives

Patient safety leads

Patient safety partners

8.1 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 Trust followed the 'mind-set' principles to underpin the processes we have put in place to allow us to implement PSIRF as set out in the supporting document (NHS England (2022), p3).

The Trust has, and will continue to, work collaboratively with Berkshire, Oxfordshire and Buckinghamshire Integrated Care Board (BOB ICB) and where applicable other Integrated Care Systems such as Frimley ICS, to ensure we have effective oversight and improvement of patient safety across our systems and to support where appropriate cross-organisational learning. This will involve participation in identified relevant forums such as Safety & Improvement Forum, regular PSIRF reviews, peer reviews and educational events.

9.0 Dissemination/Circulation/Archiving

The policy will be available on the Trust Policy Platform on Workvivo

The Trust Secretary will be responsible for archiving old versions of this document.

10.0 Implementation

This policy will be implemented in conjunction with the Patient Safety Incident Review Plan after sign off via trust and ICB processes have been met.

The policy will be reviewed in a minimum of two years, unless necessary changes are warranted prior to this. It is expected that the PSIRP as a more evolving document will require a minimum of 6 monthly reviews during the implementation phase.

Once clearance from both trust and ICB, this will be disseminated across the trust with the assistance of care groups and patient safety teams. It is expected this will be in conjunction with training materials and sessions as outlined below.

Further amendments will be subject to trust processes.

An analysis of the capacity of the patient safety team and wider safety/governance colleagues will also occur to support the plan to understand the resilience of the plan and policy and its implementation. Where there is a finite resource within the patient safety centralised team, this will be recognised and the workload and responsibilities will be balanced across corporate and care group teams accordingly.

11.0 Training

The Trust has implemented a patient safety training package to ensure that all staff are aware of their responsibilities in reporting and responding to patient safety incidents and to comply with the NHS England Health Education England Patient Safety Training Syllabus as follows:

Patient safety syllabus level 1: Essentials for patient safety	eLearning	• Listening to patients and raising concerns • The systems approach to safety: improving the way we work, rather than the performance of individual members of staff • Avoiding inappropriate blame when things don't go well • Creating a just culture that prioritises safety and is open to learning about risk and safety
Patient safety syllabus level 2: Access to practice	eLearning	• Introduction to systems thinking and risk expertise • Human factors • Safety culture

Both of the above programmes are available via the Trust Learning Matters platform, this is currently not mandatory but should be for future consideration.

- Level 1: To be undertaken by all Trust staff, clinical and non-clinical, on induction to the Trust.
- Level 2: To be undertaken by all clinical staff at AFC Band 7 or above, with **potential** to support or lead patient and staff safety incident management and learning responses.

N.B. It is anticipated that when Level 3 and Level 4 programmes are launched, patient safety specialist(s) will undertake this training.

Learning and engagement response roles: Training and Competence

The recommendation from NHS England patient safety response standards (2022) is that staff leading learning and engagement responses should undertake specific training in addition to Level 1 and Level 2, this is outlined below:

Topic	Minimum duration	Content	Learning response leads	Engagement leads	Those in PSIRF oversight roles
Systems approach to learning from patient safety incidents	2 days/12 hours	• Introduction to complex systems, systems thinking and human factors • Learning response methods: including interviewing and asking questions, capturing work as done, data synthesis, report writing, debriefs and after-action reviews • Safety action development, measurement, and monitoring	✓		✓
Oversight of learning from patient safety incidents	1 day/6 hours	• NHS PSIRF and associated documents • Effective oversight and supporting processes • Maintaining an open, transparent and improvement focused culture • PSII commissioning and planning			✓
Involving those affected by patient safety incidents in the learning process	1 day/6 hours	• Duty of Candour • Just culture • Being open and apologising • Effective communication • Effective involvement • Sharing findings • Signposting and support		✓	✓

Our aspiration is that staff leading learning and engagement responses will have undertaken the programmes outlined above, and this will be an ongoing exercise as we identify these staff and training is accessed. Our interim plan will be to ensure that those leading learning and engagement responses will be experienced in patient and staff incident management under the Serious Incident Framework, and also deemed competent in the following areas:

Learning response leads:

- Apply human factors and systems thinking principles to gather qualitative and quantitative information from a wide range of sources.
- Summarise and present complex information in a clear and logical manner and in report form.
- Manage conflicting information from different internal and external sources.

- Communicate highly complex matters and in difficult situations.

Engagement leads:

- Communicate and engage with patients, families, staff, and external agencies in a positive and compassionate way.
- Listen and hear the distress of others in a measured and supportive way.
- Maintain clear records of information gathered and contact those affected.
- Identify key risks and issues that may affect the involvement of patients, staff, and families, including any measures needed to reduce inequalities of access to participation.
- Recognise when those affected by patient safety incidents require onward signposting or referral to support services.

Support for staff leading learning and engagement responses will be provided by the Patient Safety Team and Care Group Leadership teams.
Records of formal training will be maintained by Learning Matters and monitored by the Patient Safety Team. To maintain expertise the Trust will undertake an annual networking event for all learning and engagement response leads led by the Patient Safety Team.
To facilitate safety specific continuous professional development (CPD), the Patient Safety Team will ensure additional suitable training can be accessed by staff, such as Making Families Count webinars.

Oversight roles: training and competence

Those with an oversight role on our Trust Board and Leadership teams (i.e. Executive leads) should have completed the appropriate modules from the national patient safety syllabus, this is:

- Level 1: Essentials of patient safety and essentials of patient safety for boards and senior leadership teams.

All those with an oversight role in relation to PSIRF, (i.e. Care Group Senior Leadership) will undertake continuous professional development in incident response skills and knowledge, and network with peers at least annually to build and maintain their expertise. This will be supported through the facilitation of internal and external training sessions.
As a Trust we expect staff with oversight roles to be competent in the following areas:

- Be inquisitive with sensitivity (that is, know how and when to ask the right questions to gain insight about patient safety improvement).
- Apply human factors and systems thinking principles.
- Obtain through conversations and assess both qualitative and quantitative information from a wide variety of sources.
- Constructively challenge the strength and feasibility of safety actions to improve underlying systems issues.
- Recognise when safety actions following a patient safety incident response do not take a system-based approach (e.g., inappropriate focus on revising policies without understanding 'work as done' or self-reflection instead of reviewing wider system influences).
- Summarise and present complex information in a clear and logical manner and in report form.

12.0 Monitoring of Compliance

Aspect of compliance or effectiveness being monitored	Monitoring method	Individual or dept. responsible for the monitoring	Frequency of the monitoring activity	Group/committee which will receive the findings/ monitoring report	Committee/ individual responsible for ensuring that the actions are completed
Accuracy of content	Review	Associate Director for Patient Safety and Risk	Yearly with an expectation that initial changes may occur preceding this during the PSIRF embedding period.	Patient safety committee	Patient safety committee
PSIRP	Review	Associate Director for Patient Safety and Risk	Minimum of 6 monthly during embedding of PSIRF	Patient safety committee	Patient safety committee

The Trust reserves the right to amend its monitoring requirements in order to meet the changing needs of the organisation.

13.0 Supporting Documentation and References

Patient Safety Incident Response Plan

Duty of Candour Policy

14.0 Equality Impact Assessment

Stage 1: Screening

Part 1: Initial Scoping
For each of the nine protected groups identified in the table below, respond to the identified questions with a Yes (Y); No (N); or Unclear (U)

	Age	Sex	Disability	Race	Gender Reassignment	Religion or Belief	Sexual Orientation	Marriage and Civil Partnership	Pregnancy and Maternity
Do different groups have different needs, experiences, issues and priorities in relation to the proposed policy/change proposal?	N	N	N	N	N	N	N	N	N
Is there potential for or evidence that the proposed policy/change will not promote equality of opportunity for all and promote good relations between different groups?	N	N	N	N	N	N	N	N	N
Is there potential for or evidence that the proposed policy will affect different population groups differently (including unintended discrimination against certain groups)?	N	N	N	N	N	N	N	N	N
Is there public concern (including media, academic, voluntary or sector specific interest) in potential discrimination against a particular population group or groups?	N	N	N	N	N	N	N	N	N

Part 2: Evidence and Feedback that has informed your analysis

Please identify below the data, information or feedback that you have drawn on to reach the conclusions above. This will be information that has enabled you to assess the actual or potential impacts in the context of the key needs to **eliminate unlawful discrimination**, **advance equality of opportunity** and **foster good relations** with respect to the characteristics protected by equality law. These sources could include:

- Equalities monitoring information of staff/service users affected by the identified provision/policy etc.
- Engagement (internal/external or both) with or feedback from relevant stakeholders e.g. staff; patient groups, commissioners, external agencies.
- Staff Survey Data; Patient Survey Data etc.
- Research or information available relative to the identified protected group.

- Project leads professional knowledge of the issues the policy/change is seeking to enact.

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 o 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 and staff safety risk from across the range of protected characteristics. Systems are already in place that complement the local risk management system (LRMS), allowing for patient details of those affected by patient safety incidents, to be drawn from healthcare records in order for them to be analysed to give insight into any apparent inequalities.

If the analysis under Part 1 has concluded that there are equality impacts or that the impacts are unclear (i.e. you responded 'Yes' or 'Unclear' in Part 1), **please move on to Part 4 of the assessment**. If no equality impacts are identified, **please move on to Part 3 below** to conclude the assessment

Part 3: Narrative
If you have concluded there are no equality impacts related to the policy/provision, please provide a brief narrative to explain why you have come to this conclusion:

Within our patient safety response toolkit, we will directly address if there are any particular features of an incident which indicate health inequalities that 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. This is already inbuilt into our investigation documentation and will be extended through all patient and staff safety and governance processes.

We will also address apparent health inequalities as part of our safety improvement work. We understand that our services provide care to one of the most diverse areas of the country, which also include significant numbers of Core20PLUS5 population cohort identified by NHS England and Improvement (2021). In establishing our plan and policy we will work to identify variations that signify potential inequalities by using our population data and our patient safety data to ensure that this is considered as part of the development process for future iterations of our patient safety incident response plan and this policy. Embedding organisational-wide focus on the issues of inequalities in accessing healthcare and health outcomes is an integral part of our improvement and transformation agenda.

Engagement of patient, families and staff, following a patient safety incident, and during and after any learning response is critical, and we will ensure that we use tools available to maximise the potential for them to be involved. The tools will include patient advocates, easy read, translation

and interpretation services and other methods as appropriate to meet the needs of those affected

The Trust's commitment to fostering a culture of psychological safety and continuous improvement has already been outlined. Further to this, the Trust has affirmed that it endorses a zero acceptance of racism, discrimination, and unacceptable behaviours, including violence and aggression from and toward our workforce and our patients/service users, carers and families. An element of the 'Healthy Work and Workplace' programme within the Trust's new People Strategy 2023-28 outlines how these instances can be reduced, and this is in addition to targeted actions that have been established in line with the NHS Violence, Prevention and Reduction Standards, which are aligned to the PSIRF principles.

If no equality impacts have been identified, this concludes the equality impact assessment. Please complete the declaration below:

Based on the information set out above I have decided that a full equality impact assessment is (please delete as appropriate):

Necessary / Not necessary.

This concludes the Equality Impact Assessment.

Appendix 1: Learning Response Decision Making Tool

Learning Response Decision Making Tool

Refer to Trust Patient Safety			Learning Response	Incident closure
1. Incident meets national priority for escalation as PSII	**2. Incident meets local priority for escalation as PSII**	**3. Incident may meet criteria for ad-hoc PSII**	**4. Incident meets PSR criteria**	**5. Incident may be approved with local response**
☒ ***National*** priority to be referred for PSII/review by **another team**, please specify: e.g. 'for referral to LA Safeguarding' ☐ ***National*** priority incident requiring local PSII, please specify: e.g. 'Never Event'	☒ ***Local*** priority incident requiring local PSII, please specify: e.g. 'Deterioration in health of an inpatient requiring admission to a general hospital'	☐ ***Emergent*** patient safety risk or incident with learning and improvement potential possibly requiring ad-hoc local PSII, please specify e.g. 'xx incident - contributory factors not well understood, minimal improvement activity underway' or 'unexpected incident not accounted or in PSIRP'	☐ Learning and improvement to be captured by a learning response method Select toolkit item to be used: ☐ **Swarm**, specify team/s to be involved: ☐ **After Action Review**, specify teams/s to be involved: ☐ **Thematic review**, please specify scope:	☒ Incident not for further review, give rationale: e.g. incident type and contributory factors well understood and reflected in xx improvement work

Incident for closure Please capture any relevant learning and refer to relevant improvement plan holder	Immediate and short-term actions / learning - Medium to long term actions / learning
Incident meets Patient Safety/Learning Response criteria	Please suggest any key lines of enquiry to be added to the toolkit item selected:
Incident meets national priority for escalation as PSII (1)	Please indicate other agency to be referred to and whether this has been completed – enter details in external links section
Incident meets national priority for	Please consider if specific notification outside of organisation is required and whether this has been completed – enter details in external links section

escalation as PSII (2)	
Incident meets national priority for escalation as PSII (2)	Please consider if specific notification outside of organisation is required and whether this has been completed – enter details in external links section
Incident meets local priority for escalation as PSII (3)	
Incident may meet local priority for escalation as PSII (4)	
Designated family liaison/duty of candour person identified for duration of incident investigation:	

Internal links

Internally reportable to another care group?	Yes / No	**Internally reported to:**	
Patient Safety team alerted	Yes / No		
Other Internal Links: e.g. TV team, Falls, H&S, IG:			
Necessity to remove/ restrict staff from normal tasks and details? Workforce aware?			

External links

Externally reportable?	Yes / No	**Externally reported to:**	
Media Interest?	Yes / No	**Comms team informed?**	Yes / No
Other External Links: e.g. ICB, multiagency, Police and/or HSE, Coroners Inquest, CQC involvement			

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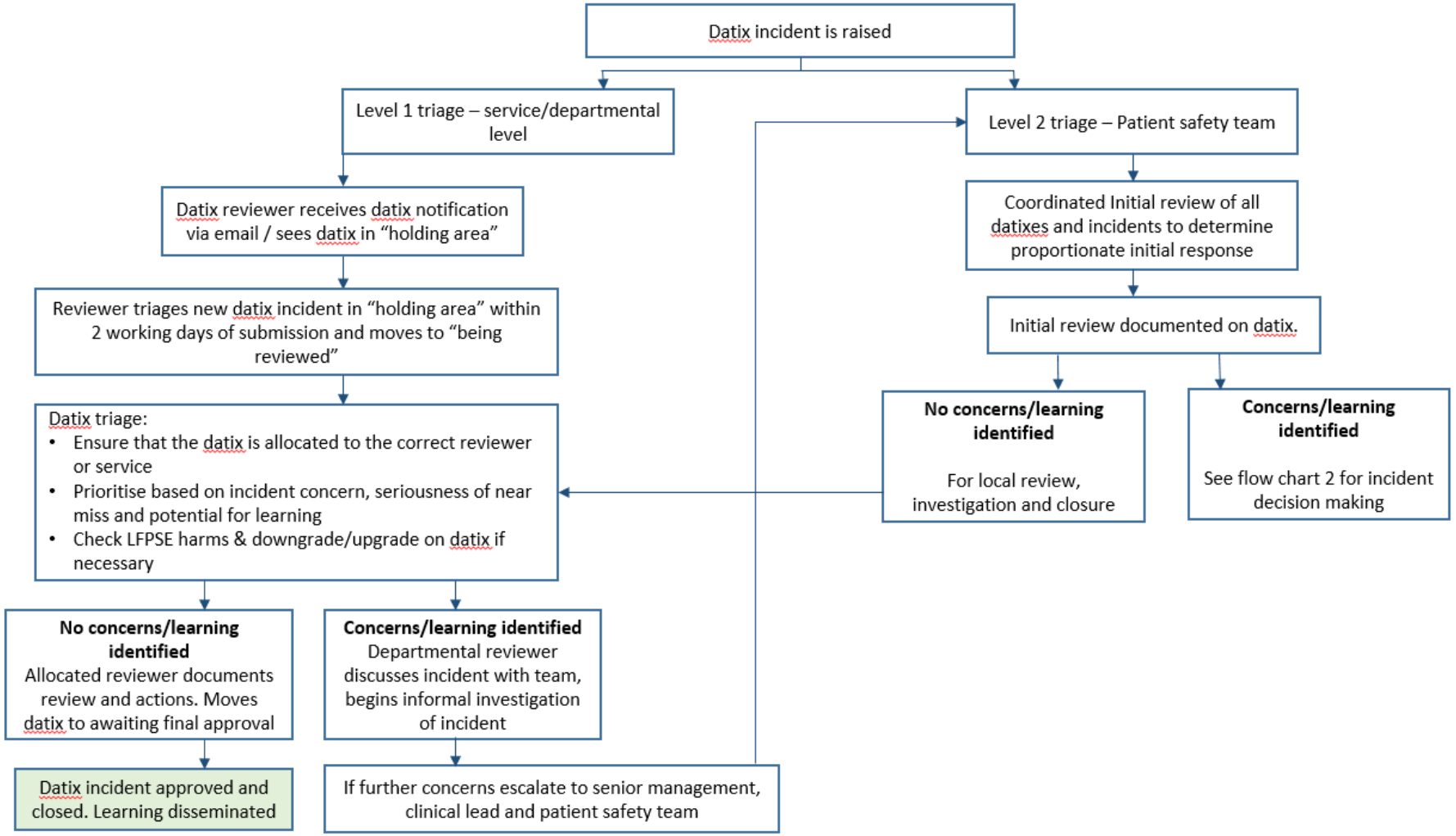
Appendix 2: PSIRF Suggested Flow Document

Patient Safety Incident process flowchart

Flow chart 1 – Datix triage and safety netting



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Patient Safety Incident process flowchart

Flow chart 2 – Incident decision making process- (to determine the learning response)

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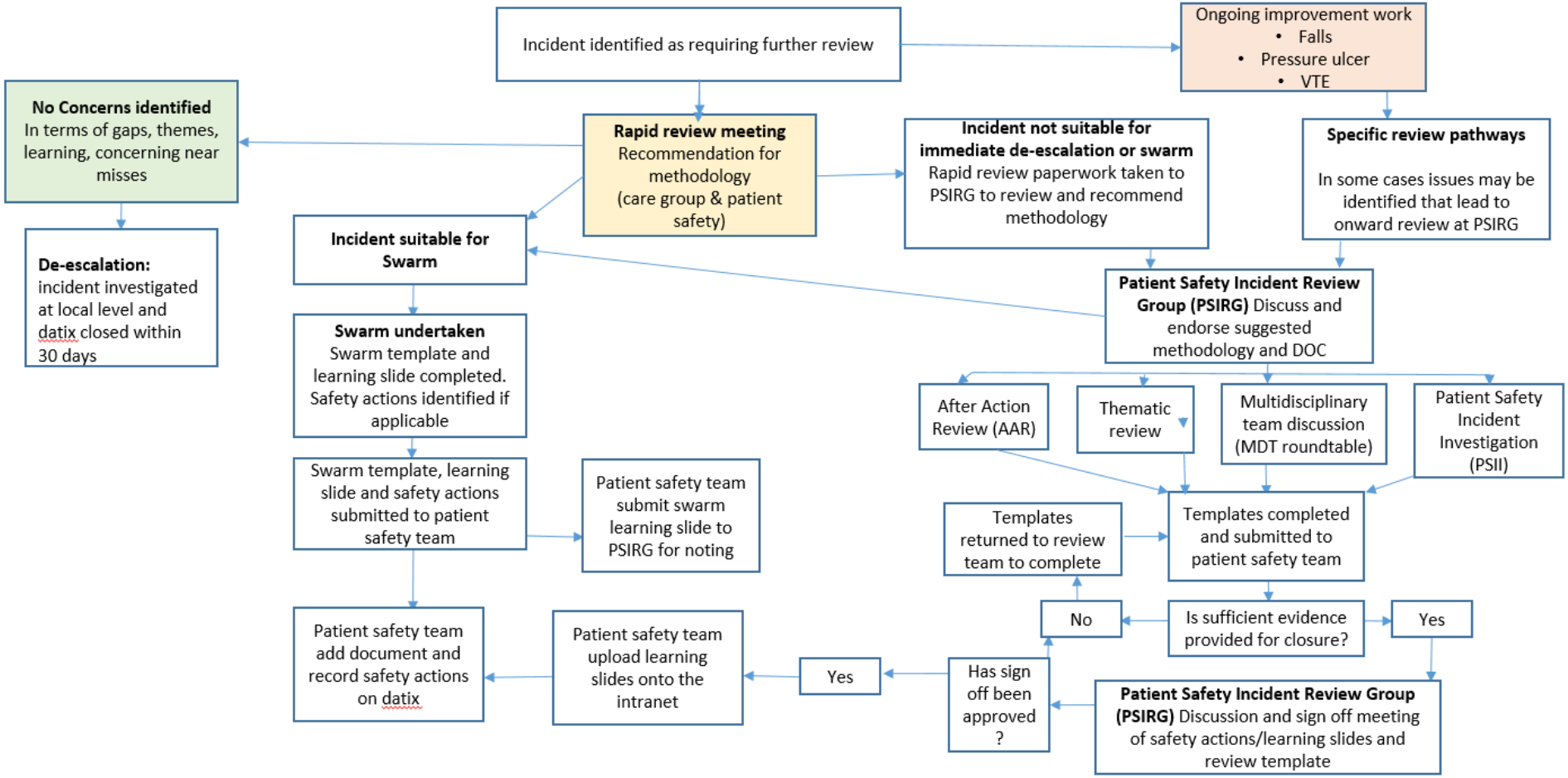

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Appendix 3: Swarm Huddle Learning Response Template

SWARM Huddle Template

Datix Incident Reference:	Incident reference number	**Incident Date:**	dd/mm/yyyy
Short Incident Description:			
Discussed with patient safety team yes/no		**Swarm Date and Time**	dd/mm/yyyy 00:00
Patient Safety Lead			
Swarm facilitator name:		**Facilitator role:**	
Duty of Candour (DOC) status:			
Attendees:			

Specific issue to be addressed by the Swarm:	

What is it: *A meeting to explore an incident in a non-punitive way and deliver learning. It is a facilitated discussion on an incident or event to analyse what happened, how it happened and decide what needs to be done immediately to reduce risk. It enables understanding and expectations of all involved and allows for learning to be captured and shared more widely.*
Safe space, invitees only (those involved in incident, agreed by the Division/Patient Safety team).

When to use it: *Swarms can be used soon after any activity or event (within a working week ideally) where care has not gone as planned - this can prevent key information being lost. Swarms can reduce blame and rumours about an incident by focussing on learning and improvement and an understanding of 'work as done'.*

Introduction and Create a safe and 'brave space'

Facilitator to introduce all participants and their role in the Swarm

Explore exactly what happened and why	
Replay the events that led to the Swarm	
Explore what happened and why, use the systems work prompts	
Identify where else in the organisation the learning may be relevant	
Are there any other services or Division where this learning needs to be shared?	
How you are going to share the learning more widely and who will take responsibility for this?	
Safety actions to be carried forward	
System Improvement Plan/Immediate Safety Actions to be taken with designated lead	
Does this contribute learning or confirm actions in any overarching safety improvement plan	Ensure details shared with patient safety lead and DoN
Date reviewed and approved at divisional clinical governance	
Actions/Next Steps agreed	

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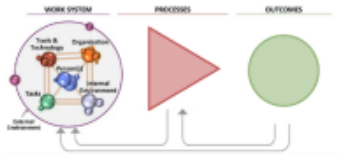
Swarm work system prompts



Tools & Technology
Equipment/tools/IT:
- design (including how information is presented)
- availability appropriateness
- reliability
- positioning
- maintenance

Alarms and/or alerts
Automated tasks
Accessibility and usability of manuals, procedures, supports

Organisation
- Patient pathways
- Information flow (how information is communicated)
- Communications workload
- How new information is flagged and where it is held
- Leadership and supervision
- Work scheduling and allocation
- Staffing levels and resourcing
- Safety/organisational culture
- Change management

Tasks
- Task demands (ie competing tasks)
- Task complexity
- Workload
- Time pressures
- Task repetition and monotony
- Task re-prioritisation or reorganisation

Person
- Patient mix
- The team (eg clinical, admin, domestic)
- Team familiarity with processes and pathways
- Clarity of roles and responsibilities
- Training and education
- Team dynamics
- Personal factors (eg stress, morale, tiredness)

Internal environment
- Physical workspace design
- Layout of the environment
- Workspace appropriateness for the tasks
- Distractions and their impact
- Interruptions and their impact
- Ambient environment (eg lighting, noise, air quality)

External environment
- Relevant national targets
- Policy and regulatory demands
- Accreditation standards
- Political decision making
- Global events

Desired Outcomes

System Performance:

Human Wellbeing:

Appreciative inquiry question:

The SEIPS model sets out desired outcomes– what are you aiming to achieve when you deliver patient care?

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Appendix 4: After Action Review Learning Response Template

After Action Review (AAR) Template

Incident Reference:	Datix number
Incident Description:	Please provide a brief description of the incident and specify level of harm to patient
Incident Date:	
AAR date and time:	
AAR facilitator:	
Attendees:	
Glossary of Abbreviations/Acronyms within text:	Please supply a key/list of any used

Rationale and Specific issues to be addressed by the AAR (From Terms of Reference):	This will be outlined in the decision making tool.

What is it: *A structured, facilitated discussion on an incident or event to identify a group's strengths, weaknesses and areas for improvement by understanding the expectations and perspectives of all those involved and capturing learning to share more*

widely. Safe space, invitees only. **When to use it:** *AARs can be used after any activity or event that has been particularly successful or unsuccessful. It is also often used at the end of a project to help populate a lessons learnt log. It is important to disseminate learning widely so that good practice can be shared and others can learn from mistakes.*	
Creating a common understanding of the experience under review:	
What happened that we can learn from?	
What did we set out to do?	
What actually happened?	
Why were there differences?	
What went well? Why?	
Reflecting on the successes and failures:	
What could have gone better? Why?	
What would you do differently next time?	
What learning has been identified?	
How will the learning be shared within your service?	
Agree as a group on any actions that need to be taken	

How you are going to share the learning more widely?	
System Improvement Plan/Immediate Safety Actions	

Date reviewed and approved at Rapid Review Meeting:	
Actions/Next Steps agreed:	

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Appendix 5: Multidisciplinary Team Review Template

Multidisciplinary Team (MDT) Roundtable Review

Top Tips:

When to use:

To identify learning from multiple patient safety incidents (including when multiple patients were harmed or where there are similar types of incidents) when it is more difficult to collect staff recollections of events either because of the passage of time or staff availability.

Purpose:

To gain insight into the real world in which care is delivered. To agree, through open discussion, the key contributory factors and system gaps.

SEIPS is a framework for understanding outcomes within complex socio-technical systems. It describes how the system can influence processes, which in turn shapes outcomes.

The system consists of six broad elements: external environment, organisation, internal environment, tools and technology, tasks and person(s).

Examples:

- delayed recognition of deteriorating patients
- medication errors
- admission or discharge-related safety events
- safety issues relating to supported/therapeutic leave from a mental health unit
- Burns or other injuries sustained by residents in a care home.

What is work as done?

By ‘work as done’ we mean how care is delivered in the real world, not how it is envisaged in policies and procedures (work as prescribed) or recounted in a walk through or a talk through (work as described).

You can find more information on how to carry out walk-through’s in the brief guide to walk through analysis in the PSIRF learning response toolkit.

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Multidisciplinary Team (MDT) Roundtable Review

Theme which has initiated this Review	

Incident Details included in this Review			
Datix WEB Number	**Care Group**	**Directorate**	**Ward/Department**

Quality Assured in the Division by:		**Designation(s):**	
Divisional Approval by:		**Date MDT Approved by the Division:**	
Attendance at Weekly Review and Approval Panel		**Date MDT document Approved at Weekly Review and Approval Panel:**	

Document Control		
Version Number	**Name of Person Updating**	**Date of Version**
1		
2		
3		
4		

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PART 1: Patient Safety Event

Questions from the patients/families: *Ensure that you are aware which patient/family asked which questions.*

1	
2	
3	
4	
5	
6	

Date of MDT Review:	

Meeting chaired by:		**Job Role:**	
Learning Response Lead Name:		**Job Role:** *Likely to be a member of the Divisional team*	
Engagement lead name: *May be the same person as the Learning Response Lead*		**Job Role:**	

Who is required at this review?
Who has insight - who works in the care setting or pathway (clinical and non-clinical)

MDT roundtable *reviews are most useful when a wide range of stakeholders share their perspective on 'work as done'*

Name	**Job Role:**

Note taker:
It is suggested that the meeting is recorded for the purpose of preparing notes to document the key information (this could be a recorded MS Teams meeting

PART 2: Preparatory work to scope the Review:

Review Of Notes:

Observational Work:

You might find that a process map is useful.
"Go and see" to understand and ask about the issue, be respectful, this is not about blame but understanding what happened for the purpose of problem solving.

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PART 3: At the Multidisciplinary Team round table review meeting:

Create safe space at the outset

Introduce everyone.
State what prompted the MDT roundtable review and how its outputs will be used.
Co-create ground rules: "We want to hear everyone's insights in today's workshop. How might we best work as a team to ensure everyone's perspective is shared?"
Share any concerns they have around describing 'work as done' and answer any questions or concerns openly and honestly.
Remind participants that you will be keeping a record the insights shared.

Use the SEIPS work system explorer to gain insight into 'work as done'.

What is the desired outcome(s)?

For system performance and human wellbeing

Use the headings below, guided by the prompts in the SEIPS model (on the final page of this document), to explore how the system influences processes

Area for Improvement		**Yes/ No**	**Identify where improvement is needed**
Work system	People		*How **can individual or team characteristics** be modified or changed to reduce risk or improve performance?*
	Tasks		*How can the **task or activity** be modified or redesigned to reduce risk or improve performance?*
	Tools And technology		*How can **tools, equipment, or technology** be modified or redesigned to reduce risk or improve performance?*
	Internal Environment		*How can the **physical environment** be modified or redesigned to reduce risk or improve performance?*
	Organisation		*How can **organisational factors** be modified or redesigned to reduce risk or improve performance?*
	External Environment		*How can **regulatory or societal factors** be modified or redesigned to reduce risk or improve performance?*

Wrap up, thank, and describe the next steps

At the end of the MDT roundtable review, summarise your understanding of the key insights identified about work as done. Clearly outline what the next steps will be, including:
How you plan to collate the outcomes of the MDT roundtable review
How you will keep participants updated after the MDT roundtable review

Remember to thank participants for their time.

PART 4: What do I need to do after the MDT roundtable review?

Triangulating of information and collating insights about work as done from the MDT review

You may or may not decide to gather further information relevant to the systems gaps and contributory factors identified in the review. This may involve hosting another MDT roundtable review workshop with different participants or collecting further information relevant to the systems gaps and contributory factors identified.

How do I use the MDT roundtable review findings to support safety improvement work?

Do the findings link in with Improving Together?

Ensuring what you have learnt about 'work as done' is fed back and integrated into your organisation's patient safety improvement work.
Ensure details are added into the Safety Actions within this document.

Share insights into systems gaps and contributory factors identified in the MDT roundtable review with those who have patient safety improvement roles. Who these stakeholders are will depend on the focus of the review and its findings. They may include:
Members of the MDT roundtable review who can influence safety improvement work locally.
Your organisation's patient safety improvement leads.
Stakeholders in the ICS who have a role in resolving systems gaps relating to commissioning decisions and pan-organisational problems.
External bodies, including equipment manufacturers, regulators, NHS England, MHRA, HSSIB, MNSI and others who have a role in national safety improvement work.

For more detail and an example of using this approach can be found at: https://www.england.nhs.uk/wp-content/uploads/2022/08/B1465-MDT-review-v1_FINAL.pdf

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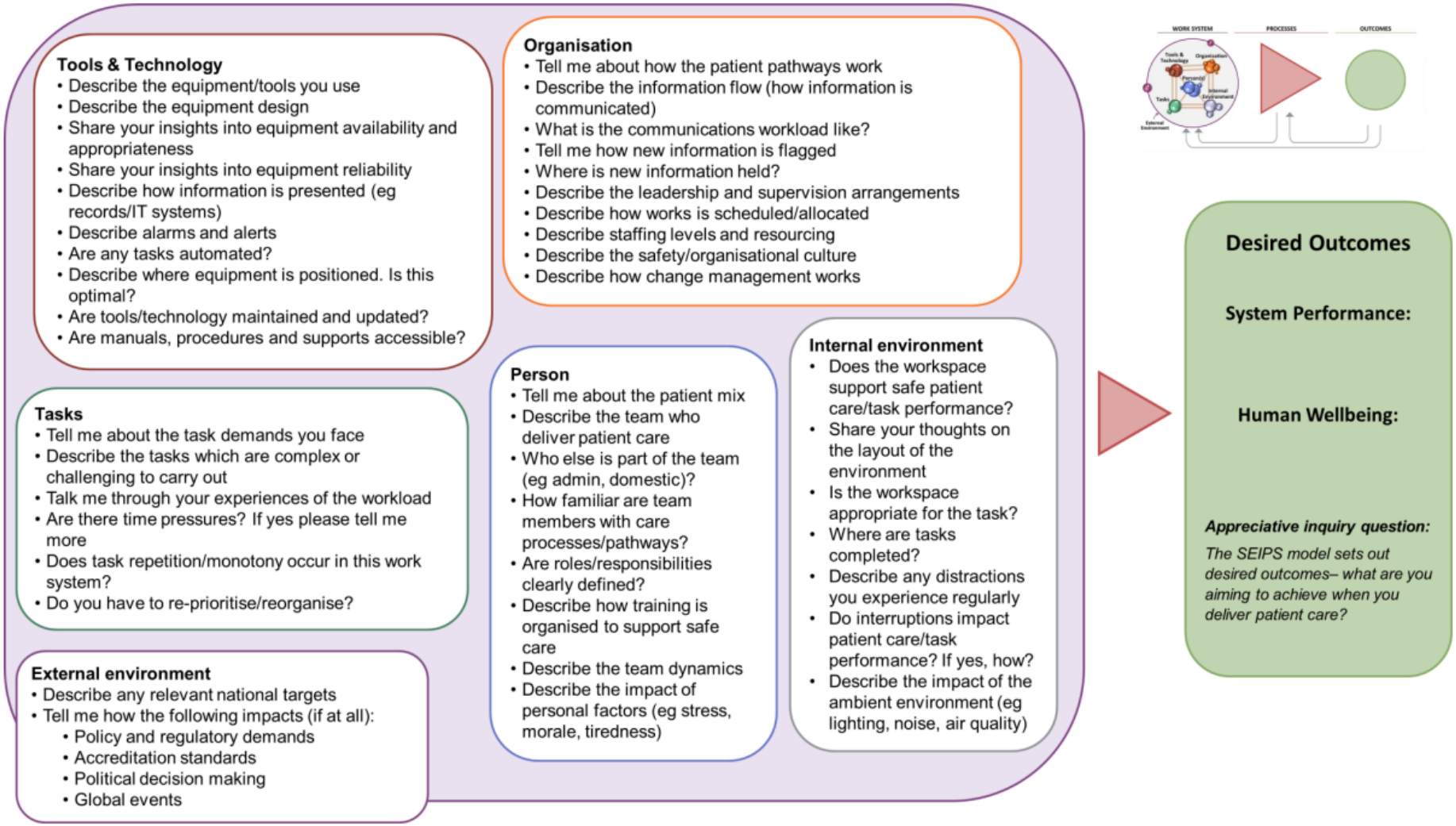
Define Safety Actions
Develop SMART safety actions from the work system improvements identified.
(SMART: - **S – specific, M - measurable, A - achievable, R - realistic, T – Timely**)

Area for improvement: [e.g. r*eview of test results*]

	Safety action description *(SMART)*	**Safety action owner *(role, team directorate)***	**Target date for implementation**	**Date Implemented**	**Tool/measure**	**Measurement frequency *(e.g. daily, monthly)***	**Responsibility for monitoring/ oversight *(E.g. specific group/ individual, etc.)***	**Planned review date *(e.g. annually)***
1.								
2.								
…								

The SEIPS work system Explorer:



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Quality Assurance Checklist to be used by Approver within the Division:

	Area of Review	Rating of Evidence			Comments to clarify rating - may be things that can be improved or content you thought worked well
		Good	Some	Little	
1	**People affected by incidents are meaningfully engaged and involved:** The report demonstrates evidence that all those affected by the incident such as staff, patients, families and carers have been actively listened to and emotionally supported where required.				*(i.e. interviews and perspectives of those affected are included in the report)*
2	**The systems approach is applied:** The report demonstrates consideration of system-based performance influencing factors (e.g. task complexity, technology, workplace design, information transfer, clinical condition of the patient, stress, fatigue, culture, leadership, policy/regulation) and how these interacted to contribute to the incident.				
3	**'Human error' is considered as a symptom of a system problem:** Human error is not concluded as the cause. Instead, multiple contributory factors which influence the event are explored.				
4	**Blame language is avoided:** Language does not directly, or indirectly infer blame of individuals or teams.				*(i.e. the nurse failed to follow policy; the doctor lost situational awareness)*
5	**Local rationality is considered:** The report clearly explains why the decisions and actions taken by individuals involved felt right at the time.				*(i.e. the situation and context faced by those individuals is explored and described)*
6	**Contrary to fact reasoning is avoided:** The report focuses on what happened and understanding why and NOT what people, departments or organisations could or should have done during or before the incident.				
7	**Safety actions are effective:** Developed collaboratively with stakeholders with consideration of wider organisation priorities and improvement work. Focus on system elements (IT, equipment, pathways, processes) not individuals. Are specific, robust, and actionable (i.e., they don't add 'safety clutter'. Are accompanied by a plan to monitor progress over time. Are demonstrably linked to the evidence and findings in the report.				
8	**The report is clear and easy to read:** It is concise and written in plain English.				*(i.e. no unexplained acronyms)*

Appendix 6: PSII Template

Patient safety incident investigation (PSII) report

On completion of your final report, please ensure you have deleted all the blue information boxes and green text.

Notes on the PSII template

This national template is designed to improve the recording and standardisation of PSII reports and facilitate national collection of findings for learning purposes. This format will continue to be evaluated and developed by the National Patient Safety Team.

General writing tips

A PSII report must be accessible to a wide audience and make sense when read on its own. The report should:

- use clear and simple everyday English whenever possible
- explain or avoid technical language
- use lists where appropriate
- Keep sentences short.

Datix Incident ID number:	
Date incident occurred:	
Report approved date:	
Approved by:	

Distribution list

List who will receive the final draft and the final report (e.g. patients/relatives/staff involved¸ board). Remove names prior to distribution.

Name	Position

About patient safety incident investigations

Patient safety incident investigations (PSIIs) are undertaken to identify new opportunities for learning and improvement. PSIIs focus on improving healthcare systems; they do not look to blame individuals. Other organisations and investigation types consider issues such as criminality, culpability or cause of death. Including blame or trying to determine whether an incident was preventable within an investigation designed for learning can lead to a culture of fear, resulting in missed opportunities for improvement.

The key aim of a PSII is to provide a clear explanation of how an organisation's systems and processes contributed to a patient safety incident. Recognising that mistakes are human, PSIIs examine 'system factors' such as the tools, technologies, environments, tasks and work processes involved. Findings from a PSII are then used to identify actions that will lead to improvements in the safety of the care patients receive.

PSIIs begin as soon as possible after the incident and are normally completed within three months. This timeframe may be extended with the agreement of those affected, including patients, families, carers and staff.

If a PSII finds significant risks that require immediate action to improve patient safety, this action will be taken as soon as possible. Some safety actions for system improvement may not follow until later, according to a safety improvement plan that is based on the findings from several investigations or other learning responses.

The investigation team follow the Duty of Candour and the Engaging and involving patients, families and staff after a patient safety guidance in their collaboration with those affected, to help them identify what happened and how this resulted in a patient safety incident. Investigators encourage human resources teams to follow the Just Culture guide in the minority of cases when staff may be referred to them.

PSIIs are led by a senior lead investigator who is trained to conduct investigations for learning. The investigators follow the guidance set out in the Patient Safety Incident Response Framework and in the national patient safety incident response standards.

A note of acknowledgement

Notes on writing a note of acknowledgement

In this brief section you should thank the patient whose experience is documented in the report along with contributions from their family and others (including carers, etc.) who gave time and shared their thoughts.

You could consider referring to the patient by name or as ‘the patient’ according to their wishes.

Also thank the healthcare staff who engaged with the investigation for their openness and willingness to support improvements.

Executive summary

Notes on writing the executive summary

To be completed **after the main report has been written.**

Incident overview

Notes on writing the incident overview for the executive summary

Add a brief, plain English description of the incident here.

Summary of key findings

Notes on writing the summary of key findings for the executive summary

Add a brief overview of the main findings here (potentially in bullet point form).

Summary of areas for improvement and safety actions

Notes on writing about areas for improvement and safety actions for the executive summary

Add a bullet point list of the areas for improvement highlighted by the investigation and list any safety actions. Note whether the area for improvement will be addressed by development of a safety improvement plan.

Some actions to address identified areas for improvement may already have been designed in existing an organisational safety improvement plan. Note that here.

Areas for improvement and safety actions must be written to stand alone, in plain English and without abbreviations.

Refer to the Safety action development guide for further details on how to write safety actions.

NB: The term ‘lesson learned’ is no longer recommended for use in PSIIs.

Contents

To update this contents table, click on the body of the table; select ‘update field’; and then ‘update page numbers only’; and then click ‘ok’.

Background and context

Notes on writing about background and context

The purpose of this section, where appropriate, is to provide a short, plain English explanation of the subject under investigation – in essence, essential pre-reading to assist understanding of the incident. It might be a description of a pulmonary embolism, aortic dissection, cognitive behavioural therapy, NEWS, etc.

It may also be worth using this section to summarise any key national standards or local policies/guidelines that are central to the investigation.

Description of the patient safety incident

Notes on writing a description of the event

The purpose of this section is to describe the patient safety incident. It should not include any analysis of the incident or findings – these come later.

Think about how best to structure the information – e.g. by day or by contact with different services on the care pathway.

It should be written in neutral language, e.g. ‘XX asked YY’ not ‘YY did not listen to XX’. Avoid language such as ‘failure’, ‘delay’ and ‘lapse’ that can prompt blame.

If the patient or family/carer has agreed, you could personalise the title of this section to ‘[NAME]’s story/experience’.

Investigation approach

Investigation team

Role	Initials	Job title	Dept/directorate and organisation
Investigation commissioner/convenor:			
Investigation lead:			

Summary of investigation process

Notes on writing about the investigation process

If useful, you should include a short paragraph outlining the investigation process:

- how the incident was reported (e.g. via trust reporting system)
- how agreement was reached to investigate (e.g. review of patient safety incident response plan, panel review, including titles of panel members)
- What happened when the investigation was complete (e.g. final report approved by whom)?
- How actions will be monitored.

Terms or reference

Notes on writing about scope

In this section you should describe any agreed boundaries (that is, what is in and out of scope) for the investigation. For example, you might want to note:

- the aspects of care to be covered by the investigation
- questions raised by the those affected that will be addressed by the investigation

If those affected by the patient safety incident (patients, families, carers and staff) agree, they should be involved in setting the terms of reference as described in the Engaging and involving patients, families and staff after a patient safety incident guidance.

A template is available in the learning response toolkit to help develop terms of reference.

Information gathering

Notes on writing about information gathering

The purpose of this section is to provide a short overview of your investigation approach. You should include a brief overview of your methods including:

- Investigation framework and any analysis methods used. Remember to keep jargon to a minimum (e.g. the investigation considered how factors such as the environment, equipment, tasks and policies influenced the decisions and actions of staff)
- interviews with key participants (including the patient/family/carer)
- observations of work as done
- documentation reviews, e.g. medical records, staff rosters, guidelines, SOPs
- Any other methods.

Recorded reflections, e.g. those used for learning portfolios, revalidation or continuing professional development purposes, are **not suitable** sources of evidence for a systems-focused PSII.

Statements are not recommended. Interviews and other information gathering approaches are preferred.

Findings

Notes on writing your findings

The purpose of this section is to summarise your analysis of the information you have gathered and to state the findings you have drawn from that analysis.

You may choose to include diagrams and/or tables to communicate your analytical reasoning and findings.

Do not re-tell the story in the description of the patient safety incident. This section is about the 'how' the incident happened, not the 'what' and 'when'.

Start with an introductory paragraph that describes the purpose of the section and structure you are going to use.

For your findings to have impact you will need to communicate them in a clear and logical way. Before you start, think about how best to structure the section, then make a plan.

You may find sub-headings useful. The structure you choose will depend on your investigation, but you could organise the information as follows:

- By the themes you have identified during the investigation – in which case put your strongest theme first
- Following the framework or the analytical method you used
- In chronological order corresponding to the care pathway described in the reference event, e.g. community care, ambulance service, acute care (taking care not to repeat the story of the reference event)
- In order of the main decision points during the incident.

Use clear, direct language, e.g. 'The investigation found…'

If the section is long and contains multiple sub-sections, consider adding a summary of key points at the end of each sub-section.

Technical terms should be kept to an absolute minimum. If they are required, you should explain them in the text (glossaries should be avoided).

Include your defined areas for improvement and safety actions (where appropriate) in the relevant places in this section.

Areas for improvement that describe broader systems issues related to the wider organisation context are best addressed in a safety improvement plan. You should describe what the next stages are with regards to developing a safety improvement plan that will include meaningful actions for system improvement.

Points where care/ practice had an important positive impact and may provide valuable learning opportunities.

Summary of findings, areas for improvement and safety actions

Notes on writing the final summary

The purpose of this section is to bring together the main findings of the investigation.

Areas for improvement and associated safety actions (if applicable) should be listed using the table provided (also available in Appendix B of the safety action development guide).

If no actions are identified the safety action summary table is not required. Instead you should describe how the areas for improvement will be addressed (e.g. refer to other ongoing improvement work, development of a safety improvement plan)

Safety action summary table

Area for improvement: [e.g. r*eview of test results*]								
	Safety action description *(SMART)*	**Safety action owner** *(role, team directorate)*	**Target date for implementation**	**Date Implemented**	**Tool/measure**	**Measurement frequency** *(e.g. daily, monthly)*	**Responsibility for monitoring/ oversight** *(e.g. specific group/ individual, etc)*	**Planned review date** *(e.g. annually)*
1.								
2.								
…								

Area for Improvement: [e.g. *nurse-to-nurse handover*]								
	Safety action description *(SMART)*	**Safety action owner** *(role, team directorate)*	**Target date for implementation**	**Date Implemented**	**Tool/measure**	**Measurement frequency** *(e.g. daily, monthly)*	**Responsibility for monitoring/ oversight** *(e.g. specific group/ individual, etc)*	**Planned review date** *(e.g. annually)*
1.								
…								

Appendices

Notes on appendices

Include any necessary additional details such as explanatory text, tables, diagrams, etc (Delete this section if there are none).

Timeline of events should be kept in here.

Date	Time	Events	Comments
		 Obtain Careplan information from a (	

References

Notes on references

Include references to national and local policy/procedure/guidance, and other data sources as required.

Appendix 7: Learning Response Review and Improvement Tool

Learning Response Review and Improvement Tool

Report details:	**ID**:	**Title**:

Development of this tool was informed by a research study which identified 'traps to avoid' in safety investigations and report writing. The tool was originally developed by NHS Scotland. It has been further refined in collaboration with the Health Services Safety Investigations Body (previously the Healthcare Safety Investigation Branch) and NHS England after being piloted in approximately 20 NHS trusts and healthcare organisations in England. The content validity of the tool is currently being assessed.

How to use this tool	The tool is intended to be used by: **1** Those writing learning response reports following a patient safety incident or complaint, to inform the development of the written report. **2** Peer reviewers of written reports to provide constructive feedback on the quality of reports and to learn from the approach of others.

Area of review (Descriptor)		**Rating scale** (Please insert 'X' in the applicable box)			**Comments/examples of text quotes** Add comments to clarify your ratings, this may be things that can be improved or content that you thought worked well and should be used in other reports
1	**People affected by incidents are meaningfully engaged and involved** The report demonstrates evidence that all those affected by the incident such as staff, patients, families and carers have been actively listened to and emotionally supported where required (i.e. interviews and perspectives of those affected are included in the report).	Good evidence ☐	Some evidence ☐	Little evidence ☐	
2	**The systems approach is applied** The report demonstrates consideration of system-based performance influencing factors (e.g. task complexity, technology, work procedures, workplace design, information transfer, clinical condition of patient, stress, fatigue, culture, leadership/management, policy/regulation) and how these interacted to contribute to the incident in question.	Good evidence ☐	Some evidence ☐	Little evidence ☐	
3	**'Human Error' is considered as a symptom of a system problem** 'Human error' or similar (e.g. nurse error, medical error, loss of situation awareness)	Good evidence	Some evidence	Little evidence	

	is not concluded to be the 'cause' of the incident. Instead, multiple contributory factors which influenced the event are explored.	☐	☐	☐	
4	**Blame language is avoided** Language does NOT directly or indirectly infer blame of individuals, teams, departments, or organisations and/or focus on human failure (i.e. the nurse failed to follow policy; the doctor lost situation awareness).	Good evidence ☐	Some evidence ☐	Little evidence ☐	
5	**Local rationality is considered** The report clearly explains why the decisions and actions taken by individuals involved felt right at the time (i.e. the situation and context faced by those individuals is explored and described).	Good evidence ☐	Some evidence ☐	Little evidence ☐	
6	**Counterfactual reasoning is avoided** The report focuses on what happened and understanding why and NOT what people, departments or organisations 'could' or 'should' have done during or before the incident.	Good evidence ☐	Some evidence ☐	Little evidence ☐	
7	**Safety actions/recommendations are effective** Safety actions/recommendations proposed:	Good evidence ☐	Some evidence ☐	Little evidence ☐	

	• have been developed collaboratively with relevant staff/stakeholders and with consideration of wider organisation priorities and improvement work • focus on system elements (IT, equipment, care processes/pathways) not individuals • are specific, robust and actionable i.e. they don't add to 'safety clutter' • are accompanied by a plan to monitor progress over time • are demonstrably linked to the evidence and findings in the report.				
8	**The written report is clear, easy to read and anonymised** The report is concise, written in plain English, uses inclusive language and anonymised i.e. it is written to 'inform rather than impress'.	Good evidence ☐	Some evidence ☐	Little evidence ☐	
9	**General comments** Is there anything else that can be improved or content that you thought worked well and should be used in other reports?				

Appendix 8: Lessons Learnt Slide

Appendix 9: PSII Draft ToRs

Patient Safety Incident Investigation Panel
Terms of Reference

1. **Purpose:**

The purpose of this incident investigation panel is to coordinate and investigate the Never Event incident that has occurred within **********. The meeting is to ensure that the investigation is underpinned by a clear term of reference, taking into consideration any findings from internal review, recommendations from the panels review and the patients/family's concerns/questions.

2. **Duties:**

Framework: To ensure that Royal Berkshire Hospitals NHS Foundation Trust develop systematic, auditable processes to promote a culture of safety, accountability and continual quality improvement (including reporting, learning and sharing good practice).

The Patient Safety Incident Response Framework (PSIRF) is a key component of the NHS Patient Safety Strategy and will outline how NHS providers should respond to patient safety incidents and how and when a patient safety investigation should be conducted. Once implementation is completed it will replace the current Serious Incident Framework.

Stakeholders/Audience: The Investigation is undertaken, and the report written for the purpose of learning. As such the report is written for delivery to the patient/relative and the NHS organisations involved. It is also prepared for sharing with any other interested parties.

Investigation timescales/schedule: This investigation is scheduled for completion within ***60*** working days.

Incident Investigation: To examine in detail the patient safety incident *INSERT REF* declared:

- Agree the Terms of Reference for the investigation
- Identify underlying causes
- Make clear, implementable recommendations
- To ratify and monitor delivery of action plans,
- To receive regular progress reports and share learning from incidents across all multidisciplinary staff and in the wider community.

Duty of Candour:
To ensure that duty of candour has been complied to, and engaging patients as appropriate within service development and service review.

Staffing:
To ensure review of current and future service-specific workforce needs in terms of capacity, competency, leadership, learning and development, and to work collaboratively to address these.

Governance:
The Trust Chief Medical Officer and Chief Nurse has overall responsibility to ensure that the Serious Incident Investigation Panel is working effectively and meets national standards. In the absence the Medical Director or Chief Nurse, their deputies will provide oversight.

Dissemination: To provide a forum for networking to:

- ensure a co-ordinated approach to the service
- facilitate good practice
- problem solve
- share information
- identify training needs and support training
- Improve Patient experience and outcome

3. Membership:

Representatives from the following are invited to attend:

Patient Safety Incident Investigation Panel Meeting
• CHAIR) Patient Safety Incident Investigators • Patient Safety Lead • Patient Safety Partner (optional) • Speciality representatives- medical • Nursing care group representatives • Head of patient safety(optional) • Associate director of risk and patient safety(optional) • Senior care group leadership representative

Chair:

- The Patient Safety Incident Investigators will act as chair of the investigation panel. In their absence Patient Safety Lead or other agreed individual shall act as chair.

4. Quorum:

The quorum necessary for this transaction of business shall be:

- Chair/Acting Chair
- Patient Safety Lead
- Speciality representatives- medical
- Senior care group leadership representative
- Nursing care group representatives

A duly convened meeting of the panel at which a quorum is present shall be competent to exercise all or any of the authorities, powers and discretions vested in, or exercisable, by the committee.

5. Conflicts of Interest:

Members and those attending may have conflicts of interest, either personal or financial. These may exist through the interests of close friends and family. These should be declared to the Chair at the earliest opportunity. The Patient Safety Team will keep a Register of interests and will update this at the beginning of each meeting.

6. Confidentiality:

Members and those attending need to respect confidentiality as appropriate. This may include any individual's sensitive information, commercially sensitive information which is "academic in confidence" such as pre-publication information. Principles of Data Protection, Caldicott and Codes of Conduct need to be respected.

7. Frequency of Meetings:

The Serious investigational panel will comprise of 3 meetings with the flexibility of more if required:

- The Initial stage
- Progress stage
- Sign off and closure stage

8. Agendas, Papers and Minutes of Meetings:

Agendas and papers will be circulated, normally one week prior to the meeting date. Minutes will be taken by local arrangement (a member of the patient safety team) and circulated to all members of the Patient Safety Incident Investigation panel. An Action Log may also be produced, as items can span multiple meetings.

Version Control and sign off		
Completed by	Description	Date
**********	Initial Draft for discussion	17/02/2024

Appendix 10: Patient Safety Incident Investigation Panel Flow/ meeting expectations

Rapidl Review (RR)

- Caregroup/ Patient Safety team to identify lead for rapid review (RR). A member of the caregroup to be present at review.
- To be completed within 72 hours.
- RR lead to ensure summary of the event and/or timeline completed prior to RR.
- At the RR the team review the records, care, and service delivery. Approximate time 30 minutes.
- **WHY did it happen?**
- Identify immediate mitigating actions and learning
- Check whether verbal **Duty of Candour (DoC)** has been completed, has it been recorded in the medical records? If not identify who will complete. Datix incident Handler to ensure DATIX updated.
- Level of investigation proposed at RR.
- Refer to Patient safety Incident response group (PSIRG) for investigation metholodology approval.
- If further investigation required agree **Draft TORs and Key questions** (this will be reviewed and adjusted as appropriate by the investigation lead/panel).
- Patient Safety Lead identified to communicate with the family to ensure their questions are included in the TORs and give progress updates with any investigation
- Completed template to be agreed and signed off by PSIRG within 72 hrs of the RR.
- Document whether a Patient Safety Incident Investigation Panel is required and key members e.g., clinician from Medicine, Surgery, Anaesthetics, Matron from care group etc on the ToRs to determine Quoracy for investigation.

Investigation Panel Process - AIMS & Preparation

- A multi-professional collaborative approach investigating a significant patient safety event using systems investigation methodology to identify learning and meaningful recommendations for improvement as appropriate.
- Investigation Lead (Chair) and panel identified at RR
- Each panel is minuted and an action log maintained
- The Panel Terms of reference (TOR) document agreed which should include key questions from the patient and/or family as appropriate.
- TORs shared with the Care group and the identified family liaison patient safety lead to communicate with the patient/family
- Chronology of events must be completed prior to the first panel meeting for presentation.
- The first panel meeting must be planned within 7 days from the date of the RR/ PSIRG approval.
- Any conflicts of interest must be raised and minuted at each panel meeting
- The panel may identify further participants to attend the panel as required as the investigation progresses

Investigation Panel First meeting

- Brief presentation and debrief of incident from the Chair
- Confirm verbal DoC has been completed, documented and letter has been sent to patient/NOK
- Review and confirm initial TORS for the investigation set at IR
- Review and confirm the correct specialists have been invited to the panel
- Allocate actions and responsibilities to panel, this may be review of nursing and medical records, SOP/Policy & guideline review, patient/staff discussions
- Set time frame for information and findings sharing (should this be shared with the panel prior to the second meeting stage).
- Agree who will bring the investigation report together
- Confirm date minutes and action log will be shared and date for next meeting
- Chair to confirm there are no declarations of interest required.

Investigation Panel Second meeting

- Minutes and actions reviewed from first panel
- Feedback from panel members from reviews and investigation
- Discussion of findings
- Review whether further investigations need to take place
- Identification of care and service delivery problems
- Review of investigation report progress
- Are there further actions to assign?
- Confirm date minutes will be shared
- Confirm date investigation report will be shared with panel for review prior to third and final Panel meeting
- Is a further panel meeting required? If so, agree a further date

Investigation Panel Third meeting, Sign Off and Closure Stage

- Care Group leadership represensative to attend to agree and sign off investigation
- Review investigation report in detail
- Review care and service delivery problems
- Identify learning
- Agree recommendations and actions, Identify action owners, completion deadlines.
- Designated Datix handler must enter the agreed actions onto Datix for tracking.
- Agree test/s of effectiveness for the action
- **Agree HOW** the learning will be shared e.g., what forums/safety communications/education sessions will dissemination occur
- Who will take responsibility for sharing and dissemination of learning and how will evidence this has happened?
- Forward to PSIRG for executive sign off
- Patient safety lead to share the report with patient/family post executive sign off

Appendix 11: National Investigation Requirements

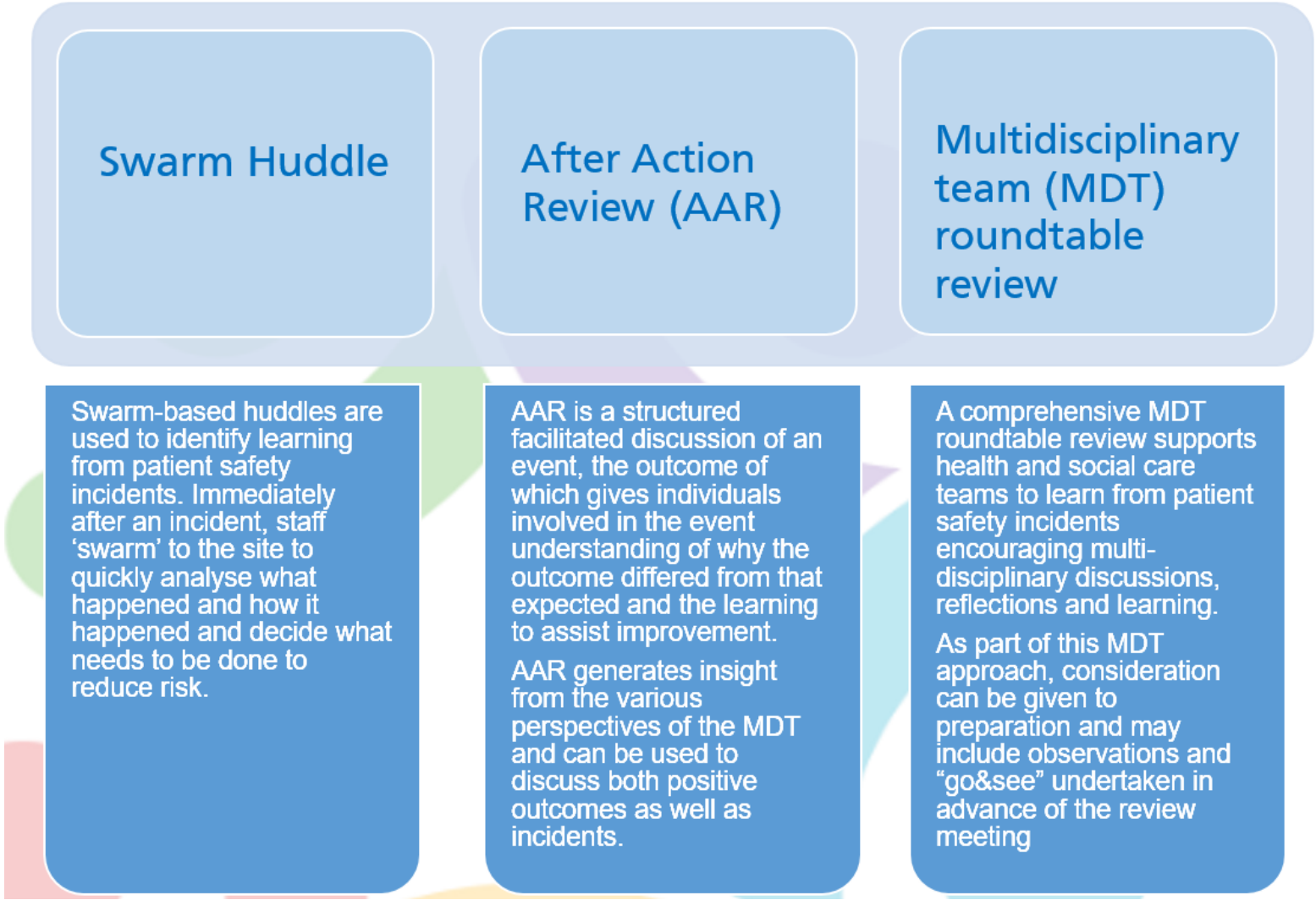
National requirements: Below are the patient safety incident types that must be responded to according to national requirements.

Events requiring a specific type of response as set out in policies or regulations:

Event	Action required
Deaths thought more likely than not due to problems in care	Locally-led Patient Safety Incident Investigation (PSII)
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	Locally-led PSII
Incidents meeting the Never Events criteria 2018, or its replacement.	Locally-led PSII
Mental health-related homicides	Referred to the NHS England Regional Independent Investigation Team (RIIT) for consideration for an independent PSII Locally-led PSII may be required
Maternity and neonatal incidents meeting Maternity and Neonatal Safety Investigation (MNSI) criteria or Special Healthcare Authority (SpHA) criteria when in place	Refer to MNSI or SpHA for independent PSII See also Appendix 1
Child deaths	Refer for Child Death Overview Panel review Locally-led PSII (or other response) may be required alongside the panel review – organisations should liaise with the panel
Deaths of persons with learning disabilities	Refer for Learning Disability Mortality Review (LeDeR) Locally-led PSII (or other response) may be required alongside the LeDeR – organisations should liaise with this
Safeguarding incidents in which: • Babies, children, or young people are on a child protection plan; looked after	Refer to local authority safeguarding lead Healthcare organisations must contribute towards domestic independent inquiries, joint targeted area inspections, child

plan or a victim of wilful neglect or domestic abuse/violence. • adults (over 18 years old) are in receipt of care and support needs from their local authority • the incident relates to FGM, Prevent (radicalisation to terrorism), modern slavery and human trafficking or domestic abuse/violence	safeguarding practice reviews, domestic homicide reviews and any other safeguarding reviews (and inquiries) 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 See: Guidance for managing incidents in NHS screening programmes
Deaths in custody (e.g. police custody, in prison, etc.) where health provision is delivered by the NHS	Any death in prison or police custody will be referred (by the relevant organisation) to the Prison and Probation Ombudsman (PPO) or the Independent Office for Police Conduct (IOPC) to carry out the relevant investigations Healthcare organisations 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

Appendix 12: Learning Methodology Flowcharts



Thematic Analysis	Patient Safety Incident Investigation (PSII)	Desktop review	Rapid Review (RR)
A thematic review can identify patterns in data to help answer questions, show links or identify issues. Thematic reviews typically use qualitative (eg open text survey responses, field sketches, incident reports and information sourced through conversations and interviews) rather than quantitative data to identify safety themes and issues	A PSII is a patient safety incident 'review methodology' adopting an 'investigative approach' for the incident response. This leads to an in-depth review of a single patient safety incident with the formulation of a comprehensive report. The Trust's PSIRP proposes what incidents may require a PSII. The decision to carry out a PSII should be based on potential for learning, PSIRP, family concerns and Trust existing	A desktop review of clinical records to gain further clarity on the nature of the incident could be undertaken. This may be supplemented with direct liaisons with the team/s involved aimed at a prompt de-escalation (or if appropriate escalation) of incidents as emerging from the desktop review.	This is a written initial review of the event. This will include a timeline of events, highlighting any immediate risks and whether there are any concerns that may require a subsequent learning response. Review whether staff and patients are ok. Incident may be closed following RR if no opportunity for further learning identified.