

Patient Safety Incident Response Policy

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	NAME	TITLE	DATE
Author	Paul Butler McLees		
Reviewer	James Wright		
Authoriser	Amjad Uppal	Executive Medical Director	

1 Purpose

This Policy supports the requirements of the NHS England Patient Safety Incident Response Framework (PSIRF) and sets out how Gloucestershire Health and Care NHS Foundation Trust (the Trust or GHC) 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. This will integrate the four key aims of the PSIRF:

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

We can align these to our existing Trust values. Our current Patient Safety Incident Response Plan sets out how this Policy will be implemented.

2 Scope

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. Processes, such as those listed below, are therefore outside the scope of 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).

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

3 Our patient safety culture

As a Trust, GHC is working to move towards an approach that balances accountability with psychological safety and seeks to look beyond the individuals involved, focussing on the systems and human factors that lead to harm.

The Trust's senior leadership have strongly embraced this work and activity is under way to establish the organisational transition to a restorative just learning culture.

Under the PSIRF, learning and improvement will become a fundamental aspect of the patient safety incident review. We aim to collaborate with those affected by a patient safety incident to identify and embed learning and improvement. This will support transparency and openness among our staff, improve reporting of incidents and foster a culture of engagement in learning and improvement. In future, this will include insight from positive activities, where practice has been exemplary.

We are committed to continuously improving the care and services we provide. We want to learn from any incident where care does not go as planned or expected to prevent recurrence.

We recognise and acknowledge the significant impact patient safety incidents can have on patients, their families, and carers.

We are clear that patient safety incident responses are conducted for the sole purpose of learning and identifying system improvements to reduce risk. Specifically, they are not to apportion blame, liability or define avoidability or cause of death.

We will use findings from staff surveys to assess our improving safety culture.

4 Patient Safety Partners

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

At GHC, we have welcomed PSPs who 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).

PSPs will provide objective feedback on patient safety improvements. They may attend governance meetings and risk and quality forums, review patient safety practice, and contribute to policies, investigations, and reports. As the role evolves, PSPs may participate in the investigation of patient safety events, assist in the implementation of patient safety improvement initiatives and develop patient safety resources. We will provide training and support specific to this new role.

The PSPs will be supported by the Trust's Patient Safety Specialist, who will set expectations and provide guidance.

The PSP positions are on an honorary basis and will be reviewed after 1 year to ensure the role remains aligned to the developing patient safety agenda.

5 Addressing health inequalities

Improving access to services and tailoring those services to the needs of the local population in an inclusive way will help address health inequalities.

We will use data intelligently to assess for disproportionate patient safety risks to patients across the range of protected characteristics. This is in line with our statutory obligations under the Equality Act (2010).

Within our patient safety response toolkit, we will directly address whether particular features of an incident suggest health inequalities, including protected characteristics, may have contributed to harm or demonstrate a risk to a particular group. We will consider inequalities when constructing our safety actions in response to an incident, and this will be reflected in our documentation and governance processes.

Engagement of the patient, family and staff following a patient safety incident is critical to the review of patient safety incidents. We will ensure that we use available

tools, such as easy read, and translation and interpretation services, to support access to our processes.

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

The PSIRF recognises that learning and improvement following a patient safety incident can only be achieved if supportive systems and processes are in place. We will work with those affected by patient safety incidents to understand and answer their questions about the incident and signpost them to support as required.

A network of Family Liaison Practitioners within the Patient Safety Team are available to guide patients, families and carers through the learning response and signpost resources and organisations that can provide specialist support.

In addition, the Patient and Carer Experience Team will support with concerns and complaints that fall outside the learning response.

7 Patient safety incident response planning

The PSIRF supports organisations to respond to incidents and safety issues in a way that maximises learning and improvement, rather than basing responses on arbitrary and subjective definitions of harm. We are able to explore patient safety incidents relevant to our context and the populations we serve. Additionally, we are mandated to review specific types of incident. Our Patient Safety Incident Response Plan details how we will achieve both these elements.

7.1 Resources and training to support patient safety incident response

The NHS England Patient Safety Response Standards (2022) sets out the resources and training required for implementation of the PSIRF.

A Learning Response Lead will be nominated in the Patient Safety Team to lead the technical aspects of the learning response. This individual will have an appropriate level of seniority and influence within the Trust – this may depend on the nature and complexity of the incident and response required, but typically learning responses will be led by staff at Band 7 and above. The Senior Leadership Team of the relevant

Service is responsible for proposing colleagues within that Service to support the learning response as subject matter experts.

Governance arrangements will ensure that learning responses are not undertaken by staff working in isolation. The Patient Safety Team will support learning responses and can provide advice on cross-system and cross-service working where this is required.

Those staff affected by patient safety incidents will be afforded the necessary managerial support and be given time to participate in learning responses. All Trust managers will work within the principles of a just and restorative culture and utilise Working Well and The Wellbeing Line to support engagement and involvement.

The Trust will utilise both internal and, if required, external subject matter experts throughout the learning response to provide expertise (for example, clinical or human factors review), advice and proofreading.

7.2 Training and competencies

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

7.2.1 General

7.2.1.1 Level one (*internal*)

This comprises a local incident e-learning module, available via Care 2 Learn, setting out the Trust's expectations of staff for reporting and responding to incidents, including an outline of staff responsibility for duty of candour. This aligns with the National Patient Safety Syllabus.

All staff, clinical and non-clinical, are expected to undertake this on induction, repeating every 3 years.

7.2.1.2 Level two (*national*)

Health Education England patient safety syllabus module (Access to Practice) is to be undertaken by all clinical staff at AFC Band 6 or above who may be asked to support or lead learning responses. This module is available as e-learning on Care 2 Learn.

7.2.2 Learning Response Leads

Any Trust learning response will be led by those who have had a minimum of 2 days of formal training and skills development in learning from patient safety incidents

and experience of learning response. Records of such training will be maintained by the Learning and Development Team as part of general education governance processes.

Learning Response Leads will have completed levels one and two of the National Patient Safety Syllabus.

Learning response leads will undertake appropriate continuous professional development on incident response skills and knowledge.

To maintain expertise, the Trust will undertake an annual networking event for all Learning Response Leads via the Senior Leadership Network.

Learning Response Leads will need to contribute to a minimum of two learning responses per year. Records of this will be maintained by the relevant Service.

As a Trust, we expect staff leading learning responses to:

- apply the principles of human factors and systems thinking to gather qualitative and quantitative information from a range of sources
- summarise and present complex information in clear and logical reports
- manage conflicting information from different internal and external sources
- communicate highly complex matters in potentially challenging situations.

Support for those new to this role will be offered by the Patient Safety Team.

7.2.3 Family Liaison Practitioners

Family Liaison Practitioners (FLPs) will have undergone a minimum of 6 hours' training (such as the duty of candour training or safety reviewer training from the Patient Safety Team).

Records of training will be maintained by the Learning and Development Team as part of the general education governance processes.

FLPs must have complete levels one and two of the National Patient Safety Syllabus.

FLPs will undertake appropriate continuous professional development on learning response skills and knowledge.

To maintain expertise, the Trust will undertake an annual networking event for all FLPs via our Trustwide leadership forums.

FLPs will need to contribute to a minimum of two learning responses per year. Records for this will be maintained by the Patient Safety Team and supported by Service Directors.

As a Trust, we expect FLPs to:

- 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.

Oversight roles

All patient safety response oversight will be led by those with a minimum of 2 days' formal training and skills development in learning from patient safety incidents and 1 day's training in oversight of learning from patient safety incidents. Records of such training will be maintained by the Learning and Development Team as part of general education governance processes.

Our Executive Leads will have completed the appropriate modules from the National Patient Safety Syllabus: Level one (essentials of patient safety and essentials of patient safety for boards and senior leadership teams).

All those with an oversight role in relation to the PSIRF will undertake continuous professional development in incident response skills and knowledge, and network with peers at least annually to build and maintain their expertise.

As a Trust, we expect staff with oversight roles to:

- be inquisitive, with sensitivity (that is, know how and when to ask the right questions to gain insight about patient safety improvement)
- understand the principles of human factors and systems thinking
- constructively challenge the strength and feasibility of safety actions to improve underlying systems issues.

8 Patient Safety Incident Response Plan

Our Patient Safety Incident Response Plan describes how the Trust intends to respond to patient safety incidents over a period of 12 months. The Plan is not a permanent set of rules that cannot be changed. We will remain flexible and consider the specific circumstances in which each patient safety incident occurred and the needs of those affected.

8.1 Reviewing the Policy and Plan

Our Patient Safety Incident Response Plan is a 'living document' that will be appropriately amended and updated as we use it to respond to patient safety incidents. We will review the Plan every 12 months to ensure our focus remains up to date. With ongoing improvement work, our patient safety incident profile (see below) 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 months.

The updated Plan will replace the previous version on the GHC website.

A rigorous planning exercise will be undertaken every 4 years, and more frequently if appropriate (as agreed with our integrated care board [ICB]), to ensure we continue to focus on areas where we can learn the most from patient harm. This 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.

9 Responding to patient safety incidents

9.1 Safety incident reporting arrangements

All staff are responsible for reporting potential and actual patient safety incidents on a Trust incident-reporting system (currently Datix) and recording the level of harm they know has been experienced by the person affected.

Services will have daily review mechanisms in place to ensure a proportionate and prompt response to patient safety incidents. Duty of candour should be considered and highlighted to teams (see Trust policy). Most incidents will only require local review within the Service. However, incidents that present a significant opportunity for learning and improvement should be escalated within the Service (see section on decision-making below).

Services will highlight to the Patient Safety Team any incident that appears to meet the requirement for external reporting.

The Patient Safety Team will liaise with external bodies and partner providers to ensure effective communication.

9.2 Decision-making for patient safety incident responses

The Trust will have arrangements in place to allow it to meet the requirements for review of patient safety incidents under PSIRF. Some incidents will require mandatory PSII, others will require review by, or referral to, another body or team depending on the incident. These are set out in our patient safety incident response plan.

PSIRF itself sets no further national rules or thresholds to determine the method of response to support learning and improvement. The Trust has developed its own response mechanisms to balance learning from incidents with exploration of issues and improvement work. In the work to create our Plan, we considered our local patient safety incident profile, which draws on insight from incidents and engagement with key internal and external stakeholders. We have used this intelligence to build our local priorities for PSII and our toolkit for responding to other patient safety incidents.

We have established a process for our response to incidents that supports clear 'Ward to Board' mechanisms for oversight of incident management and learning response.

Services will have escalation arrangements in place for monitoring patient safety incidents, including daily escalation of incidents that meet the need for rapid review. These are incidents that potentially meet PSII criteria, trigger other processes, or present an opportunity for learning and improvement or an unexpected level of risk.

The Trust's Patient Safety Panel will have delegated responsibility for oversight of the outcomes of these rapid reviews. They will ensure that recommendations are founded on a systems-based approach and safety actions are valid and contribute to existing safety improvement plans or the establishment of such plans if necessary.

The Trust's Executive will have overall oversight of these processes and will challenge the Patient Safety Panel's decision-making. In this way, the Board will be assured that the principles of the PSIRF are being followed and we are meeting the national Patient Safety Incident Response Standards.

Any incident highlighted will follow the process described in the following sections (see also Appendix).

9.2.1 Local level incidents

Services will have arrangements in place to ensure staff can report and respond to incidents. Incident responses should include immediate actions to ensure the safety of patients, the public and staff, and the identification of measures needed to mitigate a problem until further review is possible. This may include, for example, withdrawing equipment or monitoring a procedure.

Any response to an incident should be fed back to those involved or affected and appropriate support offered. Where duty of candour applies, this will be carried out according to Trust guidance.

The Patient Safety Panel may commission thematic reviews of such incidents to consider and understand potential emerging risks.

9.2.2 Incidents with positive or unclear potential for PSII

All staff (directly or through their line manager) will ensure that incidents that may require a higher level of response are notified as soon as practicable after the event through Service escalation processes (including out of hours); the notification must include the Service operations and governance personnel. Duty of candour disclosure should take place according to Trust guidance. Where it is clear that a PSII is required (for example, for a never event), the Service should notify the Patient Safety Team as soon as practicable so that the incident can be shared with Executive-level staff.

Other incidents with unclear potential for PSII will also be reported to the Patient Safety Team. Decision-making about escalation will be considered at the next Patient Safety Panel meeting. The Service will undertake a rapid review to inform this decision-making. Significant incidents that suggest an unexpected level of risk and/or potential for learning, and may require an ad-hoc PSII, should be included in this category.

The Trust Patient Safety Panel will meet at the earliest opportunity to discuss the nature of any escalated incident, immediate learning (which should be shared via an appropriate platform), any mitigation identified by the rapid review or that is still required to prevent recurrence and whether the duty of candour requirement has been met. The Panel will define the terms of reference for a PSII, which will be undertaken by an appropriate member of the Patient Safety Team. The panel will also identify the subject matter expert input required for any investigation or highlight

any cross-system working that may be necessary, as well as indicating how immediate learning should be shared.

Where an incident does not require a PSII, the Patient Safety Panel may request a patient safety review (PSR) or closure of the incident at a local level, with due consideration of any duty of candour requirements. It will be at the Panel's discretion in such circumstances to specify that a particular tool should be used to complete the PSR and how immediate learning should be shared.

9.2.3 Incidents that may require PSR

All staff (directly or through their line manager) should ensure that incidents that may require a PSR are notified as soon as practicable after the event through Service escalation processes (including out of hours) and this must include the Service Director and Associate Service Director. A rapid review will be undertaken by the Service to inform decision-making following this.

The Patient Safety Panel will meet at the earliest opportunity to discuss the nature of the incident, immediate learning (which should be shared via an appropriate platform), any mitigation needed to prevent recurrence and whether the duty of candour requirement has been met.

Where it is clear that a PSII is not required, the Patient Safety Panel will consider any incident as having potential for a PSR. They will identify the tool to be used and allocate a suitable colleague within the Service to undertake the review. This will not be any staff member involved in the incident or their immediate line manager. The Service will also specify any subject matter expert input required. The decision-making will be clearly recorded.

The Patient Safety Panel will ensure safety actions arising from PSRs and other learning responses are recorded and used to inform safety improvement plans.

The Patient Safety Team will have processes in place to communicate and escalate necessary incidents within NHS commissioning and regional organisations and the CQC, according to accepted reporting requirements. While this will include some incidents escalated for PSII, the Patient Safety Team will work with Services to have effective processes in place to ensure that any incidents meeting external reporting needs are appropriately escalated.

9.2.4 Trust Executive Patient Safety Group

The Trust will establish and maintain a clinical Executive-led Patient Safety Group to oversee the operation and decision-making of the Trust Patient Safety Panel and the

incident responses it commissions. This will support the final sign-off process for all PSIs. Through this mechanism, the Board will be assured that it meets expected oversight standards and understands the ongoing and dynamic patient safety and improvement profile of the Trust.

9.3 Responding to cross-system incidents/issues

The Patient Safety Team will forward details of incidents identified as presenting potential for significant learning and improvement for another provider directly to that organisation's patient safety team or equivalent. Where required, summary reporting will be used to share insight with another provider.

The Trust will work with partner providers and the relevant ICBs to establish and maintain robust procedures to facilitate the free flow of information and minimise delays to joint working on cross-system incidents. The Patient Safety Team will act as the liaison point for such working and have operating procedures that support effective management.

The Trust will defer to the ICB for co-ordination of a cross-system incident too complex to be managed by a single provider. We anticipate that the ICB will identify a suitable reviewer in such circumstances and agree how the learning response will be led and managed, how safety actions will be developed, and how the implemented actions will be monitored for sustainable change and improvement.

9.4 Timeframes for learning responses

9.4.1 PSIs

Where a PSI for learning is indicated, the investigation should be started as soon as possible after the incident is identified and ordinarily be completed within 3 months of the start date. No local PSI should take longer than 6 months.

The timeframe for completing a PSI will be agreed with those affected by the incident, when the terms of reference are set, provided they are willing and able to be involved in that decision. A balance must be drawn between conducting a thorough PSI, 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.

If a partner organisation requests that an investigation is paused, or the processes of an external body delay access to information, the Patient Safety Panel can consider whether to progress the PSI and determine whether further investigative activity is

necessary once the outstanding information becomes available or the external body is in a position to contribute.

In exceptional circumstances, a longer time may be required to complete a PSII. In this case, the extended timeframe should be agreed between the Trust and those affected.

9.4.2 Other learning responses

A learning response should be started as soon as possible after the incident is identified and should ordinarily be completed within 3 months of the start date. No learning response should take longer than 6 months to complete.

9.5 Safety action development and monitoring improvement

Any form of patient safety learning response should allow the circumstances of an incident or set of incidents to be understood, but this is only the beginning. To reliably reduce risk, clear and practicable safety actions are needed.

We will have systems and processes in place to design, implement and monitor safety actions using an integrated approach to reduce risk and limit the potential for future harm. This process continues from the learning response, which may identify changes to working systems that could reduce risk and potential for harm ('areas for improvement'). The Trust will generate time-specified safety actions, with defined measures, for each area for improvement. These will be monitored and reviewed.

The learning response should not describe recommendations, as this can lead to premature attempts to devise a solution. Safety actions that arise from an area for improvement depend on factors and constraints outside of the scope of a learning response. To achieve successful improvement, safety actions will be developed in a collaborative way, with a flexible approach from Services and the support of the Quality Improvement Team.

9.5.1 Development

We will use the process for developing safety actions outlined by NHS England in the Safety Action Development Guide (2022) as follows.

- Agree areas for improvement – specify where improvement is needed, without defining solutions
- Define the context – this will allow agreement on the approach to be taken to safety action development

- Define safety actions to address areas of improvement – focussed on the system and in collaboration with teams involved
- Prioritise safety actions to decide on testing for implementation
- Define safety measures to demonstrate whether the safety action is influencing what is intended as well as setting out responsibility for any resultant metrics
- Safety actions will be clearly written, follow SMART principles and have a designated owner.

9.5.2 Monitoring

Safety actions will continue to be monitored within the Service governance arrangements to ensure actions remain impactful and sustainable. Service reporting on progress with safety actions, including the outcomes of measures, will be made to the Quality Advisory Group. Safety actions with wider significance may require oversight by the Board.

9.6 Safety improvement plans

Safety improvement plans bring together findings from various responses to patient safety incidents and issues. Several overarching safety improvement plans are in place that are adapted to respond to the outcomes of improvement efforts and other external initiatives, such as national safety improvement programmes or CQUINs.

The Patient Safety Incident Response Plan outlines the local priorities for focus of investigation under the PSIRF. These offer opportunities for learning and improvement across areas where there is no existing plan or where improvement efforts have not reduced apparent risk or harm.

We will use the outcomes from existing PSRs and relevant learning responses conducted under the PSIRF to create related safety improvement plans to help to focus improvement work. Services will work collaboratively with the Patient Safety and Quality Improvement Teams and others to ensure an aligned approach.

A safety improvement plan will be developed where learning responses identify overarching systems issues outside of our local priorities. These will be identified through Service governance processes and reporting to the Quality Assurance Group, which may commission a safety improvement plan. Again, Services will work collaboratively with the Patient Safety and Quality Improvement Teams and others to ensure an aligned approach.

10 Oversight roles and responsibilities

10.1 Principles

Under the PSIRF, organisations design oversight systems to demonstrate improvement, rather than compliance with centrally mandated measures.

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

To meet these responsibilities, the Executive Medical Director will support the PSIRF as the Executive Lead.

10.1.1 Ensuring the Trust meets the National Patient Safety Standards

The Executive Medical Director will oversee the development, review and approval of the Policy and Plan, ensuring they meet the expectations set out in the Patient Safety Incident Response Standards.

The Patient Safety Team will be responsible for the ongoing development of the Plan and Policy. The work will be led by the Head of Patient Safety and Learning, who will report to the Executive Medical Director.

To continue to define our patient safety and safety improvement profile, we will undertake a thorough review of available patient safety incident insight and engagement with internal and external stakeholders.

10.1.2 Ensuring that the PSIRF is central to overarching safety governance arrangements

The Board will receive assurance regarding the implementation of the PSIRF and associated standards via existing reporting mechanisms, such as the Quality Committee and Executive Team. Safety reporting will comprise oversight question responses to ensure the Board has a formative and continuous understanding of organisational safety.

The Patient Safety Group will provide assurance to the Quality Assurance Group (QAG) and from there to the Quality Committee that the PSIRF and related workstreams have been implemented to the highest standards. Services will be expected to report on their patient safety incident learning responses and outcomes. This will include reporting on ongoing monitoring and review of the patient safety incident response plan and delivery of safety actions and improvement.

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

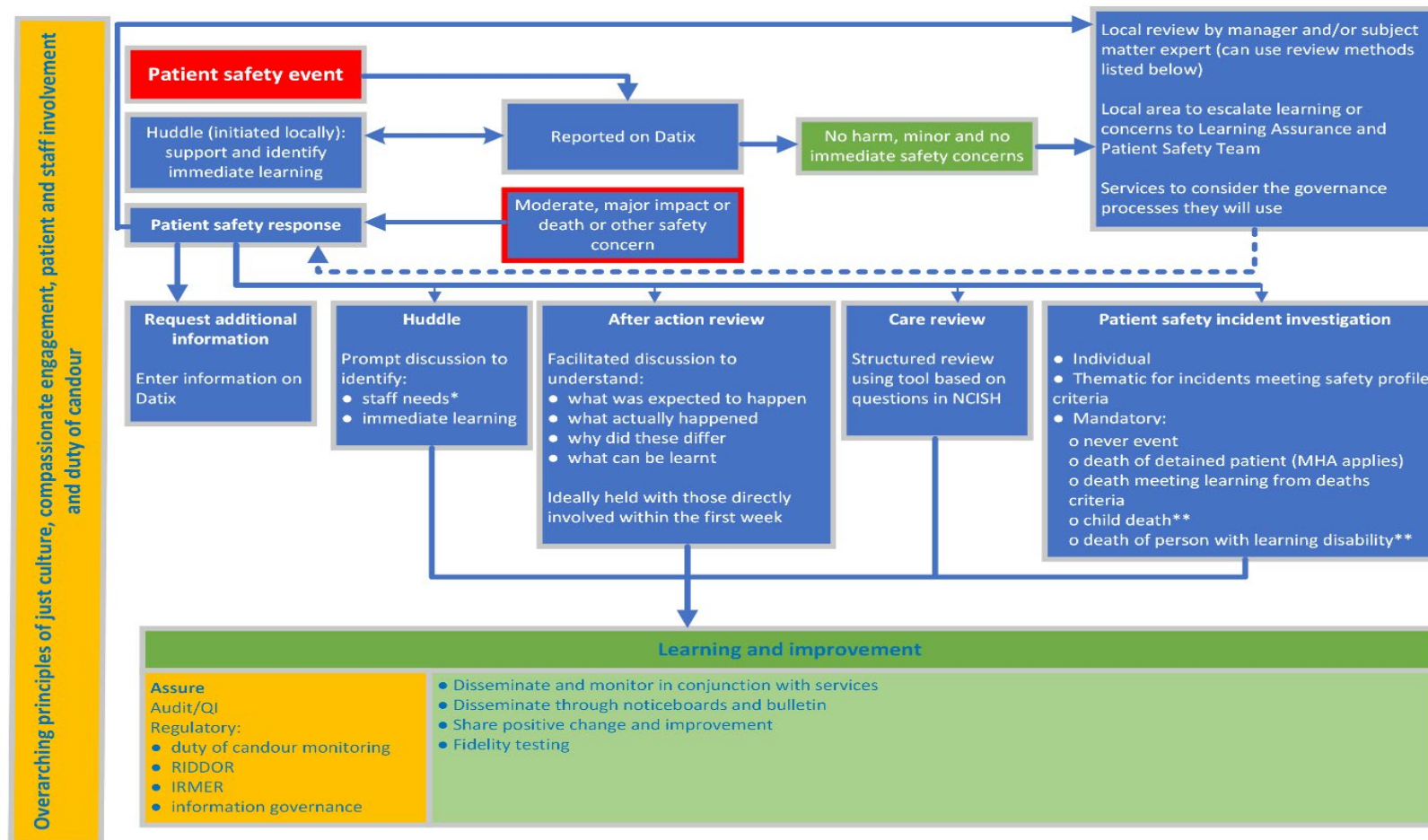
We will source and provide training, such as the Health Education England patient safety syllabus, across the organisation as appropriate to the roles and responsibilities of staff in supporting an effective organisational response to incidents.

Updates will be made to this Policy and the associated Plan as part of regular oversight. A review of this Policy and associated Plan should be undertaken at least every 3 years to comply with Trust guidance on policy development.

10.1.3 Quality assuring learning response outputs

A central Patient Safety Panel will ensure that PSIs are conducted to the highest standard, support the Executive sign-off process and ensure learning is shared and safety improvement work is adequately directed.

Appendix: Response to patient safety event



IRMER, Ionising Radiation (Medical Exposure) Regulations 2017; NCISH, National Confidential Inquiry into Suicide and Safety in Mental Health; QI, quality improvement; RIDDOR, Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013

References and resources

- NHS England (2021) [Core20PLUS5: An Approach to Reducing Health Inequalities](#)
- NHS England (2022) [Patient Safety Incident Response Standards](#)
- NHS England (2022) [Safety action development guide](#)
- [National guidance for NHS trusts engaging with bereaved families](#)
- Learning from deaths: Information for families explains what happens after a bereavement (including when a death is referred to a coroner) and how families and carers should comment on care received
www.england.nhs.uk/publication/learning-from-deaths-information-for-families