Royal Papworth Hospital NHS Foundation Trust

Document title: **Patient Safety Incident Response Framework (PSIRF) Policy**

Document number: **DN665**

Staff involved in Development (job titles):	Patient Safety Lead Clinical Governance Officer Assistant Director for Quality and Risk Associate Medical Director for Clinical Governance Clinical Governance Manager
Document author/owner:	Assistant Director for Quality and Risk
Directorate:	Nursing
Department:	Clinical Governance and Risk
For use by:	Trust-wide
Review due:	August 2026

Key points of this document

- This policy sets out the requirements of the Patient Safety Incident Response Framework (PSIRF) at Royal Papworth Hospital Foundation Trust.
- This policy should be read with the annual DXxxx Patient Safety Incident Response Plan (PSIRP) on how PSIRF is being implemented.

Contents

1. Introduction

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

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

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

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

This Patient Safety Incident Response Framework Policy should be read in conjunction with DN070 Procedure for Reporting Accidents/Adverse Events/ Incidents and Defects. Other relevant policies and procedures are detailed in the policy.

2. Objectives / Aims

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. Under this policy, response to patient safety incidents will follow a system-based approach recognising that safety is provided by interactions between different sources, and that learning does not take a 'person-focused' approach where the actions or omissions of people, or 'human error', are stated as the cause of an incident.

The following principles underpin our oversight of patient safety incident responses:

- Improvement is the focus.
- Blame restricts insight.
- Learning from patient safety incidents is a proactive step towards improvement.
- Collaboration is key.
- Psychological safety facilitates learning.
- Curiosity is powerful.

This system-based approach considers all of the interactions that may contribute to a patient safety event (e.g., person(s), tasks, tools and technology, the environment, the wider organisation etc.) and recognises that it is insufficient to look at only one element, such as the people involved. A system-based approach will identify where changes need to be made and then monitor these to improve patient safety.

3. Scope

This policy is specific to patient safety incident responses conducted solely for the purpose of learning and improvement across the Trust. It sets out our approach for responding to patient safety incidents and issues.

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.

4. Our Patient Safety Culture

The Trust organisational safety culture is reflected and incorporated with the Trust Strategy for 2020-2025 and with the Trusts values (see below), further details can be found on the Trust intranet.

Our values table:

Compassion	-	**Recognises and responds to the needs of patients and colleagues**
Excellence	-	**Makes a difference with each small improvement and by being open to new ways of working**
Collaboration	-	**We achieve more together**

We all have a part to play in offering the best patient and employee experience we possibly can, the key factors are:

- Continuous learning and improvement of safety risks
- Supportive, psychologically safe teamwork
- Enabling and empowering speaking up by all

Compassionate and Collective leadership is our underpinning principle. By supporting openness and inclusivity when safety incidents occur, it allows valuable lessons to be learnt so the same errors can be prevented from being repeated. Adopting a system-based approach stops us blaming and promotes wider organisation learning. It will help us to identify where changes need to be made and then monitor these and will ensure the delivery of an effective patient safety incident learning response that is meaningful, proportionate and we will ensure a Just Culture is core part of the response.

Professor Sir Norman Williams's Review into Gross Negligence Manslaughter in Healthcare report (2018) stated 'A just culture considers wider systemic issues where things go wrong, enabling professionals and those operating the system to learn without fear of retribution'. Our emphasis will be continuing to develop further our *'Just Culture'* of trust and respect, in which openness, transparency and learning is valued, encouraged and supported. Supporting staff to be open about mistakes allows valuable lessons to be learnt so the errors can be prevented from being repeated.

We are committed to continue building on our strong foundations of the Just Culture principles already embedded in our review of patient safety incidents and we will be launching an awareness campaign as part of the roll out of this new policy and our first annual plan. , It will focus on up to date training in Just Culture and on renewed awareness on the three core principles of embedding a Just Culture as part of our implementation of PSIRF with openness, transparency and learning being core.

Where required Trust line managers are encouraged to use the NHS England guide to support conversations between managers about whether a staff member involved in a patient safety incident requires specific individual support or intervention to work safely. The guide can be found on the NHS England website and on the Trust Website NHS_0932_JC_Guide_A3 (england.nhs.uk), with support being provided by the Trusts Human Resources team.

When an individual under our care comes to harm. Duty of Candour will be applied, and an apology will be provided in line with the Trust's DN153 Being Open and Duty of Candour Policy.

PSIRF will enhance and support our culture in creating much stronger links between a patient safety incident and learning and improvement. We aim to work in collaboration with those affected by a patient safety incident – staff, patients, families, and carers - to arrive at such learning and improvement within the culture we hope to foster. This will continue to increase

transparency and openness amongst our staff in reporting of incidents and engagement in establishing learning and improvements that follow. This will include insight from when things have gone well and where things have not gone as planned.

5. Duties, Roles and Responsibilities

Chief Executive and Board of Directors
Our principal accountability is to patients, their families, and carers. The Board also takes responsibility for leading and role modelling the development of a just, open and learning culture.

Chief Nurse and Medical Director
The executive leads are the Chief Nurse and Medical Director who have responsibility for ensuring an appropriate incident management system exists and is adhered to. That there is an embedded process through our Patient Safety Incident Response Framework Implementation Plans for the recognition, reporting and monitoring of incidents, and for effective governance and learning.

They support the formation and implementation of the Quality Strategy, taking a lead on clinical standards in relation to the quality and safety of care, and providing clinical advice to the Board.

The Serious Incident Executive Review Panel has responsibility for defining and verifying an adverse event as a Patient Safety Incident Investigation (PSII) as part of the patient safety incident response plan. The Chief Nurse and Medical Director are the executive leads for this panel.

Patient Safety Specialists (PSS)
Patient Safety Specialists are responsible for overseeing the development and implementation of the patient safety incident policy and response plan (PSIRP), they will ensure that the appropriate patient safety investigations are undertaken and that there are sufficient resources to support delivery (including support for those affected, such as named contacts for staff, patients / service users, families and carers where required). The Trust has three named PSS, Associate Medical Director for Clinical Governance, Assistant Director for Quality and Risk and Clinical Governance Manager.

Clinical Directors, Heads of Nursing, Divisional Operational Directors and other Trust wide Teams and Divisional leads (e.g Pharmacy, estates)
Ensure that incidents are reported and managed in line with internal and external requirements. Ensure that they and their staff are familiar with the PSIRF, patient safety incident response plan and policy and support the development and delivery of actions in response to patient safety reviews and investigations that relate to their area of responsibility. Provide protected time for participation in reviews / patient safety investigations as required.

Work with teams to ensure those affected by patient safety incidents have access to the support they need.

Clinical Governance Team
Will support the Assistant Director for Quality and Risk and Associate Medical Director for Clinical Governance on leading on patient safety across the Trust.

The team will ensure all reported incidents are appropriately reviewed and graded on the Trust central database (Datix) for trend analysis and reporting purposes and will ensure all incidents are effectively reviewed and investigated and appropriate actions are identified and followed up for completion.

Will ensure all relevant incidents are promptly reported and actions undertaken in line with the requirements of the relevant Trust policies, Procedure and Serious Incident Executive Review Panel (TOR). The team will also ensure all external reporting of incidents is completed where required including reporting of all patient incidents within the required timescales.

Will develop and maintain local risk management systems and relevant incident reporting systems.

Will support Assistant Director for Quality and Risk and Associate Medical Director for Clinical Governance on leading on patient safety across the Trust and are responsible for providing patient safety investigation expertise, training, providing support to all our teams and services in relation to all patient safety incidents requirements.

Learning Response Leads
Learning responses will be led by learning response leads (previously termed investigators) who have experience and training in conducting patient safety incident responses and in the involvement and engagement of those affected.

Patient Safety Partners (PSP)
The PSP is a new and evolving role developed by NHS England and NHS Improvement to help improve patient safety across the NHS. The main purpose of the role is to be a voice for people who use NHS services and ensure that patient safety is at the forefront of all that we do.

The Trust's PSP's will be volunteer role which will report to the Patient Safety Lead (or a suitable deputy) on a daily basis when they are on site and who will provide expectations and guidance for the role. The oversight for these roles will be provided by the Trust's Patient Safety Specialists (PSS).

They will be responsible for undertaking the training required to the national standard for their role as specified in the National Patient Safety Syllabus as well as other relevant training.

All Staff
Understand their responsibilities in relation to the patient safety incident response plan, policy and PSIRF and act accordingly. All staff have a responsibility to highlight any risk issues which would warrant further investigation. Staff should be fully open and co-operative with any patient safety review process.

All staff are responsible for ensuring they understand their responsibilities on how and when to report all adverse events and other dangerous occurrences to their line manager or other suitable senior person, as soon as possible after the patient safety incident, in line with DN070. All employees are required to be familiar with the Duty of Candour as detailed in the Trust's DN153 Being Open and Duty of Candour Policy on how information is to be shared with patients and/or their relatives.

Staff are to complete the mandatory required online training aligned to their role provided by the Trust through Electronic Staff Records (ESR). This is required to be updated on a 3 yearly basis and staff should attend other training on information regarding the reporting and management of incidents for their role as required - this will be offered through regular Datix training education session provided by the Clinical Governance Team and supported by Education Team.

Commissioners and commissioning organisations
Commissioners and commissioning organisations (including NHS England, NHS Improvement and the ICB) are required to:

- Ensure that they are familiar with the PSIRF and consider how their roles and responsibilities will evolve to meet its requirements.
- Assess effectiveness of systems and processes to respond to patient safety incidents in NHS-funded provider services, as demonstrated by the behaviours of openness and transparency, the existence of a just culture, and evidence of continuous learning and improvement.
- Support and enable co-ordination of cross-system review and/or investigation where activity cannot be managed at the provider level because the incident is unusually complex, difficult, or costly to manage due to multiple providers and/or services being involved across a care pathway.
- Provide improvement support where needed to support a provider's systems and processes for responding to patient safety incidents.
- Share insights and information between organisations/services that have demonstrably improved care and or reduced risk.

Commissioners of NHS services
Commissioners of NHS services will:

- Assure effective application of local PSIRPs and national patient safety investigation standards with local system leaders.
- Ensure monitoring and annual review of the PSIRP forms part of the overarching quality governance arrangements and is supported by clear

financial planning to ensure that appropriate resources are allocated to review, investigation and improvement activities.
- In line with recommendations, ensure where a regulator or oversight organisation has concerns regarding the safety of NHS-commissioned services, additional information and assurance is sought from the provider. If this involves the commissioning of an independent investigation or review, this will be additional to those in the provider's PSIRP.

6. Training and Competency

Learning Response Training
Learning response leads will have completed the mandatory level 1 (essentials of patient safety), and level 2 (access to practice) of the patient safety syllabus on the Trusts Electronic Staff Records (ESR) system. This mandatory training is to be repeated every 3 years. Further initial training will be provided for skills development in learning from patient safety incidents / safety events (sourced and provided by the Trust in conjunction with the Integrated Care System (ISC). In addition to this formal training, continuous professional development in incident response skills and knowledge will be provided by the Trust. Once trained they will contribute to a minimum of two learning responses per year.

All our staff leading learning responses will be able to:
- Apply human factors and systems thinking principles to gather qualitative and quantitative information from a wide range of sources.
- Summarise and present complex information in a clear and logical manner and in report form.
- Manage conflicting information from different internal and external sources.
- Communicate highly complex matters and in difficult situations.

Engagement and Involvement Training
Engagement and involvement with those affected by patient safety incidents will be led by learning response leads who will have had at least six hours of training in involvement and engagement.

In addition, competencies and behaviours include:
- Communicating and engaging with patients / service users, families, staff, and external agencies in a positive and compassionate way.
- Listening and hearing the distress of others in a measured and supportive way.
- Maintaining clear records of information gathered and contact with those affected.
- Identifying key risks and issues that may affect the involvement of patients / service users, families, and staff.
- Recognising when those affected by patient safety incidents require onward signposting or referral to support services.

Oversight training
All patient safety incident response oversight is led / conducted by those with at least two days formal training and skills development in learning from patient safety incidents, and one day training in oversight of these.

7. Patient Safety Partners

The NHS Patient Safety Strategy promotes the involvement of patients / service users, families, and carers as partners both in their own care and in the wider oversight of healthcare and introduces a new role to the NHS in the form of Patient Safety Partner (PSP) roles.

A Patient Safety Partner is a volunteer (sessional payments will be able to be claimed for part of their work) who is actively involved in how we learn from patient safety events. They will help to ensure that the people who use our services are at the heart of our learning and improvement by contributing to the development of the safety culture and patient safety systems, by being involved in patient safety within the organisation.

Patient Safety Partner roles are important in supporting the voices of service users to be heard at all levels of the organisation through:

- Membership of key quality and risk groups, and committees whose responsibilities include the review and analysis of safety data,
- Involvement in patient safety improvement projects,
- Working with teams and services to consider how to improve safety,
- Involvement in relevant staff patient safety training,
- Participation in projects that focus on learning and involvement,
- Encourage patients, families and carers to play an active role in their safety and any reviews or investigations,
- Contribute to action plans following investigation, particularly around actions that address the needs of patients,
- Attend and be a core member in the Trust's PSIRF Implementation and Oversight Group lead by the Trust's Patient Safety Specialists.

Our Patient Safety Partners will be part of our Integrated Care System response and we will support our PSP to attend the ICS Community of Practice (COP) to aid shared learning and support of these valuable roles. The aim of a COP is a group of people who share a common concern, a set of problems, or an interest in a topic and who come together to fulfill both individual and group goals.

We will also where possible support our PSPs to respond and support other Trusts in the ICS so they can be involved in their learning responses as an independent body as part of the Trust's review of a patient safety incident. The Trust will also reach out and gain support from other organisations within the ICS to support our learning responses where it is felt it would be useful to have an independent PSP as part of our investigation.

8. Addressing Health Inequalities

As a Trust we are committed to ensuring our services and employment practices strive to address health inequalities for everyone we serve. The King's Fund (2022) states that health inequalities are avoidable, unfair and systematic differences in health between different groups of people. There are many kinds of health inequality, and many ways in which the term is used. This means that when we talk about 'health inequality', it is useful to be clear on which measure is unequally distributed, and between which people.

The PSIRF provides a mechanism to directly address the unfair and avoidable differences in health across the population, and between different groups within society. It is recognised that within a healthcare setting, some patients are at a greater risk of being involved in a safety incident than others. It will facilitate greater flexibility to address concerns specific to health inequalities and provides the opportunity to learn from patient safety incidents that may not have met the definition of a 'Serious Incident'.

PSIRF supports the development of a just culture that reduces the inequality gap in rates of disciplinary action across our workforce, focusing on a system-based approach (not a 'person focused approach') to investigations and learning from patient safety incidents.

Our incident response processes support health equality reduction by:

- Applying a more flexible approach and intelligent use of data to help identify any disproportionate risk to patients / service users with specific characteristics which can then inform patient safety incident responses.
- Exploring and responding to issues related to health inequalities as part of the development and maintenance of our patient safety incident response policy and plans.
- Using tools in the response of patient safety incidents to prompt consideration of inequalities, including when developing safety actions.
- Engaging and involving patients / service users, families and staff following a patient safety incident with consideration of their differing needs.

We will implement the collection of demographic data and learning from our investigations and reviews to aid identification of any potential health inequalities. We will aim to use organisational data provided from those involved in complaints and incidents, alongside other information from coroners' findings (Trust Inquests), mortality reviews and patient and staff surveys. With this information and data, we can better understand and increase the diversity of people who are involved in our participation approach; these aims will tie in with our Quality Strategy (2023-2026) which has a priority on health inequalities.

9. 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. It supports the development of an effective patient safety incident response system that prioritises compassionate engagement and involvement of those affected by patient safety incidents (including patients / service users, families and staff).

Meaningful involvement of those affected in a learning response

When a learning response takes place, those affected should be involved in a meaningful way, this includes patient, family members and staff affected. The following standards are endorsed for all learning responses.

Patients/carers/family who have been affected:

- Provided with a named main contact within the organisation with whom to liaise about any learning response and support. For patients this is detailed in DN791 Guidance for Patient/ Family Liaison role.
- Allowed to bring a friend, family member or advocate of their choice with them to any meeting that is part of the learning response process they are involved in.
- Informed who will conduct any learning response and of any changes to that arrangement.
- Given the opportunity to input to the terms of reference for the learning response, including being given the opportunity to request the addition of any questions especially important to them (note this does not mean that their requests must be met, but they must have any decision not to meet their request explained to them).
- Given the opportunity to agree a realistic timeframe for any learning response.
- Informed in a timely fashion of any delays with the learning response and the reasons for them.
- Updated at specific milestones in the learning response should they wish to be.
- Given the opportunity to review the learning response report with a member of the learning response team while it is still in draft and there is a realistic possibility that their suggestions may lead to amendments. Note this does not mean that their suggestions must be incorporated but any decision not to incorporate their suggestions must be explained to them.
- Invited to contribute to the development of safety actions resulting from the learning response.
- Given the opportunity to feedback on their experience of the learning response and report (e.g. timeliness, fairness, and transparency).

Staff affected:

- All staff with knowledge of the events being reviewed are encouraged to actively participate in the learning response. That may be through

submitting written information, joining a debrief meeting, or a one-to-one conversation with a member of the divisional/business unit leadership (or their deputies) or if they would like outside support, they can also be supported by an allocated member of the Clinical Governance Team.

- An agreement with staff of the timescales for feedback of progress and findings in accordance with the type of review method being utilised, will be provided by the Patient Safety Lead Investigator.
- All contact with staff will involve the collection of their account of the events and also their views and opinions on how systems can be improved, as detailed in DN196 Statement Guidance for Staff.
- The Clinical Governance team will ensure will advise, and supply staff involved in a patient safety incident with the staff support leaflet, which contains information on the patient safety process and where psychological support can be gained.

Please refer to DN099 Managing Stress and Supporting Staff at Work Procedure, DN153 Being Open and Duty of Candour Policy and DN259 Freedom to Speak Up, raising concerns (whistleblowing) Policy.

Duty of Candour
The CQC (2022) outlines the Trust's responsibilities under the Duty of Candour as a provider of health care. The aim of Regulation 20 (CQC 2022) is to ensure we are open and transparent with people who use services and other 'relevant persons' (people acting lawfully on their behalf) in relation to care and treatment.

It also sets out some specific requirements that we must follow when things go wrong with care and treatment, including informing people about the incident, providing reasonable support, truthful information and an apology.

As a Trust we promote a culture that encourages candour, openness and honesty at all levels. This is an integral part of a culture of safety that supports organisational and personal learning. Our duty of candour is central to the requirement of involving families, friends and carers in the investigation of incidents. For further guidance please refer to the Trust's DN153 Being Open and Duty of Candour Policy.

10. Patient Safety Incident Response Planning

We will use the PSIRF to respond to patient safety incidents and safety issues in a way that promotes and maximises learning and improvement, rather than basing responses on arbitrary and subjective definitions of harm. Beyond the nationally set requirements, organisations can explore patient safety incidents relevant to their context and the populations they serve rather than only those that meet a certain defined threshold.

There are many ways our Trust can respond to a patient safety incident to learn and improve: It is important that we take a proportionate approach to patient safety incident response. Patient Safety Reviews (PSRs) include

several techniques to identify areas for improvement, immediate safety actions and to respond to any concerns raised by the affected patient, family or carer. Different techniques can be adopted depending on the intended aim and required outcome.

11. Our Patient Safety Incident Response Plan (PSIRP)

We have completed a review of four years of our incidents, risks and complaints, and alongside this have reviewed staff feedback about patient safety incidents. These have informed our initial patient safety incident response plan.

Our initial plan sets out how we intend to respond to patient safety incidents over a period of 15 months, commencing January 2024 and thereafter this will be annually (April to March each year). The plan is not a permanent set of rules that cannot be changed, and we will remain flexible and consider the specific circumstances in which each patient safety incident occurs, and the needs of those affected, as well as the plan. This policy should be read alongside the Patient Safety Incident Response Plan (PSIRP).

12. Reviewing our Patient Safety Incident Response Policy and Plan

Our patient safety incident response plan is a 'living document' that will be 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 is likely to change. This will also provide an opportunity to re-engage with stakeholders to discuss and agree any changes needed.

As the PSIRP evolves, the updated plans will be approved and published on our website, replacing the previous version. A rigorous planning exercise will be undertaken every three years (and more frequently if appropriate, as agreed with our Integrated Care Boards and Commissioners) to ensure efforts continue to be balanced between learning and improvement. This more in-depth review may include reviewing our response capacity, mapping our services, a wide review of organisational data (for example, PSII reports, improvement plans, complaints, claims, staff survey results, inequalities data, and reporting data) and wider stakeholder engagement.

13. Responding to Patient Safety Incidents

Patient safety incident (PSIs) reporting arrangements
All PSIs must be reported through LFPSE (Learning from Patient Safety Events) through our current Datix safety system which will have the required configuration to fit this new reporting requirement. We will continue to work with all statutory bodies, such as the police, and ensure that all statutory reporting is completed, e.g., to the Health and Safety Executive (HSE) and the Medicines & Healthcare Products Regulatory Agency (MHRA) where

appropriate. The processes contained within this document do not supersede the normal legal requirements to notify other agencies when required.

We will work with organisations and co-operate with any learning responses that cross organisational boundaries.

As part of incident reporting, all staff are required to:

- Report all incidents, patient safety events and near misses via the electronic incident management system, Datix.
- Ensure the details of any incidents / patient safety events are contemporaneously and objectively reported in the patient / service user's clinical record.
- Raise any concerns about situations that lead to, or could lead to, an incident, patient safety event or a near miss with their line manager or the Clinical Governance Team.
- Actively participate in any subsequent reviews or learning responses, providing a written account, attending multidisciplinary fact-finding and feedback meetings etc as needed.
- Attend a Coroner's inquest if requested.
- Undertake mandatory training in the reporting of incidents / patient safety events.
- Undertake additional training, as required, to ensure competence in relation to the Datix system.

Further details of incident reporting arrangements are detailed in DN206 Guidance for Investigation of Incidents, Complaints and Claims and DN070 Procedure for Reporting of Accidents, Adverse Events, Incidents and Defects.

We will make available appropriate support to those staff involved in an incident / patient safety event, where this is required.

14. Patient Safety Incident Response Decision-making

Patient safety incidents will be responded to with due regard to our patient safety incident response plan.

Responding proportionately to balance learning and improvement will require a thorough understanding of the local patient safety incident profile and ongoing improvement work. We will use a SEIPS (System Engineering Initiative for Patient Safety), or similar systems-based framework with knowledge of human factors science alongside advocacy of a Just Culture, to understand outcomes within complex systems for the purpose of learning.

Planning will support proactive allocation of patient safety incident response resources, as well as consideration that there will need to be a reactive element in responding to incidents. A response will always be considered for PSI that signify an unexpected level of risk and / or potential for learning and improvement but fall outside the issues or specific incidents described in our patient safety incident response plan.

We will respond to incidents in a way that maximises learning and improvement and will explore patient safety incidents relevant to the context of our organisation and the populations we serve, rather than exploring only those that meet a certain nationally defined threshold.

Emergent issues not included in the patient safety incident response plan will be identified through Serious Incident Executive Review Panel (SIERP) or Quality Risk Management Group (QRMG) where multiple sources of data, including insight from complaints and incidents, is triangulated to look for emerging themes and trends. Any resources needed to support responses to these will be allocated through the Clinical Governance Team and as part of the Quality and Improvement strategy.

Patient safety incidents requiring a learning response
We will implement the main four response types as detailed in the PSIRF to fit the patient safety incident (PSI) that has occurred:

- **Patient Safety Incident Investigation (PSII) -** An in-depth review of a single patient safety incident or cluster of events to understand what happened and how.

- **Multi Disciplinary Team (MDT) review -** An in-depth process of review, with input from different disciplines, to identify learning from multiple patient safety incidents, and to explore a safety theme, pathway, or process. To understand how care is delivered in the real world i.e. work as done.

- **Swarm huddle -** Swarm-based huddles are used to identify learning from patient safety incidents. Immediately after an incident, staff 'swarm' to the site to quickly analyse what happened and how it happened and decide what needs to be done to reduce risk.

- **After action review (AAR) -** A structured, facilitated discussion of an event, the outcome of which gives the individuals involved in the event understanding of why the outcome differed from that expected and the learning to assist improvement. AAR generates insight from the various perspectives of the MDT.

Patient safety incidents resulting in significant harm must be reported via the LFPSE (through Datix) and to notifiable partner organisations. As a minimum, PSIs (under our care) leading to unexpected death or severe harm will warrant a Patient Safety Incident Investigation. 'Near misses' and 'no harm' patient safety events may also warrant a learning response where the contributory causes are serious and under different circumstances could have led to serious injury, major permanent harm, or unexpected death.

Each incident will be considered on an individual basis and the decision as to whether a PSI meets the criteria for a learning response (and what type) will

be led by SIERP who will request a timeline of events to be presented (see TOR020 SIERP Terms of Reference). See section 16 for further detail.

The SIERP decisions, including rationale of outcome, will be minuted, approved by the Chair (a senior member of the panel) and filed on the relevant Datix record, together with all other supporting documents.

Learning response resources

The Trust will ensure that:

- Learning responses are not led by staff who were involved in the patient safety incident itself or by those who directly manage those staff.
- Learning response leads should have an appropriate level of seniority and influence within an organisation – this may depend on the nature and complexity of the incident and response required.
- Learning responses are not undertaken by staff working in isolation. A learning response team should be established to support learning responses wherever possible.
- Staff affected by patient safety incidents are given time and are supported to participate in learning responses.
- The staff we have identified to lead on Patient Safety Incident Investigations are trained in compliance with the national training requirements and have the capacity in their work plan to lead PSIIs.
- Learning response leads have dedicated paid time to conduct learning responses. If necessary, their normal roles are backfilled, or additional paid agreed if overtime is required.
- Subject matter experts with relevant knowledge and skills are involved, where necessary, throughout the learning response process to provide expertise (eg clinical or human factors review), advice and proofreading.
- There is dedicated staff resource to support engagement and involvement of those affected.

15. Responding to cross-system incidents / issues

We recognise that Patient Safety Incidents (PSIs) can often be complex and involve a number of organisations. Our Trust will work with partner providers and the relevant Integrated Care Boards (ICB) to establish and maintain robust procedures to facilitate the free flow of information and minimise delays to joint working on cross-system incidents.

Where multiple organisations need to be involved in a single learning response, the Clinical Governance Team will act as the liaison point for such working and will ensure any incidents that require cross system or partnership engagement are identified and shared through existing channels and networks, and that partnership colleagues are fully engaged in investigations and learning as required.

Our Trust will defer to the ICB for co-ordination where a cross-system incident is felt to be too complex to be managed as a single provider. We anticipate that the ICB will give support with identifying a suitable reviewer in such circumstances and will 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.

The PSII will be led by the organisation best placed to investigate the concerns and may depend on capability, capacity, or remit. Should we be asked to contribute to other organisation's PSIIs, this will be discussed and the decision minuted at SIERP to ensure there is oversight of such investigations and learning. This will be supported by each organisation's governance team. The final draft report will be shared with the relevant internal stakeholders approved by an Executive Director prior to external submission, together with approval of any learning recommendations and actions that will feed into improvement plans.

Should we need to lead on an investigation and include other organisations, representatives will be invited to participate with SIERP to contribute, support and understand the scope of the PSII, and clear timeframes for actions will be agreed.

As well as the Integrated Care System (ICS)and boards (ICB), other organisations that can support with the management of a PSII include NHS England and Improvement and The Care Quality Commission (CQC). The Chief Nurse will ensure the appropriate notifications have been made through the LFPSE, to the Integrated Care System, Commissioner, NHS England and Improvement and the CQC via delegated responsibility to the Assistant Director for Quality and Risk. This includes providing any updates as requested. The involvement of these organisations will also be considered as part of any learning response, if appropriate.

16. Timeframes for Learning Responses

A response will start as soon as possible after an incident is identified and the timeframe for completing a PSII will be agreed with those affected by the incident as part of setting the terms of reference, provided they are willing and able to be involved in that decision.

One of the most important factors in ensuring timeliness of a learning response is thorough, complete and accurate incident reporting when the circumstances are fresh in the minds of the incident reporter and the wider team. These principles are set out in the current incident reporting guidance but must be reinforced through the PSIRF.

The PSIRF provides more detail on the types of learning response most appropriate to the circumstances of the incident. Highly prescriptive timeframes for learning responses may not be helpful so the following are included as a guideline only:

- Initial incident investigation – as soon as possible, within 5 working days of reporting.
- Further learning response (e.g: AAR, MDT's, Swarm huddle) – within 20 working days of reporting
- Standard timeframe for a local-led PSII - within 60 days (3 months).
- Comprehensive (PSII) Investigation – 60 - 120 working days depending on complexity.

A toolkit of learning response types is available from NHSE at: https://www.england.nhs.uk/publication/patient-safety-learning-response-toolkit/

In exceptional circumstances (e.g. when a partner organisation requests an investigation is paused), a longer timeframe may be needed to respond to an incident. In this case, any extension to timescales will be agreed with those affected (including the patient / service users, family, carer, and staff).

The time needed to conduct a response must be balanced against the impact of long timescales on those affected by the incident and the risk that for as long as findings are not described, action to improve safety or required checks may not be taken. Where external bodies (or those affected by patient safety incidents) cannot provide information to enable timely completion, the local response leads will work with all the information they have to complete the response to the best of their ability; it may be revisited later, should new information indicate the need for further investigative activity.

The standard timeframe for a local-led PSII to be submitted to our Trust Patient Safety Improvement Group for approval of findings, is three months (60 days). The timeframe will be decided by the Trust's Serious Incident Executive Review Panel (SIERP); no local PSII should take longer than six months.

The timeframe for completing an investigation should be agreed with those affected by the incident, as part of setting the terms of reference for the PSII, provided they are willing and able to be involved in that decision. PSIIs (and other local response) should take no longer than six months on average, but this must not become a new default target. If an organisation's local responses are often taking more than 6 months, or exceeding timeframes set with those affected, then processes should be reviewed to understand how timeliness can be improved.

National Priorities- Nationally-defined incidents requiring local PSII

The table below sets out the local or national mandated responses. Royal Papworth Hospital does not directly provide mental health, maternity, or custodial services however it is possible that the organisation would be a secondary participant rather than a lead for those incident types.

Nationally-defined incidents for local PSII are set by the PSIRF and other national initiatives are listed below and how we intend to respond to these:

Patient safety incident type	Required response
Deaths thought more likely than not due to problems in care (incidents meeting the learning from deaths criteria for PSII)	Locally-led PSII by the organisation in which the event occurred/identified improvements will lead into a central quality improvement plan.
Deaths of patients detained under the Mental Health Act (1983) or where the Mental Capacity Act (2005) applies, where there is reason to think that the death may be linked to problems in care (incidents meeting the learning from deaths criteria)	Locally-led PSII by the organisation in which the event occurred/identified improvements will lead into a central quality improvement plan
Incidents meeting the Never Events criteria 2018, or its replacement	Locally-led PSII by the organisation in which the event occurred/identified improvements will lead into a central quality improvement plan
Mental health-related homicides	Referred to the NHS England Regional Independent Investigation Team (RIIT) for consideration for an independent PSII, with consideration of any local learning response
Maternity and neonatal incidents meeting Healthcare Safety Investigation Branch (HSIB) criteria or Special Healthcare Authority (SpHA) criteria when in place	Refer to HSIB or SpHA for independent PSII by the organisation in which the event occurred
Child Deaths	PSII by the organisation in which the event occurred. Liaison with the panel to agree local response type
Deaths of persons with learning disabilities	Refer for Learning Disability Mortality Review (LeDeR). Liaison with the LeDeR to agree local response type
Safeguarding incidents in which: - babies, children, or young people are on a child protection plan; looked after plan or a victim of wilful neglect or domestic abuse/violence - adults (over 18 years old) are in receipt of care and support needs from their local authority - the incident relates to FGM, Prevent (radicalisation to terrorism), modern slavery and human trafficking or domestic abuse/violence	Refer to local authority safeguarding lead. Healthcare organisations must contribute towards domestic independent inquiries, joint targeted area inspections, child safeguarding practice reviews, domestic homicide reviews and any other safeguarding reviews (and inquiries) as required to do so by the local safeguarding partnership (for children) and local safeguarding adults boards.
Incidents in NHS screening programmes	Refer to local screening quality assurance service for consideration of locally led learning response
Deaths in custody (e.g., police custody, in prison, etc) where health provision is delivered by the NHS	Any death in prison or police custody will be referred (by the relevant organisation) to the Prison and Probation Ombudsman (PPO) or the Independent Office for Police Conduct (IOPC) to carry out the relevant Investigations. Healthcare organisations must fully support these investigations where required to do so

Patient safety incident type	Required response
Domestic homicide	A domestic homicide is identified by the police usually in partnership with the community safety partnership (CSP) with whom the overall responsibility lies for establishing a review of the case

Further information can be found in the following guide:
B1465-3.-Guide-to-responding-proportionately-to-patient-safety-incidents-v1.1.pdf (england.nhs.uk)

17. Safety action development and monitoring improvement

Safety action development and monitoring improvement are key steps in our approach to continuous quality improvement of our care and safety for patients.

PSIRF moves away from the identification of 'recommendations' which may lead to solutionising at an early stage of the safety action development process.

Robust findings from PSIIs and reviews provide key insights and learning opportunities, but they are not the end of the story. Learning response methods enable collection of information to acquire knowledge. We must move from identifying the learning to implementation of the lessons.

Overview of safety action development process:

1. **Agree areas for improvement.** Specify where improvement is needed, without defining how this improvement is to be achieved.
2. **Define context.** Agree approach to developing safety actions by developing context.
3. **Define safety actions to address areas for improvement.** Continue to involve the team - make this a collaborative experience.
4. **Prioritise safety actions.** Avoid prioritising actions based on intuition/opinion alone.
5. **Define safety measures.** Identify what can be measured to determine whether the safety action is influencing what is intended. Prioritise safety measures. Document who is responsible for collecting, analysing, reporting and acting on the data collected.
6. **Write safety actions.** Document in a learning response report or safety improvement plan, including details of measurement and monitoring.
7. **Monitor and review.** Continue to be curious and monitor if safety actions are impactful and sustainable.

There will be no thresholds for when a safety improvement plan should be developed; for example, after completing a certain number of learning

responses. The decision to do so must be based on knowledge gained through the learning response process and other relevant data and will be overseen by the QRMG governance process.

Safety actions arising from a learning response should follow the SMART (Specific, Measurable, Achievable, Realistic, Time-bound) principles and thought must be given to monitoring and measures of success. Further guidance on this can be found in NHSE Guidance at https://www.england.nhs.uk/wp-content/uploads/2022/08/B1465-Safety-action-development-v1.1.pdf

It is important that monitoring of completion of safety actions does not become an end in and of itself, but rather a means to improve safety and quality outcomes and reduce risk. The Trust will use its current governance systems to focus more on measuring and monitoring these outcomes, utilising subjective as well as objective measures.

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

Reports to the Board will be shared through the oversight and governance structure (Quality reports, QRMG and onwards to Quality and Risk Committee) and will include aggregated data on:

- Patient safety incident reporting.
- Findings from patient safety incidents.
- Progress against the PSIRP.
- Results from monitoring of improvement plans from an implementation and an efficacy point of view.
- Audit and review findings.
- Results of surveys and/or feedback from patients and service users, families and carers, on their experiences of our response to patient safety incidents.
- Results of surveys and/or feedback from staff on their experiences of our response to patient safety incidents.

18. Complaints and Appeals

The Trust fully upholds the NHS Constitution, aspiring to put the patient at the heart of everything it does. Any concerns or complaints raised about a service provided by the Trust will be taken seriously and will be managed in a way that reflects the Trust values.

The Trust encourages service users to raise any concerns they may have immediately and at the time they occur by speaking to a member of staff, so that where possible for these issues to be resolved through local resolution.

To demonstrate the Trust's pledge that it will take any concerns raised seriously and ensure that they are properly investigated, investigations will be undertaken in an unbiased, non-judgmental, transparent, timely and

appropriate manner. The Trust will respond to all complaints and, the response letter will include the outcome of any investigation along with any actions and learning. This will be underpinned by the Principles of Good Complaint Handling as defined by the Parliamentary and Health Service Ombudsman (PHSO):

- Getting it right.
- Being customer focused.
- Being open and accountable.
- Acting fairly and proportionately.
- Putting things right.
- Seeking continuous improvement

Where concerns are raised the Trust's Complaints Policy (DN195) should be referred to and followed.

19. Monitoring and Audit

The safety actions and associated measure(s) will be appropriately reviewed to ensure they continue to be relevant and the issues of most concern. As part of this process, there will be documentation, recording and reviews of progress against actions and impact through governance groups and links to Quality Improvement, which may involve monitoring by a specific service area or through wider action oversight groups.

Annual clinical audits (examples such as duty of candour, record keeping, complaints compliance) will be part of our assurance process and be overseen by the Clinical Governance team, reporting outcomes of these to QRMG.

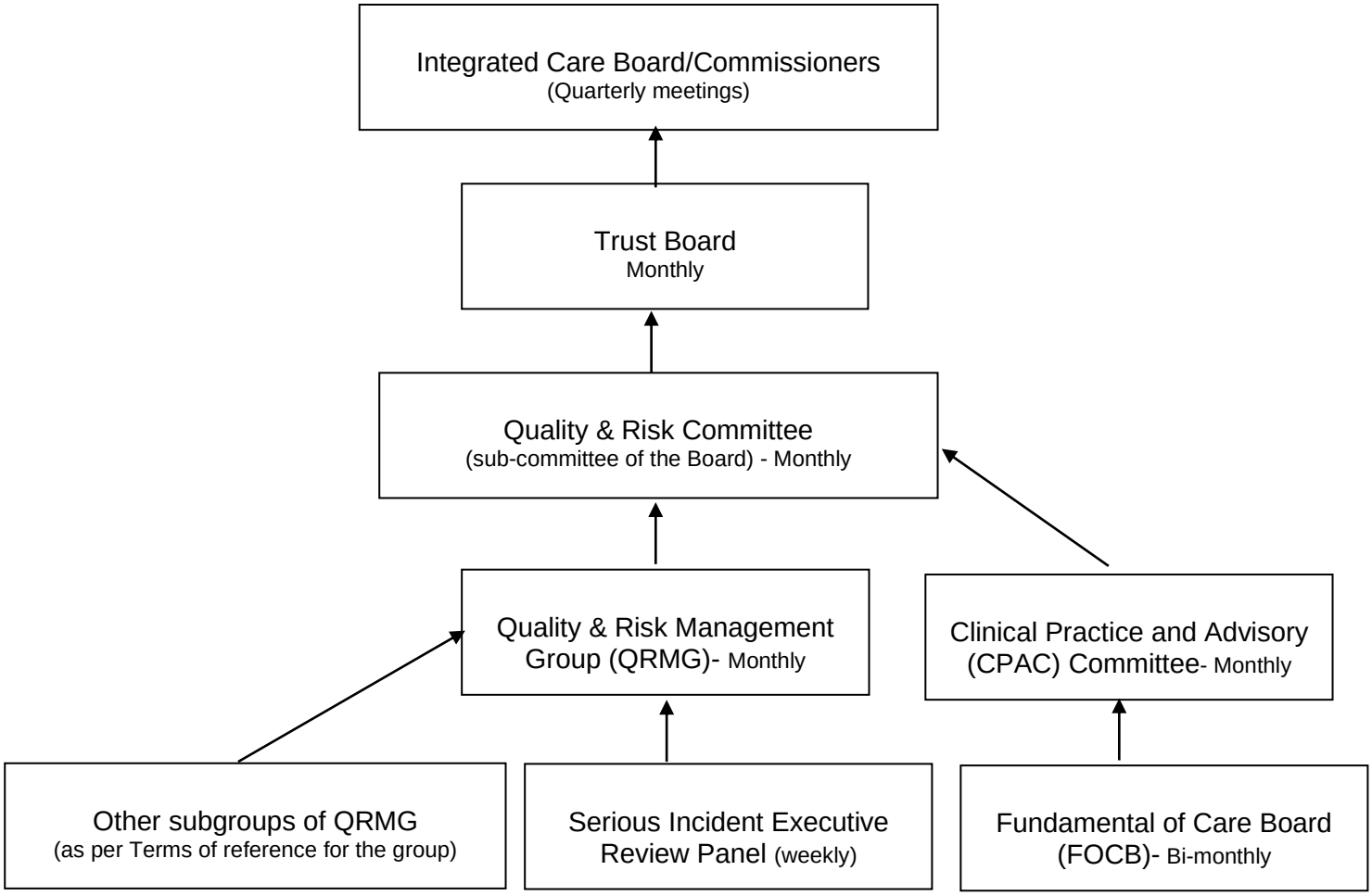
The Trust will review the implementation of the PSIRF through its regular internal Fundamentals of Care (peer reviews) which focuses on the assurance of the twelve CQC fundamentals. Oversight of these outcomes will be through the Trust Fundamentals of Care Board which reports into Clinical Practice Committee to Q&R and to the Trust Board.

Local Priorities set by the organisation will be reviewed annually. The priorities will be agreed with our ICB. The Trust priorities are within our annual our Patient Incident Response Plan (DNxxx). Each year we will work with other NHS providers, the ICB, and regulators so that systems for oversight allow for improvement, rather than compliance with prescriptive, centrally mandated measures. Roles and responsibilities are described in relation to our response to patient safety incidents, including investigator responsibilities and upholding national standards relating to patient safety incidents and can be seen within section 5 of this policy.

There is a robust system of reporting, oversight and governance in place to support a proactive approach to the identification and management of incidents and any potential gaps (see below). Reports are provided to the Quality Risk Management Group (QRMG) and onwards to the Quality and

Risk Committee (Q&R) on a monthly basis. Furthermore, quarterly reports are also provided to Q&R and information provided to the Trust Board. Quarterly meetings are also established with our Commissioner and the Integrated Care System leads for oversight and these will continue to be a place of shared learning and oversight of the Trust quality and safety governance.

Structure of Governance is below:



Monitoring Compliance

Royal Papworth Hospital
NHS Foundation Trust

What key element(s) need(s) monitoring as per local approved policy/ procedure or guidance?	Who will lead on this aspect of monitoring? Name the lead and what is the role of the multidisciplinary team or others.	What tool will be used to monitor/check/ observe/assess/ inspect/ authenticate that everything is working according to this key element from the approved policy/ procedure?	How often is the need to monitor each element? How often is the need complete a report? How often is the need to share the report?	Who or what committee will the completed report goes to. How will each report be interrogated to identify the required actions and how thoroughly should this be documented in e.g. meeting minutes.	Which committee, department or lead will undertake subsequent recommendations and action planning for any or all deficiencies and recommendations within reasonable timeframes?	How will system or practice changes be implemented the lessons learned and how will these be shared?
Element to be monitored	**Lead**	**Tool**	**Frequency**	**Reporting arrangements**	**Acting on recommendations and Lead(s)**	**Change in practice and lessons to be shared**
All reported Incidents, reviews, investigations and associated safety plans and outcomes	Assistant Director for Quality and Risk Supported by: Clinical Governnace Manager Patient Safety Lead	Quality and Reports Papworth Integrated Performance Report (PIPR)	Monthly within quality reports to QRMG Quarterly through quality reports to QRMG and Q&R commitee	QRMG Q&R Committee	All actions will be monitored through QRMG	Required changes to practice will be identified & actioned within a specific time frame. A lead member of the team will be identified to take each change forward. Lessons will be shared with all the relevant stakeholders.

Further document information

Approval – this is required for all documents. Approval should be by the relevant committee(s)*. State the name(s) of the committee(s) and the full date(s) of the relevant meeting(s): *In exceptional circumstances only, approval can be by Chair's Action or by appropriate ED or NED – state full date of approval	Quality and Risk Management Group (QRMG) 08/08/2023
Approval date (*this version*) (Day, month, year):	08/08/2023-Approved
Approval by Board of Directors or Committee of the Board **(required for Strategies and Policies only):**	Quality and Risk (Q&R) Committee- 31/08/2023 and Trust Board 07/09/2023
Date (Day, month, year):	31/08/2023
This document supports: *standards and legislation – include exact details of any CQC.*	Care Quality Commission (Registration) Regulations 2009 Care Quality Commission (Registration and Membership) (Amendment) Regulations 2012
Key associated documents:	**DN070** Procedure for Reporting of Accidents, Adverse Events, Incidents and Defects **DN099** Managing Stress and Supporting Staff at Work Procedure **DN139** Risk Management Strategy **DN153** Being Open and Duty of Candour Policy **DN195** Complaints policy **DN196** Statement Guidance for Staff **DN206** Guidance for Investigation of Incidents, Complaints and Claims **DN289** Health, Safety and Wellbeing Policy **DN892** Volunteer Policy **DN259** Freedom to Speak up, Raising Concerns (whistleblowing) Policy **DN791** Guidance for Patient/ Family Liaison role. **TOR020** Serious Incident Executive Review Panel
Counter Fraud In creating/revising this document, the contributors have considered and minimised any risks which might arise from it of fraud, theft, corruption or other illegal acts, and ensured that the document is robust enough to withstand evidential scrutiny in the event of a criminal investigation. Where appropriate, they have sought advice from the Trust's Local Counter Fraud Specialist (LCFS).	