Royal Devon University Healthcare NHS Foundation Trust

Patient safety incident response policy

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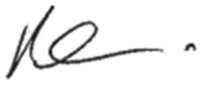
	NAME	TITLE	SIGNATURE	DATE
Author	**Robert Mann**	**Associate Director for Safety and Quality, Patient Safety Specialist**		**14/12/2023**
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Contents

Purpose

This policy supports the requirements of the Patient Safety Incident Response Framework (PSIRF) and sets out Royal Devon University Healthcare NHS Foundation Trust's approach to developing and maintaining effective systems and processes for responding to patient safety events for the purpose of learning and improving patient safety.

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

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

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

Scope

This policy is specific to patient safety incident responses conducted solely for the purpose of learning and improvement across Royal Devon services including:

- Acute Hospital Services (inpatient, outpatient, day treatment and acute hospital at home)
- Community Hospital Services (inpatient, outpatient, and day treatment)
- Urgent and Emergency Care Services
- Specialist Community Services

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

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

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.

Throughout the Trust's patient safety response to patient safety events consideration will be given to the NHS Just Culture Guide. This supports a culture of fairness, openness and learning in the NHS by making staff feel confident to speak up when things go wrong, rather than fearing blame.

Supporting staff to be open about mistakes allows valuable lessons to be learnt so the same errors can be prevented from being repeated. In any organisations or teams where a blame culture is still prevalent, this guide is a powerful tool in promoting cultural change.

A just culture guide

Supporting consistent, constructive and fair evaluation of the actions of staff involved in patient safety incidents

This guide supports a conversation between managers about whether a staff member involved in a patient safety incident requires specific individual support or intervention to work safely. Action singling out an individual is rarely appropriate - most patient safety issues have deeper causes and require wider action.

The actions of staff involved in an incident should **not** automatically be examined using this just culture guide, but it can be useful if the investigation of an incident begins to suggest a concern about an individual action. The guide highlights important principles that need to be considered before formal management action is directed at an individual staff member.

An important part of a just culture is being able to explain the approach that will be taken if an incident occurs. A just culture guide can be used by all parties to explain how they will respond to incidents, as a reference point for organisational HR and incident reporting policies, and as a communication tool to help staff, patients and families understand how the appropriate response to a member of staff involved in an incident can and should differ according to the circumstances in which an error was made. As well as protecting staff from unfair targeting, using the guide helps protect patients by removing the tendency to treat wider patient safety issues as individual issues.

Please note:

- **A just culture guide** is not a replacement for an investigation of a patient safety incident. Only a full investigation can identify the underlying causes that need to be acted on to reduce the risk of future incidents.
- **A just culture guide** can be used at any point of an investigation, but the guide may need to be revisited as more information becomes available.
- **A just culture guide** does not replace HR advice and should be used in conjunction with organisational policy.
- **The guide** can only be used to take one action (or failure to act) through the guide at a time. If multiple actions are involved in an incident they must be considered separately.

Start here - **Q1. deliberate harm test**

1a. Was there any intention to cause harm?

Yes → **Recommendation:** Follow organisational guidance for appropriate management action. This could involve: contact relevant regulatory bodies, suspension of staff, and referral to police and disciplinary processes. Wider investigation is still needed to understand how and why patients were not protected from the actions of the individual. → END HERE

No go to next question - **Q2. health test**

2a. Are there indications of substance abuse?

Yes → **Recommendation:** Follow organisational substance abuse at work guidance. Wider investigation is still needed to understand if substance abuse could have been recognised and addressed earlier. → END HERE

2b. Are there indications of physical ill health?

2c. Are there indications of mental ill health?

Yes → **Recommendation:** Follow organisational guidance for health issues affecting work, which is likely to include occupational health referral. Wider investigation is still needed to understand if health issues could have been recognised and addressed earlier. → END HERE

If **No to all** go to next question - **Q3. foresight test**

3a. Are there agreed protocols/accepted practice in place that apply to the action/omission in question?

3b. Were the protocols/accepted practice workable and in routine use?

3c. Did the individual knowingly depart from these protocols?

If No to any → **Recommendation:** Action singling out the individual is unlikely to be appropriate; the patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. These actions may include, but not be limited to, the individual. → END HERE

If **Yes to all** go to next question - **Q4. substitution test**

4a. Are there indications that other individuals from the same peer group, with comparable experience and qualifications, would behave in the same way in similar circumstances?

4b. Was the individual missed out when relevant training was provided to their peer group?

4c. Did more senior members of the team fail to provide supervision that normally should be provided?

If Yes to any → **Recommendation:** Action singling out the individual is unlikely to be appropriate; the patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. These actions may include, but not be limited to, the individual. → END HERE

If **No to all** go to next question - **Q5. mitigating circumstances**

5a. Were there any significant mitigating circumstances?

Yes → **Recommendation:** Action directed at the individual may not be appropriate; follow organisational guidance, which is likely to include senior HR advice on what degree of mitigation applies. The patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. → END HERE

If **No**

Recommendation: Follow organisational guidance for appropriate management action. This could involve individual training, performance management, competency assessments, changes to role or increased supervision, and may require relevant regulatory bodies to be contacted, staff suspension and disciplinary processes. The patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. → END HERE

improvement.nhs.uk

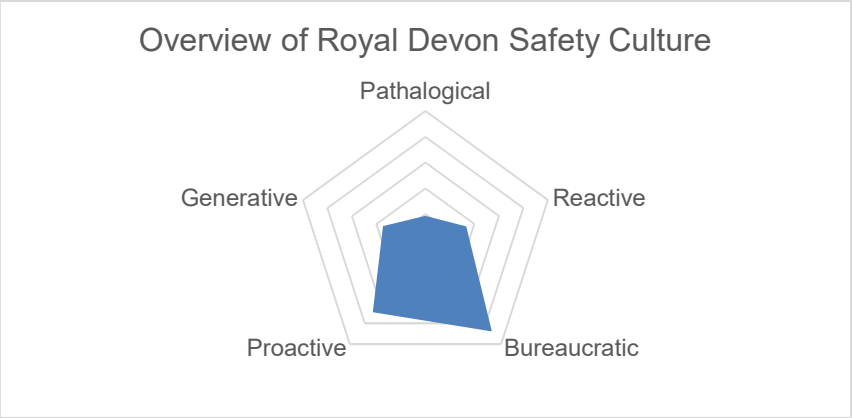
Based on the work of Professor James Reason and the National Patient Safety Agency's Incident Decision Tree

Supported by:

NHS England and NHS Improvement

Our patient safety culture

In preparation for implementing PSIRF an analysis of our Patient Safety Culture was completed using the Manchester Patient Safety Framework (MaPSaF). MaPSaF uses critical dimensions of patient safety and, for each of these, offers a description of what an organisation would look like at five levels of safety culture maturity. By safety critical dimensions we mean key areas where attitudes, values and behaviour around patient safety are likely to be reflected in the organisation's working practices. For example, how patient safety incidents are investigated and what staff education and training about risk management takes place.



The MaPSaF results indicate that as an organisation our staff are experiencing behaviours that demonstrate we are ready to move beyond bureaucracy. The safety culture of Royal Devon is probably best described as Bureaucratic – Proactive.

The Patient Safety Strategy is clear in its requirement that bureaucratic oversight should end, and that both safety systems and safety culture drive towards increasing maturity in responding to patient safety.

This move towards a proactive safety culture is enabled by a number of Trust initiatives are impacting upon our Safety culture. The Trust has launched its Strategic Objectives, "Better Together", which incorporates renewed Trust Values. Although this was the first analysis using MaPSaF the Trust has regularly explored its safety culture:

- Through the Annual Staff Survey
- Through exploration of organisational contributory factors within Serious Incident Investigations
-

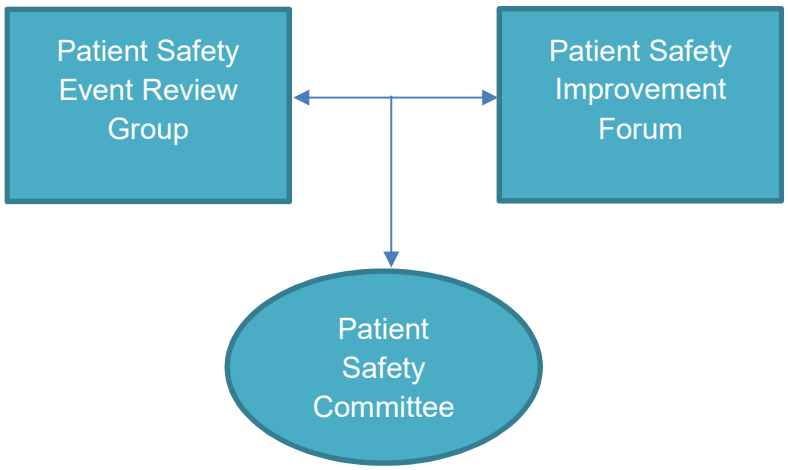
The Trust plans to repeat the MaPSFa review at regular intervals to track progress in developing a mature patient safety culture.

Patient safety partners

To support the implementation of the Patient Safety Strategy a project delivery group was established. A core principle within the terms of reference was that patient safety partners should be key members of the project delivery group, and of the governance and oversight workstream. At the point of establishing the project delivery group the Trust had no infrastructure to support patient safety partners. In order to demonstrate our commitment as an organisation to the inclusion of patient safety partners interim arrangements had to be established.

An approach was made to the NHS Leadership Academy in Leeds, who had a well-established programme of experts by experience/ expert patients for support. We arranged in partnership with NHSLA for two of their network members to support our project delivery group and workstreams. Through this mechanism, we have insured the inclusion of experienced patient voices in the design of our implementation of the Patient Safety Incident Response Framework, the development of our Patient Safety Incident Response Plan and the design of out framework for Patient Safety Oversight.

The core elements of our Oversight Framework have two groups ensuring that both the insight and improvement functions of patient safety are escalated to a dedicated sub-committee of the Board of Directors. The Trust plans to include patient safety partners will be in all three of these key elements of our patient safety infrastructure.



The next stage in the development of our patient safety partners will be the development of a patient safety partner involvement policy, which will define the role within the organisation, and the support which will be available for our patient safety partners. The Policy will include:

- recruitment and selection
- equality and diversity
- induction and training
- health, safety and welfare
- support and appraisal
- expenses and involvement payments and process for claiming expenses
- confidentiality and data protection
- a problem-solving process for dealing with any PSP performance issues (linked to the appraisal process)
- approach to reward and recognition

The policy will also include a process for measuring the impact of patient safety partner involvement.

Following the development and ratification of the Trust Patient Safety Partners Policy, The Trust will embark on recruitment process for patient safety partners. The patient safety partners policy will be reviewed once the initial partners have been in post for six months. This review will be

conducted in partnership with the partners, so that learning from our initial experience of working with patient safety partners can be included.

Addressing health inequalities

The Covid 19 Pandemic response clearly demonstrated that different social backgrounds or protected characteristics had a significant impact upon the outcomes for people. In developing our Patient Safety Incident Response Policy and Plan there has been significant consideration of how these inequalities can be monitored and addressed.

Our current Risk Management System (Datix Cloud IQ) holds minimal patient demographics so it is not straightforward to assess the impact of different patient safety events or the severity of outcome against particular communities.

In developing the Royal Devon Patient Safety Incident Response Plan we broadened our data analysis beyond traditional incident data to attempt to mitigate against this weakness in our insight. This included reviewing complaints and feedback from patients, carers and system feedback from our partners. In supporting our Patient Experience Strategy, we have commissioned Healthwatch to undertake reviews of specific services, which has been reported into the Patient Experience Committee and provided additional context for our understanding of health inequalities.

We also triangulated information against issues raised with the Freedom to Speak Up Guardians, this was to ensure that there were no areas of concern that were being raised via the guardians which were not being reflected within our analysis.

The Trust has already developed a range of steering / operational groups to monitor and improve the outcomes for people who are at risk of experiencing health inequalities. These working groups report across the full spectrum of our Quality Governance: Safety, Experience and Effectiveness. Each of these areas has a dedicated Board of Directors Sub-Committee to provide oversight, and provide check and challenge to ensure

We have commenced work with our electronic patient record provider (Epic) to explore linking the demographics between the EPR and Risk management systems. This will significantly improve our analysis and reporting capabilities. The development work will continue, and we are working to have established report processes in place for the end of Quarter 1 2024-2025.

In the interim our systems-based approach to developing learning will enable us to identify any health inequalities themes from investigations and learning responses. These will feed into the Patient Safety Improvement Forum, so that identified health inequalities can be incorporated into our overarching Patient Safety Improvement Plan.

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

The Royal Devon acknowledges that we can only achieve meaningful learning and improvement following patient safety events if supportive systems and processes are in place to engage with the people who had been affected. Affected people is a broad term, which includes:

- The person or patient to whom the incident occurred
- Their family or other significant people (which may include parents, partners, siblings, children, guardians, carers, and others who have a direct and close relationship with the individual to whom the incident occurred.)
- The staff who were directly involved in the event or its impact.

The national guidance on involving affected people following patient safety events focuses on how to achieve compassionate engagement and involvement by:

1. supporting healthcare organisations to review and amend the systems they have in place to ensure an effective process of engagement and involvement with those affected by patient safety incidents
2. providing practical advice to support compassionate engagement with those affected by patient safety incidents
3. providing practical advice to enable meaningful involvement as part of a patient safety incident investigation (PSII), although the principles and approaches described can be applied to any type of patient safety incident and/or response method.

To achieve this affected people will have a single point of contact; The intent is to identify a formal liaison role, but in the interim, this will be undertaken by the person leading the learning response. All contacts with affected people will be recorded in the progress notes in Datix, creating a record of the support offered to affected people throughout the process, together with

Principles to inform the design of processes for engaging and involving affected people

1. **Apologies are meaningful.**
   Apologies need to demonstrate understanding of the potential impact of the incident on those involved, and a commitment to address their questions and concerns. Ideally, an apology communicates a sense of accountability for the harm experienced, but not responsibility for it ahead of investigation. Getting an apology right is important – it sets the tone for everything that follows. Apologising is also a crucial part of the Duty of Candour.

2. **Approach is individualised**
   Engagement and involvement should be flexible and adapt to individual and changing needs. These needs could be practical, physical, or emotional. Engagement leads should recognise that every response might need to be different, based on an understanding of the different needs and circumstances of those affected by an incident.

3. **Timing is sensitive**

Some people can feel they are being engaged and involved too slowly or too quickly, or at insensitive times. Engagement leads need to talk to those affected about the timing and structure of engagement and involvement, and any key dates to avoid (eg birthdays, funeral dates, anniversaries), particularly where someone has lost a loved one.

4. **Those affected are treated with respect and compassion**
   Everyone involved in a learning response should be treated respectfully. There should be a duty of care to everyone involved in the patient safety incident and subsequent response, and opportunities provided for open communication and support through the process. Overlooking the relational elements of a learning response can lead to a breakdown of trust between those involved (including patients, families, and healthcare staff) and the organisation.

5. **Guidance and clarity are provided**
   Patients, families, and healthcare staff can find the processes that follow a patient safety incident confusing. Those outside the health service, and even some within it, may not know what a patient safety incident is, why the incident they were involved in is being investigated or what the learning response entails. Patients, families, and healthcare staff can feel powerless and ill-equipped for the processes following a patient safety incident. Therefore, all communications and materials need to clearly describe the process and its purpose, and not assume any prior understanding. 6.

6. **Those affected are 'heard'**
   Everyone affected by a patient safety incident should have the opportunity to be listened to and share their experience. They will all have their individual perspective on what happened and each one is valid in building a comprehensive picture to support learning. Importantly, the opportunity to be listened to is also part of restoring trust and repairing relationships between organisations and staff, patients, and families.

7. **Approach is collaborative and open**
   An investigation process that is collaborative and open with information, and provides answers, can reduce the chance litigation will be used as a route for being heard. The decision to litigate is a difficult one. Organisations must not assume that litigation is always about establishing blame – some feel it is the only way to get answers to their questions.

8. **Subjectivity is accepted**
   Everyone will experience the same incident in different ways. No one truth should be prioritised over others. Engagement leads should ensure that patients, families, and healthcare staff are all viewed as credible sources of information in response to a patient safety incident.

9. **Strive for equity**
   Organisations may differ from patients, families, and healthcare staff in what they consider is the appropriate response to a patient safety incident. The opportunity for learning should be weighed against the needs of those affected by the incident. Engagement leads need to understand and seek information on the impact of how they

choose response types on those affected by incidents and be aware of the risk of introducing inequity into the process of safety responses

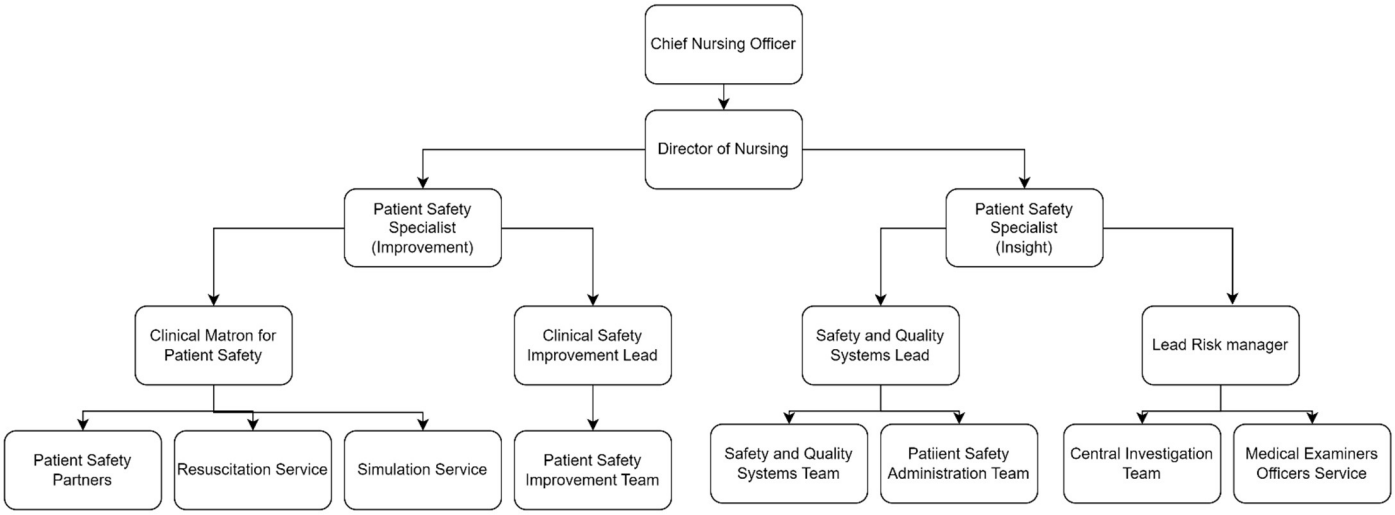
Patient safety incident response planning

PSIRF supports organisations to respond to incidents and safety issues in a way that maximises learning and improvement, rather than basing responses on arbitrary and subjective definitions of harm. Beyond nationally set requirements, organisations can explore patient safety incidents relevant to their context and the populations they serve rather than only those that meet a certain defined threshold. The central Patient Safety Team is being aligned to provide ongoing support and resource to the Divisions with Patient Safety insight, learning and improvement.

Resources and training to support patient safety incident response

The Trust has reviewed its resources and training against the NHS Patient Safety Incident Response Standards to ensure that it will be able to meet the requirements set within its incident response plan and policy.

Under the Executive Leadership of the Chief Nursing Officer the central patient safety team is being aligned to the key PSIRF functions of Insight and Improvement.



The Trust's Patient Safety Specialists will be accountable for delivery of the portfolio's for insight and improvement. They will establish a daily virtual drop in, so that Divisional Representatives are supported with the identification of patient safety events, providing a compassionate response and assigning a proportionate learning response. The realignment of the central team will provide the following resource to support Divisional patient safety event responses.

Central Investigation Team	The team will undertake the Patient Safety Incident Investigations required by the patient Safety Incident Response Plan. They will hold a weekly Learning Huddle to support Divisions with learning responses, and activities such as trending and theming from after action reviews and huddles. The Investigation leads will continue to feed into Divisional Governance to support consistency across clinical services.
Patient Safety Improvement Team	The team will manage the patient safety improvement programme, ensuring it remains fit for purpose. Using the learning from patient safety events they will prioritise and support patient safety improvement activity within the Divisions. The Patient Safety Improvement Forum will provide the route for Divisions to be supported with their improvement activity. Where improvement work which is outside the scope of the patient safety portfolio is identified the relevant staff will be signposted to the Trust transformation team for support.
Patient Safety Partners	Support of Patient Safety Partners has been identified and is built into the Job Plan for the Clinical Matron for Patient Safety. This will provide our partners with a consistent source of support, development and supervision.
Safety and Quality Systems Team	The Safety and Quality will support the applied analysis of patient safety and risk information. They will develop a range of Divisional governance and quality dashboards and standing reports using the Business Intelligence capacity of our risk management system. They will facilitate live interrogation of our safety and quality systems within our patient safety and oversight framework.

In line with the patient safety incident response standards the Trust has followed the PSIRF Training Requirements, making the following packages available to Trust staff, with access to training in line with the Training Needs Analysis conducted by the Patient Safety Strategy Implementation Project Delivery Group.

Topic	Minimum Duration	Content	
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	
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	
Continuing professional development (CPD)	At least annually	• To stay up to date with best practice (e.g. through conferences, webinars, etc) • Contribute to a minimum of two learning responses	

Our patient safety incident response plan

The patient safety incident response plan sets out how Royal Devon University Healthcare NHS Foundation Trust intends to respond to patient safety events over a period of 12 to 18 months. The plan is not permanent and will be refreshed on a regular basis. We will remain flexible and consider the specific circumstances in which patient safety issues and incidents occurred and the needs of those affected.

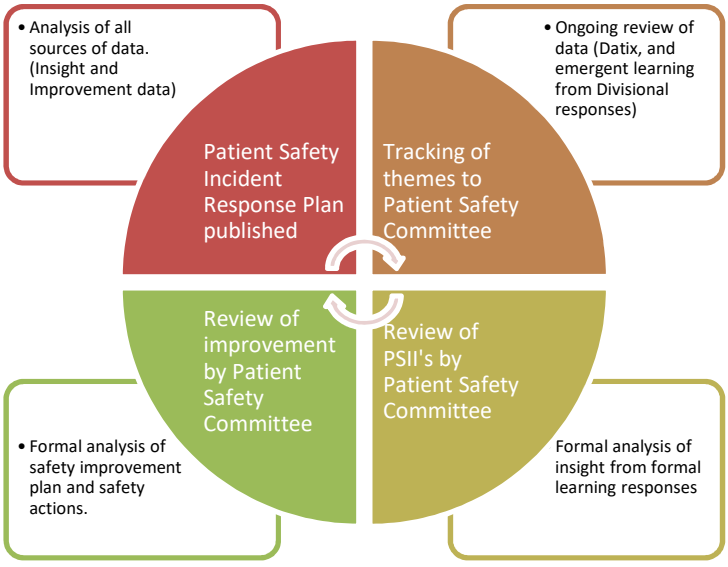
The plan establishes how the Trust will ensure that we undertake the appropriate learning responses to patient safety events where a particular response is nationally required. In addition, the plan describes the learning activity we will undertake as part of our local focus on patient safety events.

The Patient Safety Incident Response Plan is published on our Trust website and can be accessed here Link to Policy

Reviewing our patient safety incident response policy and plan

We will review the plan every 12 to 18 months to ensure our focus remains up to date; with ongoing improvement work our patient safety incident profile is likely to change. This will also provide an opportunity to re-engage with stakeholders to discuss and agree any changes made in the previous 12 to 18 months.

The Royal Devon Patient Safety Incident Review Plan will be subject to a constant cycle of review and refresh. As learning from data analysis, learning reviews/ investigations and improvement activity all escalate to a single governance forum it will allow the synthesis required to challenge the relevance of our overarching plan.



A rigorous planning exercise will be undertaken every four years and more frequently if appropriate (as agreed with our integrated care board (ICB)) to ensure efforts continue to be balanced between learning and improvement. This more in-depth review will include reviewing our response capacity, mapping our services, a wide review of organisational data (for example, patient safety incident investigation (PSII) reports, improvement plans, complaints, claims, staff survey results, inequalities data, and reporting data) and wider stakeholder engagement. The approval process will ensure that the response plan and policy on our public facing website are always the current version.

Responding to patient safety incidents

Patient safety incident reporting arrangements

Reporting an incident

Completing an incident report using Datix is all you need to do to ensure the organisation is able to respond.

Any member of staff with access to the Trust Intranet is able to report an incident. Reporting of learning from both incidents and good care should be completed on the Trust's risk management system, Datix Cloud IQ. This can be accessed from the Intranet homepage.

All patient safety events should be reported as soon as is reasonably practicable after they occur.

Clicking the "Datix: report an incident" icon will open up the incident form. As staff make selections the form will update, so that they staff are only asked questions relevant to the safety event they are recording.

When the submit button is pressed the incident will be formally logged, and relevant people will be notified. (For example, if a staff member reports an incident which they believe contained a safeguarding concern this will notify the safeguarding team; If you report a pressure ulcer this will notify the tissue viability team.) Datix also notifies key people within your Division.

What events to report: Type of event

Every patient safety event is an opportunity to learn and improve; which makes our services safer for the people who access them. This includes:

Near Miss Incidents	A near miss is an error that has the potential to cause harm, but fails to reach the patient due to either through chance or because it is intercepted by planned or unplanned interventions
No Harm Incidents	An accident, act or omission which reaches the patient, but does not cause any physical or psychological harm
Incidents with Harm	An accident, act or omission which reaches the patient, which has caused any degree of physical or psychological harm
Good Care	An event where a patient has a more positive outcome due to an intentional act or omission on the part of a team or team member.

The Royal Devon encourages all colleagues to report patient safety events, particularly from the examples above. The Trust expects that all incidents which result in harm will be reported, and that team/ward leaders will support staff to report safety events.

Definitions of Harm

The following definitions of harm should be used when reporting an incident

Grade of Harm	Physical Harm	Psychological harm
No Harm	No physical harm	No psychological harm
Low Harm	Low physical harm is when **all of the** following apply: • minimal harm occurred - patient(s) required extra observation or minor treatment • did not or is unlikely to need further healthcare beyond a single GP, community healthcare professional, emergency department or clinic visit • did not or is unlikely to need further treatment beyond dressing changes or short courses of oral medication • did not or is unlikely to affect that patient's independence • did not or is unlikely to affect the success of treatment for existing health conditions	Low psychological harm is when **at least one** of the following apply: • distress that did not or is unlikely to need extra treatment beyond a single GP, community healthcare professional, emergency department or clinic visit • distress that did not or is unlikely to affect the patient's normal activities for more than a few days • distress that did not or is unlikely to result in a new mental health diagnosis or a significant deterioration in an existing mental health condition
Moderate Harm	Moderate harm is when **at least one** of the following apply: • has needed or is likely to need healthcare beyond a single GP, community healthcare professional, emergency department or clinic visit, and beyond dressing changes or short courses of medication, but less than 2 weeks additional inpatient care and/or less than 6 months of	Moderate psychological harm is when **at least one** of the following apply: • distress that did or is likely to need a course of treatment that extends for less than six months • distress that did or is likely to affect the patient's normal activities for more than a few days but is unlikely to affect the patient's ability to live independently for more than six months

Grade of Harm	Physical Harm	Psychological harm
	further treatment, and did not need immediate life-saving intervention • has limited or is likely to limit the patient's independence, but for less than 6 months • has affected or is likely to affect the success of treatment, but without meeting the criteria for reduced life expectancy or accelerated disability described under severe harm	• distress that did or is likely to result in a new mental health diagnosis, or a significant deterioration in an existing mental health condition, but where recovery is expected within six months
Severe Harm	Severe harm is when **at least one** of the following apply: • permanent harm / permanent alteration of the physiology • needed immediate life-saving clinical intervention • is likely to have reduced the patient's life expectancy • needed or is likely to need additional inpatient care of more than 2 weeks and/or more than 6 months of further treatment • has, or is likely to have, exacerbated or hastened permanent or long term (greater than 6 months) disability, of their existing health conditions • has limited or is likely to limit the patient's independence for 6 months or more	Severe psychological harm is when **at least one** of the following apply: • distress that did or is likely to need a course of treatment that continues for more than six months • distress that did or is likely to affect the patient's normal activities or ability to live independently for more than six months • distress that did or is likely to result in a new mental health diagnosis, or a significant deterioration in an existing mental health condition, and recovery is not expected within six months
Fatal	You should select this option if, at the time of reporting, the patient has died and the incident that you are recording may have contributed to the death, including stillbirth or pregnancy loss.	

The definition of harm is based upon what is apparent at the time of reporting an incident and can be amended later.

Example:

A health care assistant responds to a noise in a bay, and finds a patient on the floor with an injury to their head. The patient is unresponsive and emergency help is summoned. The patient is confirmed as deceased.

This is reported as a fall / patient found on floor/ fatal.

Subsequent post mortem identifies that the patient had a significant unexpected cardiac event, which caused loss of consciousness and death. The fall would then be re-graded to no harm as it did not contribute to the patient's death

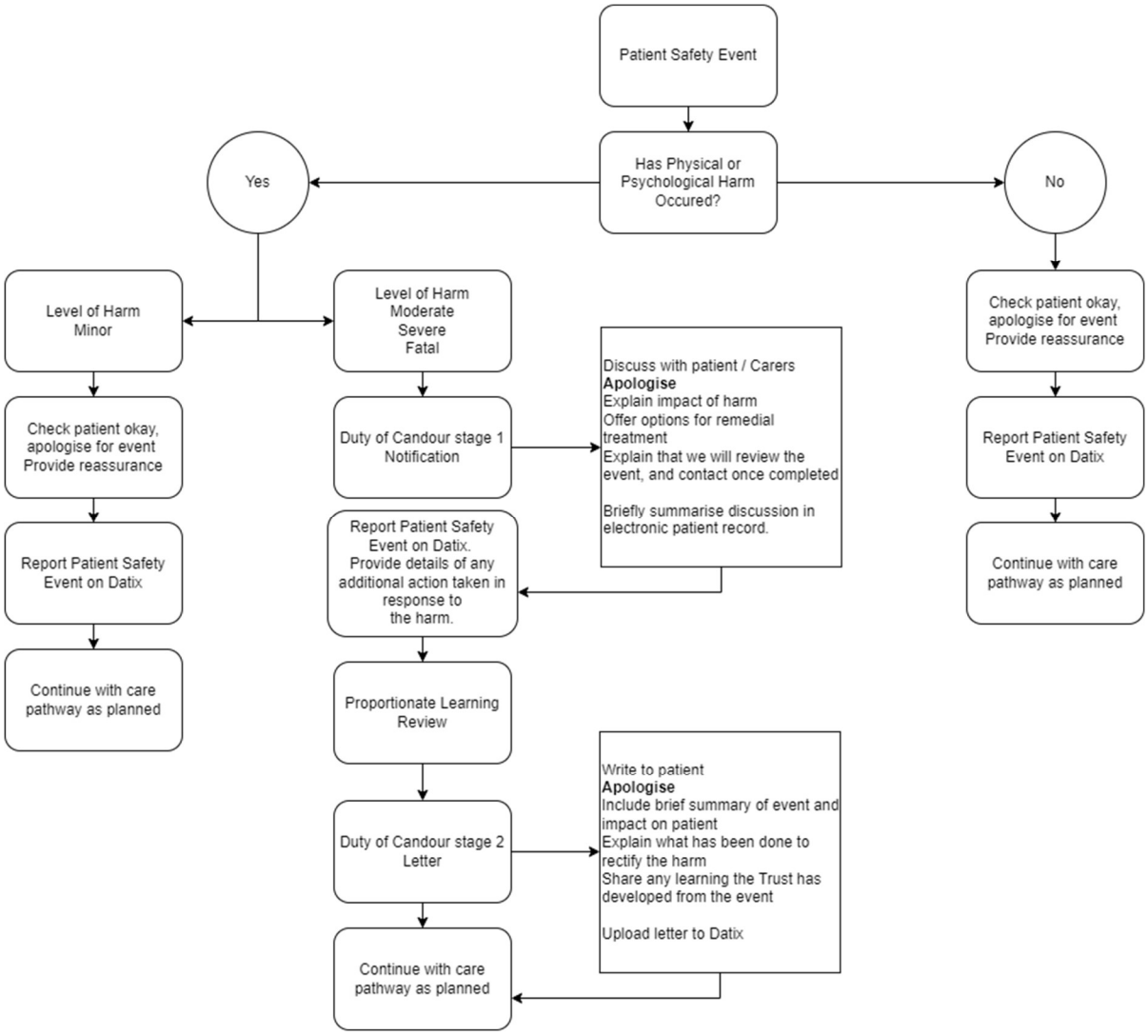
What events to report: Location of event

Patient safety events should be reported when they are first identified, regardless of where they occur. We are able to report incidents which occurred whilst are patients were at home, or receiving health or social care from other agencies. Divisional safety/governance leads in partnership with the Patient Safety Specialists / Safety team will ensure that the appropriate notifications are made to other agencies for the event to be responded to.

Saying Sorry

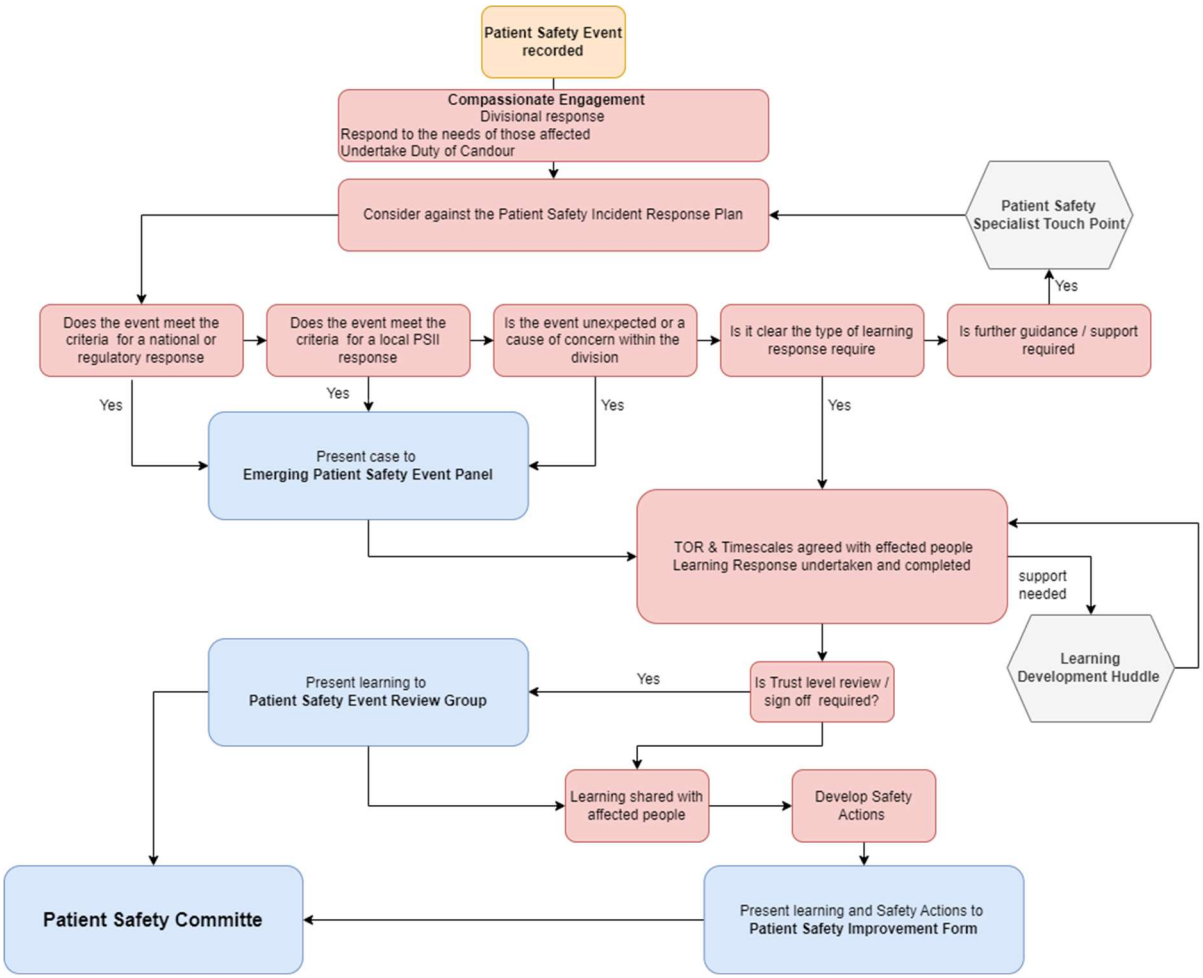
There is never a situation where saying sorry to someone affected by a patient safety event is the wrong thing to do.

Where a patient safety event has (or is reasonably believed to have) resulted in a moderate or greater degree of harm then a formal response under regulation 20 of the Health and Social Care Act (Duty of Candour) should be considered. The flowchart below illustrates the requirements of Duty of Candour



Patient safety incident response decision-making tree

Each Division has governance support who are able to assist with decision making around proportionate learning responses. They are in a position to escalate to the Divisional Leadership who will ensure that affected people receive a compassionate response.

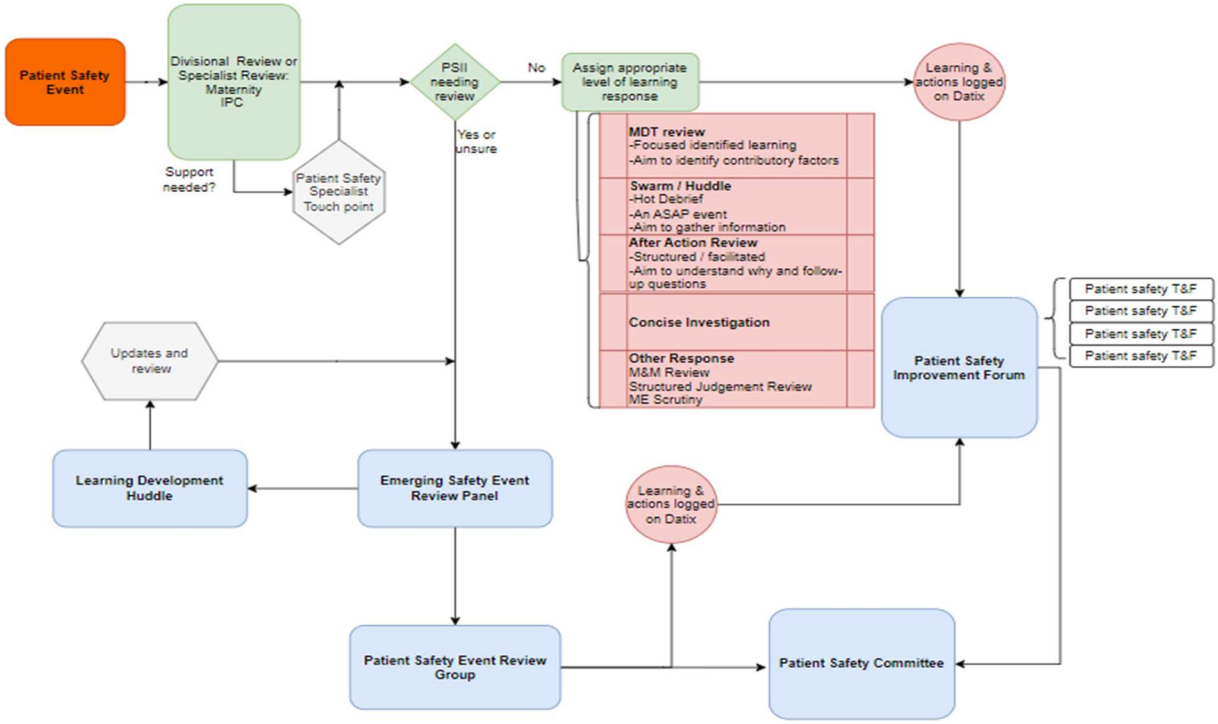


Any patient safety event will be assessed against the Patient Safety Incident Response Plan to ensure that any response is proportionate and compassionate.

If it is unclear how to proceed with an event there is the opportunity to drop in to a Patient Safety Specialist Touch Point. These will be established daily for the first three months of PSIRF. The PSS will advise on the most proportionate learning response and the need for escalation

Oversight Framework

The decision-making process mirrors the Governance and Oversight arrangements for patient safety.

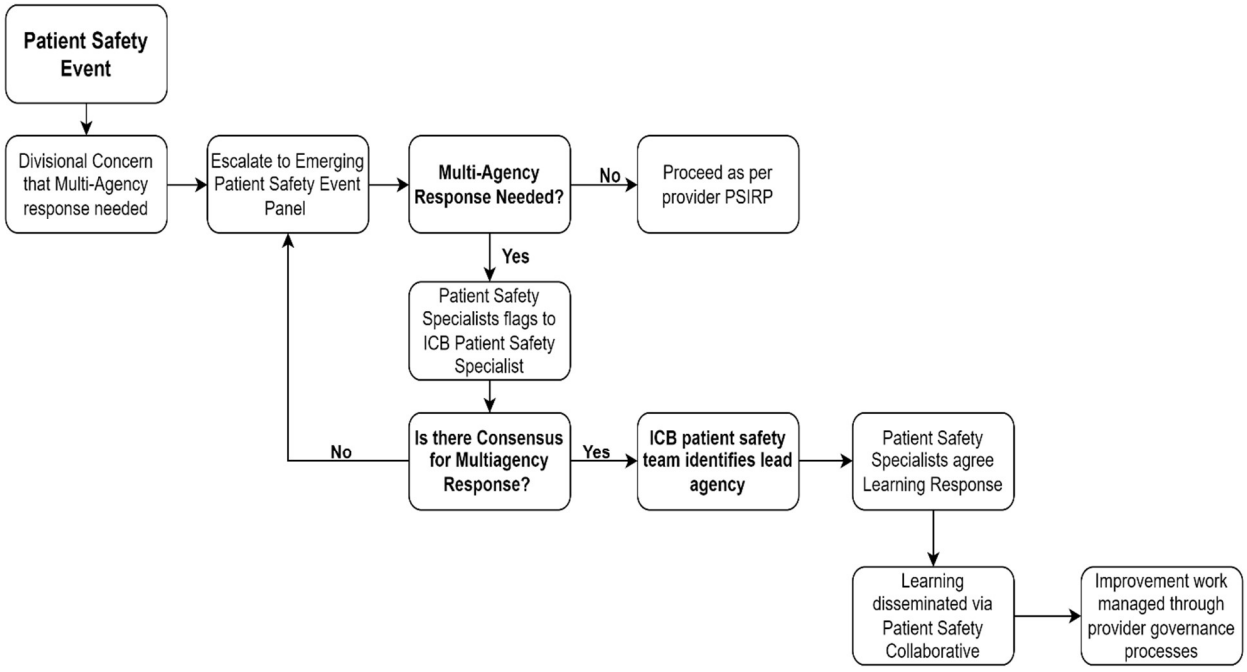


Emerging Patient Safety Event Review Panel	• Agrees if PSII is needed • Identifies need for Multi-agency response. • Advises on alternative Learning Approaches • Forum for flagging concerns and new emerging trends in patient safety
Patient Safety Event Review Group	• Signs off investigations / learning requiring formal review • Involves staff / services affected in identifying key learning • Ensures the the views of the affected person or family are fully reflected in the report, and that their concerns are addressed • Critiques learning and proposed safety actions
Patient Safety Improvement Forum	• Reviews insight and learning • Prioritises improvement activity • Manages the Trust's Patient Safety Improvement Plan • Supports local patient safety improvement activity related to patient safety
Patient Safety Committee	• This is the Board sub-committee which holds the organisations oversight of Patient Safety. • Is accountable to the Board of Directors on the quality of our response to patient safety events • Is sighted on all patient safety activity, insight and improvement. • Ratifies the Incident Response Policy, Response Plan and Improvement Plan

Responding to cross-system incidents/issues

The aim of the oversight framework is to create a system where learning responses are managed as locally as possible to facilitate the involvement of those affected by the event and those responsible for delivery of the service in which the event or incident relates to. However, where a response involves multiple providers or services across a care pathway the Trust may seek to initiate a system response.

The emerging patient safety event panel will hold a standing agenda item for potential cross system response requests requiring ICB support. It will be the final internal arbitrator within the Royal Devon for the need for a Multi-Agency response. The Panel must use their judgement and seek the views of local partners to ensure learning responses are co-ordinated at the most appropriate level of the system.



The emerging patient safety event panel will hold a standing agenda item for potential cross system response requests requiring ICB support. It will be the final internal arbitrator within the Royal Devon for the need for a Multi-Agency response. The Panel must use their judgement and seek the views of local partners to ensure learning responses are co-ordinated at the most appropriate level of the system.

The emergent patient safety event panel will hold a standing agenda item for potential cross system response requests requiring ICB support. The initial scoping with the ICB and partners will agree the role and responsibilities of the different agencies involved, including who should undertake the responsibility of lead agency.

Timeframes for learning responses

One of the aims in employing a range of proportionate methodologies is to ensure timely learning which can be shared with those affected, and used to develop safety actions / contribute to overarching

Learning Response	Indicative timeframes	Process for agreeing timescales	Exceptions
Huddle / swarm	2 weeks – 4 weeks	The Divisional team will agree timescales on a case by case basis. Huddle should occur 3 – 5 working days following incident. The huddle documentation should be uploaded to Datix and identified learning shared with affected people	If the initial ward / team huddle does not occur in 3 – 5 days consider alternative methodology.
After Action Review	2 weeks – 6 weeks	The Divisional team will agree timescales on a case by case basis.	
MDT Review / Round table	4 weeks – 8 weeks	The Divisional team will agree timescales on a case by case basis.	
M&M Review	6 weeks – 12 weeks	The Speciality team will agree timescales on a case by case basis.	Cases requiring M&M review to generate learning should be prioritised
Concise Learning Review	3 months	Concise Learning Reviews will be Commissioned by The Emergent Patient Safety Event Panel or Divisional ADN	
Patient Safety Incident Investigation	3 months – 6 months	The initial timescale will be agreed by the Emerging Patient Safety Event Panel. This will then be reviewed with the effected person and revised in agreement with them.	

Multi-Agency / Cross System Reviews	4 months – 6 months	The Emergent Patient Safety Event Panel will commission a request for Multi-Agency Review.	The Lead Agency for the review will be agreed in collaboration with the other agencys.

Safety action development and monitoring improvement

Areas for improvement can relate to a specific local context or to the context of the wider organisation.

Overview of safety action development according to context

	Local Context	Organisational Context
Definition	Specific area for improvement highlighted by a single (or multiple) learning responses	Broader area for improvement identified across several learning responses – likely not in response to any single patient safety incident but incidents with common contributory factors across events. Likely require radical system redesign
Examples of areas that may require improvement	Environment layout and characteristics (eg light, noise) Tool design Task design Training	Deep routed organisational issues, likely with long histories and dynamics, eg: • Staffing, rotas, etc • IT infrastructure • Workload • Fatigue • Culture • Handovers • Procurement • Policies
Development Team	Learning response team Involvement of local team to design and implement Patient Safety Quality improvement team Those affected by the incident	Learning response team Involvement of local and broader team to design and implement (eg leadership, management) Patient Safety Quality improvement team Those affected by the incident
Tools	SEIPS adaptation of the Human Factors Intervention Matrix (HFIX) iFACES criteria and scoring rubric	
Methods for Developing Safety Actions	Interviews Observations Focus groups Desktop reviews Simulation/testing Standards quality improvement methods such as PDSA cycles	Qualitative review of patient safety learning response findings Surveys Literature reviews – what has worked well elsewhere? Focus groups Consensus panel – reaches a wider group of members with experience of work

Expectation for Recording	Included in learning response report (eg patient safety incident investigation (PSII) report) after an individual incident response or in wider safety improvement plan as appropriate.	Included in a safety improvement plan bringing together findings from various responses

Defining safety measures is a three-step process:

The development of safety actions and the monitoring of improvement will be a primary function of the Patient Safety Improvement Forum. This forum will bring together the necessary team members to develop effective safety measures.

The forum will also monitor and review safety improvement actions to ensure that they remain impactful and are sustainable.

The Patient Safety Committee will be accountable to the Board of Directors for ensuring that our Patient Safety Improvement Plan remains relevant to our incident profile, effective and is leading to sustainable improvement across the organisation.

Safety improvement plans

The Royal Devon has established patient safety workstreams in place for areas of improvement. These are represented in our **Patient Safety on a Page** Plan

This plan provides a high-level overview of the patient safety priorities for the Royal Devon. This does not present the totality of Patient Safety Work undertaken by the organisation.

<table>
<tr><th colspan="3">Patient Safety on a Page</th></tr>
<tr><td colspan="3">Care of the deteriorating patient
The aim of the Managing Deterioration Safety Improvement Programme is to reduce deterioration-associated harm by improving the prevention, identification, escalation and response to physical deterioration, through better system co-ordination and as part of safe and reliable pathways of care. Oversight for this workstream will be undertaken by the Resuscitation Group
• Current priorities within this workstream include:
• Escalation response times
• Proposal for development of a Critical Outreach Team
• Skills Development: Ensuring key staff are mapped against ILS training on high risk clinical areas</td></tr>
<tr><td>Reducing harm from falls
Oversight for this workstream will be undertaken by the Falls Reduction Project Group. Current priorities include:
• Review of Falls Policy (Completed).
• Establishing a falls practitioner post for Eastern services (Completed).
• Running a falls improvement project across 4 HFOP Wards</td><td>Rapid tranquilisation
Oversight for this workstream will be undertaken by the Medicines Safety Group. Current Priorities for this workstream include:
• Review of current policy and educational materials
• Educational Campaign
• Policy re-launch</td><td>Reducing pressure ulcers
Oversight for this workstream will be undertaken by the Tissue Viability Steering Group. Current priorities include:
• Establishing a Trust-wide Steering Group
• Reviewing validation and reporting processes</td></tr>
<tr><td colspan="3">Implementation of NatSSIPs 2
NatSSIPs 2 re-launches the WHO checklist. It mandates key stop moments when the standard pathway is confirmed and patient-specific details clarified. A NatSSIPs 2 Task and Finish Group was formed with the purpose of overseeing the implementation of the National Safety Standards for Invasive Procedures version 2 (NatSSIPs 2) published in January 2023.
Priorities for this workstream include:
• Identification of settings where NatSSIPs processes are relevant and assessing levels of risk and operational impact
• Collaborative work with the Integrated Care Board and other providers across the Devon healthcare system.
• Optimisation of the Electronic Patient Record in supporting use of LocSSIPs</td></tr>
</table>

In addition to our core patient safety improvement plan the Trust has a number of work programmes led by multidisciplinary groups, these include:

- Mental Health Steering Group, which is leading on the Trust's restrictive interventions and enhanced care and observations work streams.

- End of Life Steering Group, which is leading on the Trust's improvements in Advanced Directives, End of Life Care Planning and use of Treatment Escalation Plans.
- Learning Disability Operational Group

Oversight roles and responsibilities

Oversight of patient safety incident response has traditionally included activity to hold provider organisations to account for the quality of their patient safety incident investigation reports. Oversight under PSIRF focuses on engagement and empowerment rather than the more traditional command and control.

Oversight Mindset

The following principles underpin the oversight of the Trust's patient safety incident response:

1. **Improvement is the focus**
   PSIRF oversight should focus on enabling and monitoring improvement in the safety of care, not simply monitoring investigation quality.
2. **Blame restricts insight**
   Oversight should ensure learning focuses on identifying the system factors that contribute to patient safety incidents, not finding individuals to blame.
3. **Learning from patient safety incidents is a proactive step towards improvement**
   Responding to a patient safety incident for learning is an active strategy towards continuous improvement, not a reflection of an organisation having done something wrong.
4. **Collaboration is key**
   A meaningful approach to oversight cannot be developed and maintained by individuals or organisations working in isolation – it must be done collaboratively.
5. **Psychological safety allows learning to occur**
   Oversight requires a climate of openness to encourage consideration of different perspectives, discussion around weaknesses and a willingness to suggest solutions. 6. Curiosity is powerful Leaders have a unique opportunity to do more than measure and monitor. They can and should use their position of power to influence improvement through curiosity. A valuable characteristic for oversight is asking questions to understand rather than to judge

Oversight roles and responsibilities

The Board of Directors (or those with delegated responsibility, including members of the patient safety sub-committees), is responsible and accountable for effective patient safety incident management in their organisation. This includes supporting and participating in cross system/multi-agency responses and/or independent patient safety incident investigations (PSIIs) where required. The board of Directors should identify a PSIRF executive lead to support the responsibilities outlined below.

PSIRF executive lead responsibilities

- Ensure the organisation meets national patient safety incident response standards
- Ensure PSIRF is central to overarching safety governance arrangements:

    - Patient safety incident reporting and response data, learning response findings, safety actions, safety improvement plans, and progress are discussed at the board of Director's patient safety sub-committee
    - Roles, training, processes, accountabilities, and responsibilities of staff are in place to support an effective organisational response to incidents.

- Quality assure learning response outputs. The PSIRF executive lead should be responsible for reviewing PSII reports in line with the patient safety incident response standards and signing it off as finalised.
- Ensuring processes are in place to ensure that all safety actions implemented in response to learning or wider safety improvement plan(s) are monitored, to check they are delivering the required improvement.
- Progress on individual actions should be reviewed at appropriate intervals using relevant data, and an overall assessment of the delivery of all safety actions at least every four years as part of the requirements to review patient safety incident response plans.

Complaints and appeals

Even with ongoing engagement and involvement of affected people there may still be times when people feel dissatisfied with the response the Trust has provided following a learning review. In this event; It is the Trust's responsibility to seek early resolution to any issues raised, in line with the NHS Complaint Standards.

- Initially there should be a discussion between the affected person and their lead contact.
- If they are unable to resolve the issues this should be escalated to a patient safety specialist who will meet with the dissatisfied affected person.
- In the event that this resolution is unsuccessful the patient safety specialist will support the affected person to log a formal complaint through the Trust via the Patient Experience pathway.
- This pathway will enable access to the complaints appeal process and the Parliamentary Ombudsman

Appendix One: EQUALITY IMPACT ASSESSMENT TOOL

Name of document	Patient Safety Incident Response Policy
Division/Directorate and service area	Corporate, Nursing and Professions
Name, job title and contact details of person completing the assessment	Robert Mann Associate Director for Safety and Quality, Patient Safety Specialist robert.mann@nhs.net
Date completed:	12 September 2023

The purpose of this tool is to:

- **identify** the equality issues related to a policy, procedure or strategy
- **summarise the work done** during the development of the document to reduce negative impacts or to maximise benefit
- **highlight unresolved issues** with the policy/procedure/strategy which cannot be removed but which will be monitored, and set out how this will be done.

1. What is the main purpose of this document?

This Policy sets out the approach to managing and learning from patient safety events, and establishing a trust wide approach to patient safety improvement

2. Who does it mainly affect? *(Please insert an "x" as appropriate:)*

Carers ☐ Staff ☒ Patients ☒ Other (please specify)

3. Who might the policy have a 'differential' effect on, considering the "protected characteristics" below? (By *differential* we mean, for example that a policy may have a noticeably more positive or negative impact on a particular group e.g. it may be more beneficial for women than for men)

Please insert an "x" in the appropriate box *(x)*

Protected characteristic	Relevant	Not relevant
Age	☐	☒
Disability	☐	☒
Sex - *including: Transgender, and Pregnancy / Maternity*	☐	☒
Race	☐	☒
Religion / belief	☐	☒
Sexual orientation – *including: Marriage / Civil Partnership*	☐	☒

4. Apart from those with protected characteristics, which other groups in society might this document be particularly relevant to… (e.g. those affected by homelessness, bariatric patients, end of life patients, those with carers etc.)?

This policy will have a significant impact on those affected by patient safety events, staff, patient and carers; as the national patient safety framework will ensure that they are involved in developing the learning responses from events. Reviews of incidents will use systems-based methodology which supports just culture principles and avoids blame.

5. Do you think the document meets our human rights obligations? ☒

Feel free to expand on any human rights considerations in question 6 below.

A quick guide to human rights:

- ***Fairness –*** *how have you made sure it treat everyone justly?*
- ***Respect –*** *how have you made sure it respects everyone as a person?*
- ***Equality –*** *how does it give everyone an equal chance to get whatever it is offering?*
- ***Dignity –*** *have you made sure it treats everyone with dignity?*
- ***Autonomy –*** *Does it enable people to make decisions for themselves?*

6. Looking back at questions 3, 4 and 5, can you summarise what has been done during the production of this document and your consultation process to support our equality / human rights / inclusion commitments?

This policy has been coproduced with patient representatives and members from partner organisations. This policy describes how the Royal Devon will enact the requirements of the NHS Patient Safety Strategy 2019. This was subject to an in-depth equality impact assessment, which will be published alongside the Strategy on the Trust Website.

7. If you have noted any 'missed opportunities', or perhaps noted that there remains some concern about a potentially negative impact please note this below and how this will be monitored/addressed.

"Protected characteristic":	
Issue:	
How is this going to be monitored/ addressed in the future:	
Group that will be responsible for ensuring this carried out:	

Appendix Two: Associated policies and procedures

Details to Follow

Appendix Three: Terms of Reference: Emerging Safety Event Panel

Emerging Patient Safety Event Panel

Terms of Reference

These Terms of Reference are used as evidence for:	
Care Quality Commission Regulation:	12, Safe Care and treatment 20, Duty of Candour
Other (*please specify)*:	NHS Patient Safety Strategy (2019) NHS Patient Safety Incident Response Framework (2022)

1. Accountability

1.1. The Emerging Patient Safety Event Panel reports to the Patient Safety Committee which is a sub-committee of the Board of Directors.

2. Purpose

2.1. The Emerging Patient Safety Event Panel will review incidents being escalated from the Divisions against the Royal Devon Patient Safety Incident Response Plan; ensuring that proportionate approaches to learn from patient safety events are being applied consistently across all clinical services.

2.2. The panel will track emerging trends in patient safety events, from a range of sources including

i. Local insight from Divisions escalating concerns
ii. Insight from Devon Patient Safety Collaborative
iii. National Insight from the Central Alerting System

3. Membership

3.1. The Emerging Patient Safety Events Panel membership shall consist of:

Trust Directors of Nursing (Chair and Deputy Chair)

Trust Medical Directors

Patient Safety Specialists

Assistant Director of Governance

Trust Risk Manager

Clinical Matron for Patient Safety

3.2. The membership will be reviewed annually, in line with updating the Terms of Reference.

3.3. Divisional Representatives will attend for a pre-arranged 15-minute timeslot to present their emerging patient safety concern to the panel.

3.4. The Chief Nursing Officer and Chief Medical Officer shall have an open invite to attend the panel, as the executive leads for patient safety. They will receive all relevant documentation for the panel.

4. A Quorum

4.1. A quorum will consist of not less than six members of the Group with at least the following members present:

- Chair or Deputy Chair (Trust Director)
- A Patient Safety Specialist
- Two other members

5. Procedures

5.1. The Emerging Patient Safety Event Panel shall appoint a secretary to prepare agendas, keep minutes and deal with any other matters concerning the administration of the Group. The secretary will be responsible for maintaining in real time the repository for the Terms of Reference, agenda, minutes and the action and attendance log on the Governance shared drive.

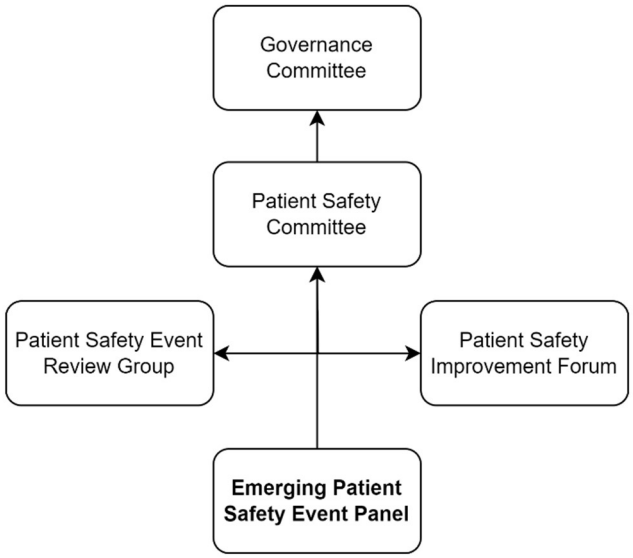
5.2. Any member of staff may raise an issue with the Chair, normally by written submission. The Chair will decide whether or not the issue shall be included in the group business. The individual raising the matter will be invited to attend.

5.3. The Chair/Deputy Chair will ensure agendas are prepared and maintain minutes and deal with any other matters concerning the administration of the group. The Chair/Deputy Chair will approve the minutes of all meetings.

5.4. The Associate Director for Safety and Quality (Insight) will prepare escalation reports from the Group to the Patient Safety Committee.

5.5. The Divisional Clinical Representatives will represent their clinical Divisions and their Divisional Governance Group within the Incident Review Group. They will be expected to provide updates from the Group to DGG.

5.6. Key reporting Structures are:



6. Frequency of Meetings

6.1. Meetings will be held weekly; the Chair can stand down the meeting if there are no specific items to review. The group will meet a minimum of 18 times per year.

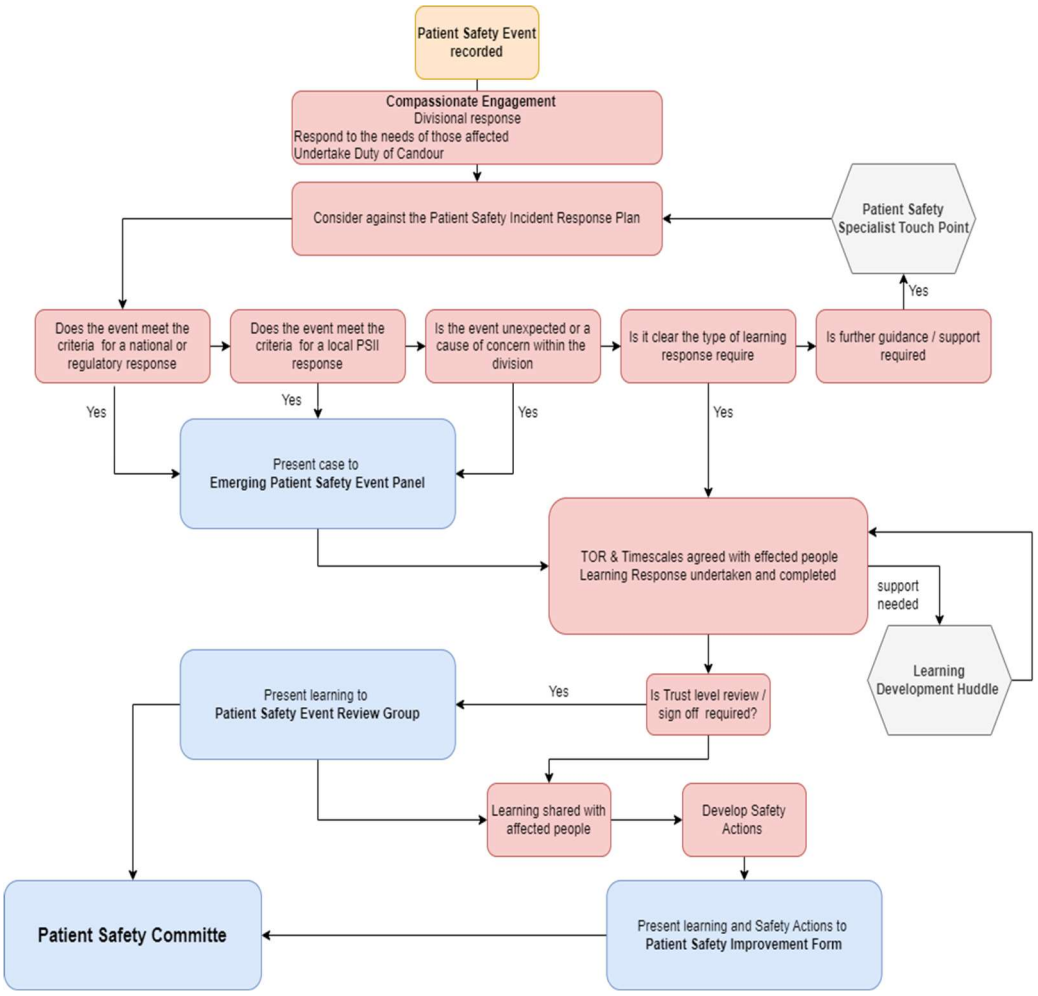
6.2. Extraordinary meetings may be called at the request of any three members of the group or at the request of the Patient Safety Committee.

7. Duties and Responsibilities

7.1.
- Receive, review and apply critical challenge to emerging patient safety events escalated from the Divisional Teams which are:
  - Events which are identified as requiring Patient Safety Incident Investigation (either national or local reporting requirements) within the Trust's Patient Safety Incident Response Plan.
  - Events which potentially meet the requirement for Patient Safety Incident Investigation (either national or local reporting requirements) within the Trust's Patient Safety Incident Response Plan.
  - The Division are seeking reassurance and advice on the appropriate proportionate response to a patient safety event.

    - The Division wish to flag an event as being of concern; or possibly indicating an emergent patient safety trend.
- To review patient safety events which may require a multi-agency or system response, and to escalate these to the integrated care board in line with the Trusts Patient Safety Incident Response Policy
- Receive regular insight reports:
    - Monthly Harm Reports of all patient safety events which have resulted in moderate or more significant harm.
    - Quarterly Low Harm Reports, of patient safety events which resulted in no or low harm
- Ensure adherence to the Trusts Patient Safety Incident Response Policy and Plan.
- Operate a systematic and proportionate approach to learning, ensuring consistency of approach across Divisions.
- To ensure that compassionate engagement has been enacted for everyone effected by a patient safety event, and where required Duty of Candour has been appropriately brokered.
- Receive alerts from the Central Alerting Service, ensuring that the Patient Safety Specialists have proportionately responded to and actioned the alert.
- To commission Safety Briefings based upon learning from events and immediate safety actions taken by teams and reported to the Group
- To receive patient safety event SPC analysis charts to review emerging trends in incidents.

7.2. **Patient Safety Event Decision Making Tree**



8. Monitoring the effectiveness of the committee/group/forum

8.1. Ensure members have attended at least 75% of meetings annually and the quorum is consistently met.

8.2. The Emerging Patient Safety Event Panel will provide an exception report to the Patient Safety Committee on themes arising from events and any concerns, risks or items of escalation for the Committee in line with the Committee reporting schedule. The Patient Safety Committee subsequently reports to the Board through the Governance Committee.

8.3. The Patient Safety Committee will review the Terms of Reference of the Emerging Patient Safety Event annually to ensure that it remains fit for purpose and is facilitated to discharge its duties.

Appendix Four: Patient Safety Event Review Group

Emerging Patient Safety Event Panel

Terms of Reference

These Terms of Reference are used as evidence for:	
Care Quality Commission Regulation:	12, Safe Care and treatment 20, Duty of Candour
Other (*please specify)*:	NHS Patient Safety Strategy (2019) NHS Patient Safety Incident Response Framework (2022)

1. Accountability

1.1. The Patient Safety Event Review Group reports to the Patient Safety Committee which is a sub-committee of the Board of Directors

2. Purpose

2.1. The Patient Safety Event Review Group will review incident investigations and learning from being escalated from the Divisions against the Royal Devon Patient Safety Incident Response Plan; ensuring that proportionate approaches to learn from patient safety events are being applied consistently across all clinical services.

2.2. The panel will track undertake the final quality review of patient safety incident investigations prior to their presentation to the Patient Safety Committee for Executive ratification.

3. Membership

3.1. The Incident Review Group membership shall consist of:

- Trust Directors of Nursing (Chair and Deputy Chair)
- Trust Medical Directors
- Patient Safety Specialists
- Patient Safety Partners
- Assistant Director of Governance
- Trust Risk Manager
- Clinical Matron for Patient Safety
- Integrated Care Board Representative

3.2. The following individuals shall be required to attend by standing invitation of the Chair to provide specialist advice to the Committee:

- Patient Safety Incident Investigators
- Staff affected / involved with an incident
- Divisional Leads for Quality and Safety
- Medication Safety Officer
- Medical Device Safety Officer
- Divisional representatives (Governance or Clinical by prior arrangement with Divisional Triumvirates)

3.3. The membership will be reviewed annually, in line with updating the Terms of Reference.

3.4. Divisional Representatives will attend with the lead investigator for a pre-arranged timeslot to present to the group. People affected will also be invited to contribute to the identification of learning. Timeslots will be:

- Presenting a patient safety incident investigation – 30 minutes
- Presenting learning from Divisional patient safety activity – 15 minutes

3.5. The Chief Nursing Officer and Chief Medical Officer shall have an open invite to attend the group, as the Executive Leads for Patient Safety.

4. A Quorum

4.1. A quorum will consist of not less than six members of the Group with at least the following members present, of which three must be clinical

- Chair or Deputy Chair
- A Patient Safety Specialist
- A Patient Safety Partner (Once appointed)
- Three other members of the Group

5. Procedures

5.1. The Patient Safety Event Review Group shall appoint a secretary to prepare agendas, keep minutes and deal with any other matters concerning the administration of the Group. The secretary will be responsible for maintaining in real time the repository for the Terms of Reference, agenda, minutes and the action and attendance log on the Governance shared drive.

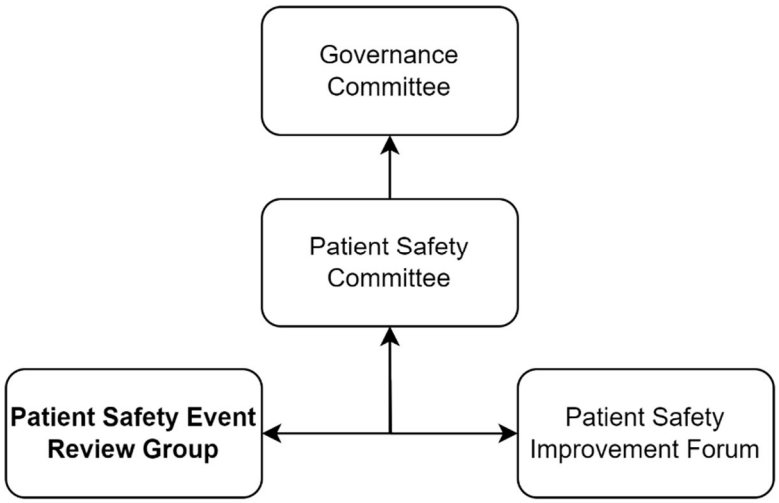
5.2. Any member of staff may raise an issue with the Chair, normally by written submission. The Chair will decide whether or not the issue shall be included in the group business. The individual raising the matter will be invited to attend.

5.3. The Chair/Deputy Chair will ensure agendas are prepared and maintain minutes and deal with any other matters concerning the administration of the group. The Chair/Deputy Chair will approve the minutes of all meetings.

5.4. A Patient Safety Specialist will prepare escalation reports from the Group to the Patient Safety Committee.

5.5. The Divisional Clinical Representatives will represent their clinical Divisions and their Divisional Governance Group within the Patient Safety Event Review Group. They will be expected to share learning identified by the Group to DGG, and for cascade to the relevant speciality governance forums.

5.6. Key reporting Structures are:



6. Frequency of Meetings

6.1. Meetings will be held every two weeks; however, the Chair can stand down the meeting if there are no specific events or learning to be discussed. The group will meet a minimum of 8 times per year.

6.2. Extraordinary meetings may be called at the request of any three members of the group or at the request of the Patient Safety Committee.

7. Duties and Responsibilities

- Receive, review and apply critical challenge to all patient safety events which meet the criteria for Patient Safety Incident Investigations (PSII) as defined in the Royal Devon Patient Safety Incident Response Plan.

- Receive, review and apply critical challenge to all legacy Serious Incidents (SI) investigation reports.
- The Group will approve PSII reports prior to escalation to the Patient Safety Committee, ensuring that:
- The report has addressed any concerns or issues raised by the people affected by the event.
- The report meets the terms of reference which were established with the Emergent Patient Safety Event Panel.
- The report has clearly identified systems-based learning and safety actions which will support transference of learning into practice
- The Group will ensure that affected people (staff, patients, family or carers) have the opportunity to attend the group (if they wish to do so) for the presentation of the investigation report into the event they were involved in.
- The Group will ensure that affected people have opportunity to comment upon the learning identified and the safety actions which have been developed.
- Identify the appropriate escalation channels for identified learning and safety actions, including:
    - Patient Safety Improvement Forum
    - Highlighting to specific Speciality or Divisional Governance forums
    - Sharing with the Integrated Care Board through escalation to the Devon and Cornwall Patient Safety collaborative.
    - Publication through iBulletin and Safety Briefings
- The Group will provide assurance to the Patient Safety Committee that the Trust is meeting its obligations under the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 regulation 20: Duty of Candour.
- The Group will act as the editorial board for iBulletin; the Royal Devon's regular patient safety newsletter.
- The Group will oversee the Trust's safety and quality systems; and act as the approving group for any local changes to Datix
- The Group will undertake a quarterly review of the Trusts Patient Safety Incident Response Plan, to ensure it is being progressed and remains fit for purpose.

8. Monitoring the effectiveness of the committee/group/forum

8.1. Ensure members have attended at least 60% of meetings annually and the quorum is consistently met.

8.2. The Patient Safety Event Review Group will provide an exception report to each Patient Safety Committee. It will escalate Patient Safety Incident Investigation reports and legacy Never Event Investigation reports to the Patient Safety Committee and subsequently reporting to the Board through the Governance Committee.

8.3. The Patient Safety Committee will review the Terms of Reference of the Patient Safety Event Review Group annually to ensure that it remains fit for purpose and is facilitated to discharge its duties.

Appendix Five: Patient Safety Committee

PATIENT SAFETY COMMITTEE

Terms of Reference

These Terms of Reference are used as evidence for:	
Care Quality Commission Regulation:	12, Safe care and treatment 17, Good governance 20, Duty of candour
Other (*please specify)*:	NHS Patient Safety Strategy (2019) NHS Patient Safety Incident Response Framework (2022)

1. Accountability

1.1 The Patient Safety Committee reports to the Governance Committee which is a Board Committee reporting to the Board of Directors.

2. Purpose

2.1 In line with national and local priorities, the Patient Safety Committee will:

2.2 Provide the strategic assurance of effective management of Patient Safety within the Trust and determines priorities for action.

2.3 Oversee the Trusts implementation of the Patient Safety Incident Response Plan and monitor compliance with the Patient Safety Incident Response Policy.

2.4 Review and ratify Patient Safety incident Investigation Reports.

2.5 Monitor the effectiveness of the Trust's Patient Safety Improvement Programme, ratifying the priorities within the plan, and seek assurance that learning is being embedded into effective quality improvement activity.

2.6 Receive reports from the sub groups (see 3.2) and report by exception, areas of risk and/or assurance to escalate to the Governance Committee.

3. Membership

3.1 The Patient Safety Committee membership shall consist of:

- Chief Nursing Officer (Co-Chair - joint accountability with CMO)
- Chief Medical Officer (Co-Chair - joint accountability with CNO)
- Chief Operating Officer
- Chief People Officer
- Trust Director of Nursing (with responsibility for Patient Safety)

- Trust Medical Directors
- Associate Medical Directors
- Associate Directors of Nursing
- Divisional Directors
- Patient Safety Specialists
- Director of Governance / Assistant Director of Governance
- Trust Risk Managers
- Patient Safety Partners
- Devon Integrated Care Board Representative

3.2 Chairs of reporting sub-groups in attendance when required as per the schedule of reports:

- Patient Safety Event Review Group (Previously Incident Review Group)
- Patient Safety Improvement Forum
- Infection Control and Decontamination Assurance Group
- Medical Devices Steering Group
- Radiation Safety Group
- Mortality Review Group

3.3 The Committee will review the membership of the Committee annually to ensure that it reflects the requirements of governance within the Trust.

3.4 The Chief Nursing Officer and Chief Medical Officer shall co-chair the Patient Safety Committee as Executive Leads with joint accountability for Patient Safety.

3.5 Individuals may be co-opted for specific projects and reports.

4. A Quorum

4.1 A quorum will consist of the Chair, and no fewer than 5 members of the Group with at least the following members present:

- Chair
- Senior Clinician: Chief Nursing Officer/Chief Medical Officer/Medical Director/Director of Nursing
- Senior Operational Manager: Chief Operating Officer/Divisional Director or nominated deputy
- One External Member i.e. Devon Integrated Care Board Representative, Patient Safety Partner

5. Procedures

5.1 The Patient Safety Committee shall appoint a secretary to prepare agendas, keep minutes and deal with any other matters concerning the administration of the Committee. The secretary shall be responsible for maintaining, real time, the repository for agendas, minutes, actions log and attendance log on the Governance Shared Drive. All meetings will be held virtually on MS Teams.

5.2 Any member of staff may raise an issue with the Chair, normally by written submission. The Chair will decide whether or not the issue shall be included in the Committee's business. The individual raising the matter may be invited to attend.

5.3 The Patient Safety Committee will provide an assurance report to the Governance Committee after each meeting.

6. Frequency of Meetings

6.1 The Committee will meet six-weekly, with no fewer than 7 meetings within a financial reporting year.

6.2 Extraordinary meetings may be called at the request of the Chair or at the request of any three members of the Governance Committee or the Chair of the Board of Directors.

7. Duties and Responsibilities

7.1 The role of the Patient Safety Committee is to:

- Develop and ensure implementation of the Trusts Patient Safety Incident Response Policy.
- Ensure, through promotion of the Patient Safety Incident Response Policy and associated documents, that responsibility for patient safety is owned and enacted by all levels of staff within the organisation.
- Provide strategic oversight and ensure implementation of the Patient Safety Incident Response Plan.
- Provide assurance to the Board of Directors via Governance Committee that the Trust is analysing patient safety insight to identify emergent patient safety trends.
- Ensure the organisation actively investigates; analyses and learns from patient safety events, including Patient Safety Incidents (PSIs) via reports from the Patient Safety Event Review Group.
- Provide strategic overview of the Trust's Patient Safety Improvement Plan.
- Provide assurance to the Board of Directors via Governance Committee that patient safety improvements are being completed in line with the Patient Safety Incident Response Plan, that action plans are in place and monitored through to completion, and that completed projects are undergoing adoption and spread.

- Provide assurance that the Trust is meeting its obligations under regulation 20 of the Health and Social Care Act (Duty of Candour).

- Provide strategic direction for the assurance of infection control, including decontamination.

- Provide reports in accordance with the Governance Committee Schedule of Reports.

- Approve procedure documents (strategies, policies, protocols and procedures) relating to Patient Safety in accordance with the Trusts Policy for the development, ratification and management of procedural documents.

8. Monitoring the effectiveness of the committee

8.1 Ensure members have attended at least 6 meetings annually and the quorum is consistently met.

8.2 Ensure that each sub-groups provide reports in accordance with the Patient Safety Committee Report Schedule.

8.3 Ensure timescales for the production of reports from the Committee to the Governance Committee are consistently met.

9. Review

9.1 The Patient Safety Committee will review the Terms of Reference (ToR) document annually to ensure that it remains fit for purpose and is best facilitated to discharge its duties, and will submit the draft ToRs to the Governance Committee for approval.