

Patient Safety Incident Response Policy and Incident Reporting Guideline

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Author(s) Name and Title:	Ria Carter, Patient Safety Lead Nurse		
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1. Glossary of Terms

Term/Acronym	Definition
AAR	After Action Review (AAR) is a method of evaluation that is used when the outcomes of an activity or event, have been particularly successful or unsuccessful.
Arbitrary or Subjective	Chosen randomly or influenced by/based on personal beliefs or feelings, rather than on facts
Division	A grouping of multi-disciplinary staff working together to provide care within a certain speciality.
CQC	Care Quality Commission - independent regulator of health and social care in <i>England</i>
Definitions of Harm	Unanticipated, unforeseen incidents (eg, patient injuries, care complications, or death) which are a direct result of the care dispensed rather than the patient's underlying disease
Duty of Candour	Being open and honest with patients and families when treatment or care goes wrong. This is undertaken verbally and in written form also.
Emergent Property	A characteristic an entity (patient safety) gains when it becomes part of a bigger system
Governance Structures	System that provides a framework for managing organisations
HFACS	Human Factors Analysis and Classification System a user-friendly, cost-effective and evidence-based approach to incident investigation, based on the goal of understanding organisational systems.
HSE	Health and Safety Executive
HSIB	Health and Safety Investigation Branch
Human Error	<i>A human error is an action or decision which was not intended that has negative consequences or fails to achieve the desired outcome</i>
Inequalities data	Facts and statistics collected relating to health inequalities which are unfair and avoidable differences in health across the population, and between different groups within society.
Integrated Care Board (ICB)	Statutory organisation that brings NHS and care organisations together locally to improve population health and establish shared strategic priorities within the NHS.
Be Fair Tool	The treating of staff involved in a patient safety incident in a consistent, constructive and fair way.
MHRA	Medicines and Healthcare products Regulatory Agency
Neonatal Death	A baby born at any time during the pregnancy who lives, even briefly, but dies within four weeks of being born

Never Events	A nationally recognised category of incidents that could cause harm to people that should never happen and can be prevented.
NHSE	National Health Service England
Paradigm Shift	An important change that happens when the usual way of thinking about or doing something is replaced by a new and different way
Principles of Proportionality	The least intrusive response appropriate to the risk presented
PSII	Patient Safety Incident Investigation.
RIDDOR	Reporting of Injuries, Diseases and Dangerous Occurrences Regulations
SEIPS	System Engineering Initiative for Patient Safety - a framework for understanding outcomes within complex socio-technical systems.
SI	Serious Incident
SOP	Standard Operating Procedures
Stakeholder	People or groups who have an interest in what an organisation does, and who are affected by its decisions and actions.
Statistical Process Control (SPC)	A tool used in the NHS to understand whether change results in improvement. It provides an easy way for people to track the impact of improvement projects.
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.

2. Purpose

This policy supports the requirements of the NHS England Patient Safety Incident Response Framework (PSIRF) and sets out Liverpool Heart and Chest Hospital NHS Foundation Trust's 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 the 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.

The PSIRF sets no further national rules or thresholds to determine what method of response should be used to support learning and improvement. **Instead, organisations are now able to balance effort between learning through responding to incidents or exploring issues and improvement work.**

3. Scope

This policy is specific to patient safety incident responses conducted solely for the purpose of learning and improvement across all patient facing services and departments delivering NHS and Private Patient care.

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, therefore, do not solely focus on the actions of individuals, or 'human error', even when these are reported to be the cause of an incident.

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

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

4. Roles and Responsibilities

Chief Executive and Executive Board

- Ensures the Trust has adequate systems for the reporting of all incidents and near misses
- The Chief Executive and Board provide the strategic leadership to promote and develop the Trust's safety culture. This includes responsibility for effective risk management within the Trust and to ensure the organisation complies with its statutory obligations. This is in line with national guidance in regard to Well-Led organisations (Monitor and CQC April 2015).

Director of Nursing

- Has the Executive Lead for PSIRF

- Ensures organisational learning occurs following the investigation into reported incidents and near misses.
- Implementation of this policy
- Will ensure the Trust Board are appraised accordingly, in line with our PSIRF processes and given full oversight via the Trust Patient Safety Panel.

Head of Risk Management

- Will support the Director of Risk and Governance in ensuring the policy is implemented
- Will act in an advisory capacity to the Risk Management Team with regards to the grading of incidents
- Will ensure the investigation process is followed by the Divisions in regards to completion of timely Rapid Reviews for all relevant incidents
- Will work collaboratively with the Patient Safety Lead Nurse to ensure the investigation process is followed with regards to timescales and the completion of Patient Safety Incident Investigations (PSII's).
- Will ensure the Trust Board are appraised accordingly, in line with our PSIRF processes and given full oversight via the Trust Patient Safety Panel.

Risk Management Team

With oversight from the Patient Safety Lead Nurse, the Risk Management Team will:

- Ensure all reported incidents and near misses are recorded, assigned a manager
- Review incidents and trends on an organisation wide basis
- Ensure monthly reports extracted from the InPhase system detailing all reported incidents and near misses within clinical areas or departments are forwarded to Divisional Directors of Operations, Associate Medical Directors, Divisional Directors of Nursing and Heads of Departments.
- Maintain a contemporaneous record of all PSII's performed within the Trust
- Report relevant incidents to monitoring organisations as required (i.e. Monitor, Care Quality Commission)
- Ensure reports are available on request from Knowsley Place
- Will ensure that the Executive Team are alerted as per policy, if an incident is reported that may possess the potential to require a PSII.
- Liaise with the medications safety officer and medical devices officer when required.

Divisional Triumvirate/ Clinical Leads

Divisional Directors of Operations' (DDoO's), Divisional Directors of Nursing (DivDon's), Associate Medical Directors (AMD) and clinical leads in each service are responsible for the implementation of this policy in their service area which ensures:

- The Service meets its obligations as described within this policy, which includes the Duty of Candour and the requirement to engage compassionately with those involved in incidents.
- That appropriate and effective incident reporting processes are in place within the designated area.

- All staff within their work environment to include all bank and agency staff, are made aware and given guidance on the incident reporting process.
- Action is taken to contain an incident when identified in order to minimise harm.
- Incidents are reviewed as in line with the recommended investigatory time frame, and discussed within the Divisional Patient Safety Panel where applicable
- Support and updates are provided at the weekly Patient Safety Incident Response Group in relation to divisional incidents.
- Identified actions from incidents are acted upon in a timely manner as per the timeframes within the action plan
- Themes and trends from incidents are acted upon and learning is shared within their division
- In situations where significant risks have been identified and where local control measures are considered to be potentially inadequate, these risks are escalated via the risk identification process.
- Effective and timely communication with staff and patients, their carers and family and the provision of appropriate support.

All staff

All staff will follow the procedure outlined in this policy which includes:

- Attending to people's immediate needs following an incident and maintaining / re-establishing a safe care environment
- Being familiar with and implement the procedure for reporting any patient safety incidents
- Ensuring effective incident management by completing a web-based incident report form on InPhase when either directly involved in an incident or injured as a result of an incident.
- Reporting all incidents including near misses within their span of duty.
- Co-operating with all reviews or investigations that the Trust undertakes. This is in line with various NHS and Professional Codes of Conduct and Trust policy.
- Will ensure that all nosocomial infections are reported as incidents

Freedom to Speak Up Guardian/Speak up Advocates

The Freedom to Speak Up Guardian is responsible for supporting staff when they have a concern so that they feel able to raise matters freely and safely in relation to patient safety, treatment or standards of care. This role is key in helping to increase the profile of raising concerns in the Trust and the Guardian can provide confidential advice and support to staff in relation to concerns they have. The Guardian provides support to ensure that employee concerns have been fully explored.

5. Our patient safety culture

Liverpool Heart and Chest Hospital NHS Foundation Trust promotes a Being Fair approach (in line with the NHS [Being Fair Tool](#)) to any work planned or underway to improve safety culture. Research into organisational safety has repeatedly found that an open and transparent culture, where colleagues feel able to report incidents and raise concerns without fear of recrimination, is essential to improving safety.

The Trust encourages and supports incident reporting where any member of staff feels something has happened, or may happen, which has led to, or may lead to, harm to patients or staff. Staff should never be left feeling isolated and uninformed about what will happen following a patient safety incident. LHCH has a continuous learning culture and offers a wide range of learning and developmental opportunities, promoting a culture that encourages lifelong learning for all staff. Please refer to the Incident Reporting Policy for more information on how incidents are reported and managed in an open and transparent manner to focus on learning without blame.

We have a very positive patient safety culture within LHCH, with a variety of patient safety initiative already strongly embedded across the organisation. Examples of these are:

1. HALT
2. Safety Seven
3. Freedom To Speak Up
4. Daily Trust Safety Huddle
5. Weekly Patient Safety Learning Meeting

We want speaking up to improve the services we provide for patients and the environment our staff work in. Where it identifies improvements that can be made, we will ensure necessary changes are made, and are working effectively. Lessons will be shared with teams across the Trust, or more widely, as appropriate. Any patient safety issue, incident or concern that have been raised will be discussed with relevant departmental and divisional managers to ensure that we understand exactly what you are worried about. If we decide to investigate, we will tell you how long we expect the investigation to take and agree with you how to keep you up to date with its progress.

We want everyone in the Trust to feel safe to speak up and confident that it will be followed by a prompt response. Further information is provided in the “Freedom to Speak up Policy for the NHS” alongside additional policies including the “Disciplinary Policy” that

sets out the process for managing employee conduct. All policies can be found on the staff Intranet.

All our staff are required to complete the first module of Speaking up which is mandatory across the Trust.

People need to feel confident that if they call out poor behaviour, they will not experience detriment or retaliation. Creating and promoting psychologically safe spaces by promoting positive working relationships helps make staff feel secure, supported, and confident to speak up. Speaking up will ensure that as a Trust we have the right culture to hear staff concerns and recommendations for improvements, and to respond fairly and appropriately to those speaking up for patient safety in our organisation. More information can be found within our Trust Freedom to Speak Up Policy on the staff intranet.

We support our managers/supervisors to listen to the issue raised and take action to resolve it wherever possible. In most cases, it's important that this opportunity is fully explored, which may be with facilitated conversations and/or mediation. Where an investigation is needed, this will be objective and conducted by someone who is suitably independent (this might be someone outside our organisation or from a different part of the organisation) and trained in investigations. It will reach a conclusion within a reasonable timescale and a report will be produced that identifies any issues to prevent problems recurring.

The FTSU Guardian will review the concerns raised with the Executive and Non-Executive Leads for FTSU to ascertain if there are themes. The FTSU Guardian submits data to the National Guardians Office each quarter who in turn reviews all submissions nationally to see if there are any themes locally or nationally. Our most senior leaders receive a report quarterly providing a thematic overview of speaking up by our staff to our FTSU guardian(s).

Good governance is essential, and we will ensure that all staff have easy access to information on how to speak up and that individuals will be referred to the national Speaking Up Support Scheme: <https://www.england.nhs.uk/ourwork/freedom-to-speak-up/developing-freedom-to-speak-up-arrangements-in-the-nhs/staff> . Further supporting documents include:

- Maintaining High Professional Standards Policy
- Guidelines for supporting staff involved in Traumatic/Stressful Incidents/Complaints or Claims
- NHS England Fit and Proper Person Test

The Trust encourages and supports incident reporting where any member of staff feels something has happened, or may happen, which has led to, or may lead to, harm to patients (or staff). Please refer to the “Incident Reporting Policy” for more information on how incidents are reported and managed in an open and transparent manner to focus on

learning without blame. PSIRF will create much stronger links between a patient safety incident and learning and improvement. We will aim to work in partnership with those affected by a patient safety incident, staff, patients, families, and carers. Engagement is key.

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.

To boost our safety culture, we have a daily Trust wide safety huddle for any member of staff at any level to attend and safety huddles at all levels of our Trust where any patient safety concerns can be raised and followed up. The safety huddle is then minuted and shared Trust wide via email. Departments have safety huddles in order to identify risks emerging or known and the insight offered from incidents that have occurred and therefore an opportunity to share any learning.

With regards to medications the Trust holds a weekly safe medications MDT to discuss any incidents that have occurred the previous week, obtaining an MDT view, sharing quick learning and ensuring mitigations are discussed and applied where appropriate. This is also supported by our weekly patient safety learning meeting (PSLM) which is chaired by the Deputy Director of Nursing and supported by the Patient Safety Leads. Incidents and learning responses are discussed and shared, as well as an opportunity for theme recognition and an MDT approach to discussing concerns raised.

We also have a network of patient safety champions (PSCs), with the aim of improving identification, reporting and resolution of safety issues in clinical areas.

Our PSCs, drawn from a range of clinical and non-clinical backgrounds, will be a key link between staff in clinical areas, ward and department managers, the Risk and Governance team, the Patient Safety Lead and Trust senior management.

Some key aspects of the PSC role is:

- Collaborate with departmental / ward managers in representing their base department at Safety Huddle, Team Brief and Sharing and Learning events
- Raise the profile of safety campaigns locally
- Help to embed the *Be Civil, Be Kind* and Being Fair campaigns in their department
- Promote the introduction of the new Safety / Governance Sharepoint and assist colleagues in its usage
- Link with colleagues to identify and escalate local safety concerns / issues
- Collaborate with other champions and the PSL in safety walk-rounds of clinical areas
- Attend the Safety Champions Forum bimonthly to network and share ideas and learning
- Share and introducing examples of best practice from other departments to their own
- Represent LHCH at local and national events relevant to Patient Safety
- Identify and share good practice

- Assist the Trust and their local area with awareness of the new Patient Safety Incident Response Framework

6. Patient safety partners

The Trust has established 2 roles for patient safety partners in line with the NHSE guidance [Framework for involving patients in patient safety](#). Patient Safety Partners (PSP) will have an important role in supporting our PSIRF providing a patient perspective to developments and innovations to drive continuous improvement.

A Patient Safety Partner (PSP) is involved in the designing of safer healthcare at all levels in the organisation. This means maximising the things that go right and minimising the things that go wrong for patients when they are receiving treatment, care and services from us. PSPs will use their lived experience as a patient, carer, family member or a member of the local community to support and advise on activities, policies and procedures that will improve patient safety and help us to deliver high quality care.

PSPs will work alongside staff, volunteers and patients, attend meetings (face-to-face and online), be involved in projects to co-design developments of patient safety initiatives, and join (and participate in) key conversations and meetings in the Trust focusing on patient safety. They will have a mind-set for improving outcomes, whilst representing the patient, carer, family view and ensuring committee/meeting members are “walking in the patients’ shoes”. More information can be found within our Trust Patient Safety Partner Policy on the staff intranet.

PSPs are provided with any support requirements they may need to maximise their opportunities for involvement and ensure they are fully supported and enabled.

Key aspects of their role and examples of work they will undertake and support within LHCH include:

- Helping make sure patient safety is at the forefront of all we do
- Membership of safety and quality committees, such as Sharing and Learning and Infection Prevention Committee meetings
- Involvement in patient safety improvement projects
- Working with the Trust Board to consider how to improve safety
- Involvement in staff patient safety training
- Participation in investigation oversight groups
- Regular networking with other local and regional PSP's



PSP poster role.pdf

7. Addressing health inequalities

As a provider of acute and community services, the Trust has a key role to play in tackling health inequalities in partnership with our local partner agencies and services. However, most of the fundamental factors driving inequalities in health are beyond the responsibility of the health care system, for example our education system; economic and community development in our most deprived neighbourhoods; employment levels; pay and conditions; and availability and quality of housing.

Through our implementation of PSIRF, we will seek to utilise data and learning from investigations to identify actual and potential health inequalities and make recommendations to our Trust Board and partner agencies on how to tackle these. The more holistic, integrated approach to patient safety under PSIRF will require the Trust to be more collaborative with the patient experience and inclusivity agenda and ensure investigations and learning do not overlook these important aspects of the wider health and societal agenda.

Our engagement with patients, families and carers following a patient safety investigation must also recognise diverse needs and ensure inclusivity for all. Any potential inclusivity or diversity issues must always be identified through the investigation process and engagement with patients and families, for example, during the duty of candour / being open process.

The Analytics, Data Engineering and Research teams have been working together with the divisions to explore the health inequalities of access to care within Liverpool Heart and Chest Hospital. Health inequalities work at LHCH will be developed by a new Health Inequalities working group chaired by the Associate Director of Data & Analytics. This group will provide a quarterly report as part of the Strategic Operating Framework. These reports will be presented to Operational Board and then onto Board of Directors.

8. 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, families and staff). This involves working with those affected by patient safety incidents to understand and answer any questions they have in relation to the incident and signpost them to support as required.

Those affected by a patient safety incident may have a range of needs (including clinical needs) as a result and these must be met where possible. This is part of our duty of care. Meeting people's needs not only helps alleviate the harm experienced, but also helps avoid compounding the harm. While we cannot change the fact that an incident has happened, it is always within our gift to compassionately engage with those affected, listen to, and answer their questions and try to meet their needs.

It is recognised from experience and research that patients and families often provide a unique, or different perspective to the circumstances around patient safety incidents, and / or may have different questions or needs to that of the Trust. Engaging with those affected by a patient safety incident substantially improves our understanding of what happened, and potentially how to prevent a similar incident in future.

Processes for engaging and involving those affected by patient safety incidents will be applied as follows:

- Apologies are meaningful. Apologising is a crucial part of the Duty of Candour.
- Approach is individualised.
- Timing is sensitive.
- Those affected are treated with respect and compassion.
- Guidance and clarity are provided. Patients, families, and healthcare staff can find the processes that follow a patient safety incident confusing.
- Those affected are 'heard'. Everyone affected by a patient safety incident should have the opportunity to be listened to and share their experience.
- Approach is collaborative and open.
- Subjectivity is accepted.
- Strive for equity.

This policy therefore reinforces existing guidance relating to the duty of candour and 'being open' and recognises the need to involve patients and families as soon as possible in all stages of any investigation, or improvement planning, unless they express a desire not to be involved.

Involving Patients & Families

The Trust recognises the importance of and is committed to involving patients and families following patient safety incidents, engaging them in the investigation process and to fulfil the duty of candour requirements. It is recognised from experience and research that patients and families often provide a unique, or different perspective to the circumstances around patient safety incidents, and / or may have different questions or needs to that of the organisation. This policy therefore reinforces existing guidance relating to the requirements of statutory duty of candour, compassionate engagement in the event of any incident, and 'being open', and recognises the need to involve patients and families as soon as possible in all stages of any investigation, or improvement planning, unless they express a desire not to be involved. Further guidance in relation to involving patients and families following a patient safety incident is available from NHSE at: <https://www.england.nhs.uk/publication/patient-safety-incident-response-framework-and-supporting-guidance/#heading-2> and within our Trust Be Open Policy,

Involving Staff, Colleagues and Partners

Similarly, involvement of staff and colleagues (including partner agencies) is of paramount importance when responding to a patient safety incident to ensure a holistic and inclusive approach from the outset. Again, this reinforces existing guidance such as our incident reporting and management policy, though it is recognised this approach must not be restricted to only those incidents that meet a threshold of harm or predefined categories. We will continue to promote, support and encourage our colleagues and partners to report any incident or near-misses, with an enhanced focus on incident, or groups of incidents, which provide the greatest opportunities for learning and improvement.

We welcome speaking up as it is vital that our staff feel safe and are encouraged to speak up in order to raise their concerns to keep patients and staff safe to support the working environment for our staff. Anyone can speak up including health care professionals, non-clinical workers, receptionists, directors, managers, contractors, volunteers, students, trainee's, junior doctors, locum doctors, bank and agency workers and former employees.

We encourage our staff to report concerns internally for us to act promptly as this is the quickest way for us to respond to incidents. However, you can report concerns externally to the Care Quality Committee (CQC) for quality and safety concerns about the services it regulates.

This is an approach which is already embedded within LHCH, and as an organisation we will continue to provide support and guidance utilising the principles of good change management, so staff remain engaged and involved throughout the processes. We will therefore ensure regular communication and involvement through our communication framework and our wider organisational governance structures.

It is also recognised that staff and colleagues need to continually feel supported to speak out and openly report incidents and concerns without fear of recrimination or blame. We will continue to closely monitor incident reporting levels and continue promote an open and fair culture to support this.

See also the trust guidance and policies on duty of candour / being open and FTSU, as well as NHSE Involving those affected by incidents: [B1465-2.-Engaging-and-involving...-v1-FINAL.pdf \(england.nhs.uk\)](#).



Just Culture
poster.pdf

9. Patient safety incident response planning

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

As a Trust we welcome this approach so we can focus our resources on incidents, or groups of incidents that provide the greatest opportunities for learning and improving safety. It is also recognised that our planning needs to account for other sources of feedback and intelligence such as complaints, risks, legal claims, mortality reviews and other forms of direct feedback from staff and patients. PSIRF guidance specifies the following standards that our plans should reflect:

1. A thorough analysis of relevant organisational data
2. Collaborative stakeholder engagement
3. A clear rationale for the response to each identified patient safety incident type

They will also be:

1. Updated as required and in accordance with emerging intelligence and improvement efforts
2. Published on our external facing website

Our associated patient safety incident response plan (PSIRP) will reflect these standards and will be published alongside this overarching policy framework. This will be updated every 12 months.

Resources and training to support patient safety incident response

PSIRF recognises that resources and capacity to investigate and learn effectively from patient safety incidents is finite. It is therefore essential that as an organisation we evaluate our capacity and resources to deliver our plan. The PSIRP provides more specific details in relation to this including the number of comprehensive investigations that may be required for single or small groups of incidents that do not fall into one of the broader improvement workstreams/priorities. The Trust has in place governance arrangements to ensure that learning responses are led by appropriate individuals, i.e. staff who were not involved in the patient safety incident itself or by those who directly manage those staff. Learning responses are not taken in isolation. Subject matter experts with relevant knowledge and skills will be involved, where necessary, throughout the learning response process to provide expertise, advice, or proof reading.

Currently Patient Safety is led through the Risk Management Team and the Clinical Trust Patient Safety Lead and these have the following working time equivalent posts to support and facilitate the PSIRF framework, as part of their roles:

- 1 x Clinical Trust Patient Safety Lead
- 1 x Head of Risk Management
- 1 x Patient Safety Lead Nurse
- 1 x Governance Systems Analyst

There is also a pool of 45 trained individuals who can undertake comprehensive investigations, though the majority have a substantive clinical or governance role. Again, our PSIRP will detail more specifically which incidents will require a comprehensive investigation with an indication of how many of these we expect to complete in a year. The pool of investigators have been trained by an external facilitator who is listed as an approved provider to deliver Patient Safety Lot 4, noted within the NHSE website.

All staff are required to complete mandatory patient safety training Levels 1 and 2, which covers the basic requirements of reporting, investigating and learning from incidents. This is a starting point for all our staff and includes and covers, listening to patients and raising concerns, the systems approach to safety, where instead of focusing on the performance of individual members of staff, we try to improve the way we work, avoiding inappropriate blame when things don't go well, creating a fair culture that prioritises safety and is open to learning about risk and safety.

It is therefore expected that Divisional managers will involve all relevant staff in more routine / low risk incident reviews, though further advice and guidance can always be provided by the Risk Management Team if required. It is important that the organisation seeks regular feedback from colleagues with regard to investigating and learning from incidents and considers whether any additional or bespoke training is required, either more widely or targeted at specific staff groups or individuals.

Those trained to Lots 4a-c will be facilitators of Patient Safety Review's across the Trust going forward, and then cascade this training to colleagues to promote facilitating PSR's following patient safety incidents.

Engagement leads will have completed level 1 and level 2 training and will have undertaken a minimum of 6 hours training relating to "Involving those affected by patient safety incidents in the learning process".

Those in PSIRF oversight roles will have completed level 1 and level 2 training, a systems approach to learning from patient safety incidents equivalent to 2 days/12 hours training, oversight of learning from patient safety incidents which is equivalent to 6 hours training and involving those affected by patient safety incidents in the learning process, 6 hours of training.

Our patient safety incident response plan

Our plan (PSIRP) sets out how we intend to respond to patient safety incidents over a period of 12 to 24 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, as well as the plan.

The PSIRP is based on a thorough analysis of themes and trends from all incidents from 2018-2022 (including low harm, no harm and near misses), complaints and concerns, learning and recommendations from Serious Incidents (conducted under the previous framework), mortality reviews, legal claims and inquests, risks and risk registers and feedback from staff and patients. The priorities identified in the PSIRP will be regularly reviewed against quality governance reports and surveillance to ensure they are responsive to unforeseen or emerging risks.

The plan is based on a thorough analysis of themes, patterns, and trends from:

- Serious Incident Investigations (last 5 years)
- Health inequalities data (associated with SI review)
- Complaints / PALS
- Safeguarding reviews
- Mortality reviews
- Freedom to speak up concerns
- Trust staff survey annual results
- Legal claims (new / ongoing / settled)
- Inquests
- Quality improvement and Service evaluation projects

Reviewing our patient safety incident response policy and plan

As referred to above, 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 18 months to ensure our focus remains up to date. It is recognised that with ongoing improvement work our patient safety incident profile is likely to change. This will also provide an opportunity to re-engage with stakeholders to discuss and agree any changes made in the previous 18 months.

Updated plans will be published on our website, replacing any previous versions.

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

10. Responding to patient safety incidents

PSIRF guidance states:

“Where an incident type is well understood – for example, because previous incidents of this type have been thoroughly investigated and national or local improvement plans targeted at the contributory factors are being implemented and monitored for effectiveness – resources may be better directed at improvement rather than repeat investigation (or other type of learning response).”

(PSIRF supporting guidance, Guide to responding proportionately to patient safety incidents. NHSE 2022)

Patient safety incident reporting arrangements

Patient safety incident reporting will remain in line with the Trusts Incident Reporting Policy, with all staff encouraged where possible to report all patient safety incidents using our InPhase system. The level of harm will also be recorded by the reporter. See the table below for definitions of harm. These reports will then be routinely uploaded to the national data base (Learning From Patient Safety Events-LFPSE) to support national learning.

Some incident types will require specific reporting and/or review processes to be followed. This is documented in our PSIRF Plan as well as the required response/action.

Daily review mechanisms are already established to ensure that patient safety incidents are responded to proportionately and in a timely manner. This will also consider the requirements for The Duty of Candour, as per the Be Open Policy.

New guidance on Level of Harm selection on the Learning From Patient Safety Events can be found here: <https://www.england.nhs.uk/long-read/policy-guidance-on-recording-patient-safety-events-and-levels-of-harm/>, and details on previous harm grades and new harm grades are listed below.

Previous harm grades	New physical harm grades	New psychological harm grades
No Harm	No physical harm	No psychological harm
Low harm	Low physical harm	Low psychological harm

Most incidents will only require a local review

Moderate harm	Moderate physical harm	Moderate psychological harm
Severe harm	Severe physical harm	Severe psychological harm
Death	Fatal	n/a

within the service, however, if it is felt that there is an opportunity to learn from and improve, these should be escalated appropriately to the Divisions.

Divisional operational and senior managers along with governance teams 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. Likewise, we will ensure we are responsive to incidents reported by partner colleagues that require input from the Trust, primarily by directing enquires to the relevant clinical teams or colleagues and seeking assurance that engagement, information sharing and learning has been achieved, or taken forward.

11. Responding to cross-system incidents/issues

With regards to any cross-system incidents, an appropriate member of the Risk Management team will email to our lead commissioner by emailing sui.function@nhs.net from PSIRF@lhch.nhs.uk to trigger ICB/S processes under PSIRF. Certain incidents require external reporting to national bodies such as HSIB, HSE, RIDDOR and MHRA, this will also be the responsibility of the Head of Risk Management to undertake.

Regionally, all Trusts have set up a generic PSIRF email account for their respective Trust, to ensure no missed communications and a smooth dialogue can occur between other Trusts were required.

If more than one organisation is involved in the care and service delivery in which a patient safety incident has occurred, the organisation that identifies the incident is responsible for recognising the need to alert relevant stakeholders to initiate discussions about subsequent investigation and actions. All relevant stakeholders involved should work together to undertake one single investigation wherever this is possible and appropriate. The integrated care system should help to facilitate discussions relating to who is the most appropriate organisation to take responsibility for co-ordinating the investigation process.

12. Mortality process and issues

Our Trust has a well-established a monthly Mortality Review Group to provide oversight of compliance with the mortality review process and to provide the Trust with the assurance that causes, and contributory factors of all in-patient deaths have been considered and are appropriately responded to in an open and transparent manner.

Under PSIRF, not all deaths reviewed by a coroner will be subject to a full Patient Safety Incident Investigation (PSII). Under the new Framework, the learning response within the NHS should not be expected to make judgments about cause of death. If a PSII is undertaken regarding a death that will be reviewed by a coroner, the coroner will receive the PSII report. If a different learning response is undertaken, the output from the response will be shared with the coroner.

As highlighted, not all deaths reviewed by a coroner will receive a full patient safety incident investigation (PSII). In some cases, there will be a different learning response such as a case review, MDT, Swarm Huddle or an After-Action Review. The output from that response will be shared with the coroner.

The mortality review process will continue as per Mortality Review Policy, with a Structured Judgement Review carried out initially. If following the Structured Judgement Review, there is an incident which falls into the National Priorities category or has the potential to be a Patient Safety Incident Investigation then the processes for these would follow as per Appendix 3, or if there is a potential for learning or more information required, then a methodology from the PSIRF toolkit should be utilised, and the Patient Safety Review route (Appendix 2) followed. The mortality review policy will also be updated in line with PSIRF processes.

Patient safety incident response decision-making

As explained above, reporting of incidents should continue in line with existing Trust policy and guidance. The Trust also has governance and assurance systems to ensure oversight of incidents both Divisional and Trust wide. Corporate and Governance teams work with clinical and operational managers to ensure the following arrangements are in place:

- Identification and escalation of any incidents that have, or may have caused significant harm (moderate, severe or death)
- Identification of themes, trends or clusters of incidents within a specific service
- Identification of themes, trends or clusters of incidents relating to specific types of incidents
- Identification of any incidents relating to local risks and issues (eg – CQC concerns)

- Identification of any incidents requiring external reporting or scrutiny (eg – Never Events, Neonatal deaths, RIDDOR)
- Identification of any other incidents of concern, such as serious near-misses or significant failures in established safety procedures
- Identification of any incidents that have significant learning for the organisation.

The Head of Risk Management and Patient Safety Lead Nurse review the data regularly to identify and track emerging themes and trends outside of normal variation, this information is presented to the Quality, Safety and Experience Committee on a quarterly basis. This information will be reviewed regularly against our identified priorities in the PSIRP to determine whether any shift in focus is required, which will be agreed by the Quality Safety Experience Committee if required.

As outlined in the Incident Management Policy, the process for completion of a Patient Safety Rapid Review, to determine any further investigation or escalation required will remain. This, however will now include a wider range of options for further investigation outlined in the PSIRF. The principles of proportionality and a focus on incidents that provide the greatest opportunity for learning will be central to this decision making under the Trust's PSIRP. This may often mean no further investigation is required, especially where the incident falls within one of the improvement themes identified in the PSIRP.

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 event. These are set out in our Patient Safety Incident Response Plan.

To improve safety and manage risk within our Trust it is important that all events from which learning can be extracted are identified and managed with this framework to support improvement.

It is recognised that some incidents may still require a case based comprehensive investigation. Where this is the case, reference must be made to available investigatory capacity and resources as detailed in the PSIRP. In cases such as this, there will also be an Engagement Lead assigned to the investigation to support with patient, family and staff involvement. In incidents such as this, the Divisional and Trust Patient Safety Panels will use the following criteria to assist in determining whether a PSII is warranted or not:

Locally-defined patient safety incidents requiring PSII:

Criteria for selection of incidents for PSII:

- a. actual and potential **impact of outcome** of the incident (harm to people, service quality, public confidence, products, funds, etc)
- b. **likelihood of recurrence** (including scale, scope and spread)
- c. **potential for learning** in terms of:
 - enhanced knowledge and understanding
 - improved efficiency and effectiveness (control potential)
 - opportunity for influence on wider systems improvement.

Locally-defined emergent patient safety incidents requiring PSII (Ad Hoc):

An unexpected patient safety incident which signifies an **extreme level of risk** for patients, families and carers, staff or organisations, and where the **potential for new learning and improvement is so great** (within or across a healthcare service/pathway) that it warrants the use of extra resources to mount a comprehensive PSII response.

The process for reporting incidents will not change and the decision-making process can be seen in the flow chart below and within Appendix 1-3. Our Trust has a weekly safety meeting where the responsibility will be for the review of investigations relating to local priorities or moderate harm incidents and the consideration of incidents for PSII or PSR and for an oversight of the outcomes to ensure that any recommendations are established in a system-based approach and safety actions are completed with Divisional representation. The Divisional Patient Safety Panel, with Trust Patient Safety Panel overall agreement, will be responsible for:

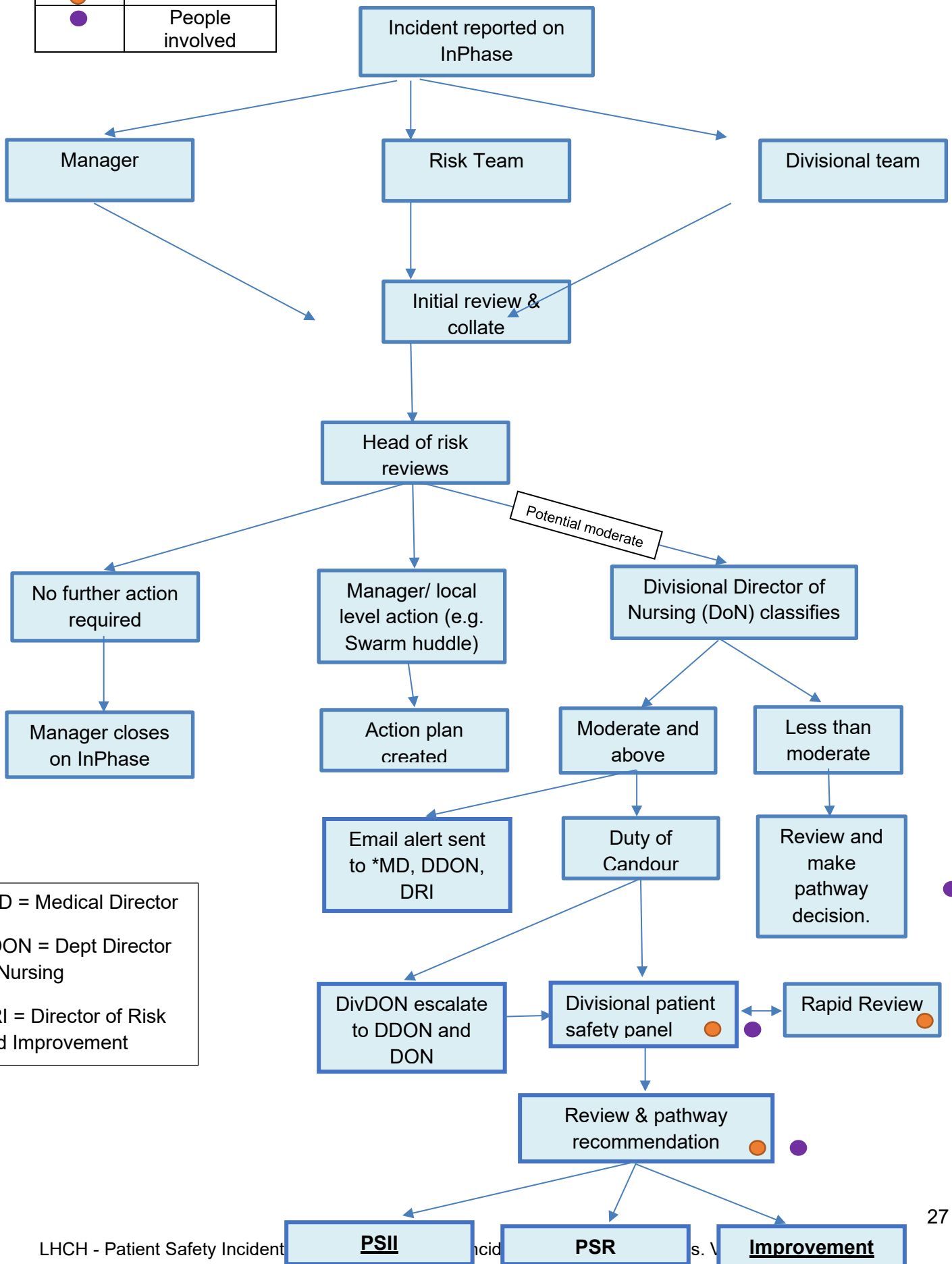
- Identifying the Lead investigator
- Establish a team
- Setting Terms of Reference
- Allocate tasks
- Agree timescales and reviews-
- Patient Safety Incident Investigation (PSII) to be completed using PSII template. Recommendations added to Investigation system for tracking.

Divisions will monitor the QI programmes for local priorities. This gives the Board assurance that as a Trust we are complying with the PSIRF response standards.

Below is the incident process that LHCH will follow for the reporting and escalating of incidents and appendices for required supporting templates and documents, further templates for alternative incident response processes are within the Appendices (1-3):

	Process step
●	Document
●	People involved

Initial PSIRF Process



Please follow relevant pathway in appendix

Certain patient safety incidents are reportable externally via a mandatory reporting system e.g. specific categories of infection and hospital acquired pressure ulcers. This reporting will remain unchanged. For these incidents a review will be initiated by the specialist services using a tailored patient review template. These will be sent to the relevant local managers. If moderate or above harm is suspected the review will then be submitted to the relevant Divisional Director of Nursing as outlined in the PSIRF process above.

Timeframes for learning responses

Learning responses must balance the need for timeliness and capture of information as close to the event as possible, with thoroughness and a sufficient level of investigation to identify the key contributory factors and associated learning for improvement.

“The first step when embarking on a process to learn and improve after a patient safety incident is to make efforts to understand the context and develop a deep understanding of work processes. It can be tempting to rush to identify what needs to change, but this cannot be done without understanding work as done, and the system factors that influence this. A thorough understanding of the work system can be gained using a learning response method such as investigation, multidisciplinary team review or after action review, supplemented with a system-based framework to guide thinking (eg SEIPS, Yorkshire Contributory Factors Framework, HFACS, etc).” (NHSE PSIRF Guidance: Safety Action Development, p17)

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 PSIRP 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 including further Rapid Review investigation – as soon as possible, within 5 working days of reporting
- Further learning response (eg: MDT Review, After Action Review, Swarm huddle) – within 10 working days of reporting
- Comprehensive Investigation (PSII) – 60 - 120 working days depending on complexity, the timeframe for the completion of a PSII will be agreed with those affected, as part of the terms of reference, as long as they are wanting to be involved.

Where external bodies (or those affected by patient safety incidents) cannot provide information, to enable completion within six months or the agreed timeframe, the PSII leads should 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.

In some incidences, longer timeframes may be required for completion of the PSII. In this case, any extended timeframe should be agreed between the Trust and those affected.

A toolkit of our Trust agreed learning response types are attached below. We have agreed to use the following learning responses when reviewing an incident, to assist us in information gathering and highlighting any learning:

- **Swarm Huddle** – **What is it:** *A meeting to explore an incident in a non-punitive way and deliver learning. It is a facilitated discussion on an incident or event to analyse what happened, how it happened and decide what needs to be done immediately to reduce risk. It enables understanding and expectations of all involved and allows for learning to be captured and shared more widely. Safe space, invitees only (those involved in incident).* **When to use it:** *Swarms can be used soon after any activity or event (within a working week ideally) where care has not gone as planned - this can prevent key information being lost. Swarms can reduce blame and rumours about an incident by focussing on learning and improvement and an understanding of 'work as done'.*
- **After Action Review** - **What is it:** *A structured, facilitated discussion on an incident or event to identify a group's strengths, weaknesses and areas for improvement by understanding the expectations and perspectives of all those involved and capturing learning to share more widely. Safe space, invitees only (those involved in incident).* **When to use it:** *AARs can be used after any activity or event that has been particularly successful or unsuccessful. It is also often used at the end of a project to help populate a lessons learnt log. It is important to disseminate learning widely so that good practice can be shared and others can learn from mistakes.*
- **MDT Review** – **What is it:** *An open discussion to determine the key contributory factors and system gaps in patient safety incidents. Good tool to use when it is more difficult to collect staff recollections of events either because of the passage of time or staff availability.* **When to use it:** *Identify learning from multiple patient safety incidents (including incidents where multiple patients were harmed or where there are similar types of incidents). To explore a safety theme, pathway, or process. Thematic analysis.*
- **Rapid Review** – **What is it:** *A timely and affordable approach that can provide actionable and relevant evidence to strengthen policies and systems in healthcare. It is a form of rapid investigation that takes account of a broad range of data sources to inform the scope of enquiry. The approach aims to rapidly assess the evidence base using a systematic methodology to produce a transparent overview of the secondary-level evidence landscape that can be used to inform further work.* **When to use it:** *It is useful to help refine a broad question, as well as identify potential gaps in the evidence.*

Further details can be found from NHSE at: <https://www.england.nhs.uk/publication/patient-safety-learning-response-toolkit/>



LHCH Rapid Review
including Divisional



Swarm template
draft LHCH V1.0.docx



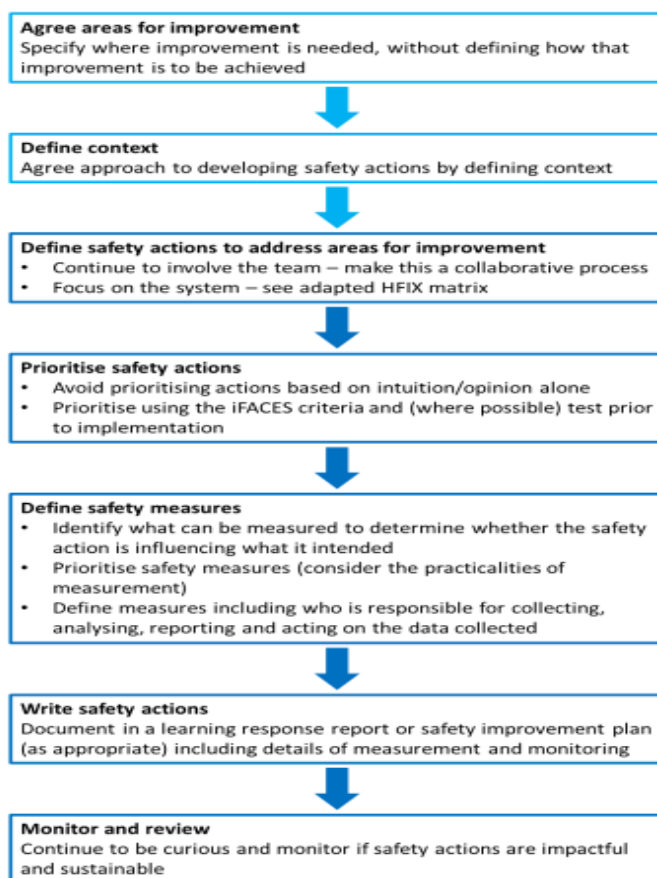
After Action Review
LHCH.docx

Safety action development and monitoring improvement

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

“Learning response methods enable the collection of information to acquire knowledge. This is important, but it is only the beginning. A thorough human factors analysis of a patient safety incident does not always translate into better safety actions to reduce risk. You must move from identifying the learning to implementation of the lessons. Without an integrated process for designing, implementing, and monitoring safety actions, attempts to reduce risk and potential for harm will be limited.”

The following diagram summarises how safety actions should be developed and overseen:



Recognising that the first step when embarking on a process to learn and improve after a patient safety incident is to make efforts to understand the context and develop a deep understanding of work processes. It is important to understand “work as done” and the systems factors that influence work. Areas for improvement can relate to a specific local context or to the context of the wider organisation. Findings from PSIs and PSRs provide key insights and learning opportunities, but they are not the end of the story. PSIRF moves away from the identification of ‘recommendations’ which may lead to solutions at an early stage of the safety action development process.

By identifying and agreeing aspects of the work system where change could reduce risk and potential for harm (ie ‘areas for improvement’ or system issues). Actions to reduce risk (ie safety actions) are then generated in relation to each defined area for improvement. Following this, measures to monitor safety actions and the review steps are defined.

A Quality Improvement approach is valuable in this aspect of learning and improvement following a patient safety investigation. It will therefore be necessary to ensure close links are developed and maintained with the Quality Improvement Team so their expertise and guidance can be utilised when developing the learning response and safety actions. PSIRF therefore provides an opportunity to strengthen this and for the QI and Patient Safety functions to work more closely together. Quality Improvement to support embedded learning and improvement following a patient safety investigation is key to improving patient safety outcomes. Close links have been and will continue to be developed and maintained with the Improvement Team. PSIRF provides an opportunity to strengthen this and for the QI and Patient Safety functions to work hand in hand.

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>

Monitoring of completion and effectiveness of safety actions will be through organisational governance processes reporting within Divisions and their associated governance meetings with audit support and will be further reported to Quality Safety Experience Committee. The Risk Management Team will maintain an overview across the organisation to identify themes, trends and triangulation with other sources of information that may reflect improvements and reduction of risk.

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 must therefore develop governance systems focused more on measuring and monitoring these outcomes, utilising subjective as well as objective measures.

Safety improvement plans at Liverpool Heart and Chest Hospital

As referred to throughout the policy, the Trust has developed a Patient Safety Incident Response Plan (PSIRP) that clarifies what our improvement priority areas or emergent themes are. The PSIRP details how we will ensure patient safety incidents are investigated in a more holistic and inclusive way, to identify learning and safety actions which will reduce risk and improve safety and quality.

These themes, as detailed in the PSIRP, are based on an extensive analysis of historic data and information from a range of sources (eg: incident trends, complaints, mortality reviews, risk registers, legal claims and inquests) and feedback from staff and patients. Whilst the PSIRP identifies the broad organisational priorities, it is recognised there may be more specific priorities and improvements identified at a more local specialised level, which although will not form part of the overarching plan, can still be approached utilising the more holistic and inclusive PSIRF approach. The Risk Management Team will provide support and guidance, as required, to teams in this regard. The QI team can also assist in these improvements and identify where there is overlap with existing and developing QI programmes across the Trust.

The Trust has overarching safety improvement plans already in place including individual safety improvement plans that focus on specific services. Where overarching system issues are identified by learning responses outside of the Trust local priorities, a safety improvement plan may be developed. These will be identified through the Patient Safety Learning Meeting (PSLM) and approved by the Trust Patient Safety Panel. Monitoring of progress will be overseen by a forum agreed by the Trust Patient Safety Panel, and fed into the Quality, Safety and Experience Committee.

The Trust is reviewing governance processes in line with the PSIRF guidance so it is clear how the PSIRP improvement priorities will be overseen through Quality and Corporate governance structures and processes. Specialty level improvements will be managed locally with assurance and reporting to the associated work group, then, Corporate oversight and assurance committees to provide 'ward to board' assurance.

13. Oversight roles and responsibilities

“When working under PSIRF, NHS providers, integrated care boards (ICBs) and regulators should design their systems for oversight “in a way that allows organisations to demonstrate [improvement], rather than compliance with prescriptive, centrally mandated measures”. To achieve this, organisations must look carefully not only at what they need to improve but also what they need to stop doing (eg panels to declare or review Serious Incident investigations).”

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

Responsibility for oversight of the PSIRF for provider organisations sits with the Trust Board. The Executive Lead is the Director of Nursing and Quality who holds responsibility for effective monitoring and oversight of PSIRF. The ‘Responding to patient safety incidents’ section above also describes some of the more operational principles that underpin this approach.

The Trust recognises and is committed to close working, in partnership, with the local ICB and other national commissioning bodies as required. Representatives from the ICB will sit on PSIRF implementation groups. Oversight and assurance arrangements will be developed through joint planning and arrangements must incorporate the key principles detailed in the guidance above, namely:

1. Compassionate engagement and involvement of those affected by patient safety incidents
2. Policy, planning and governance
3. Competence and capacity
4. Proportionate responses
5. Safety actions and improvement

As referred to above, it is important that under PSIRF there is a paradigm shift from monitoring of process, timescales and outputs to meaningful measures of improvement, quality and safety, and outcomes for patients. It should be noted that similarly the ICB’s role will focus on oversight of PSIRF plans / priorities and monitoring progress with improvements. There will no longer be a requirement to ‘declare’ an SI and have individual patient safety responses ‘signed off’ by commissioners. However, they will wish to seek assurances that improvements and priorities under PSIRF are progressing and delivering improvements in quality and safety. The metrics, measures (objective and subjective) and evidence required to do this will need to be defined within the PSIRP for each priority which will be agreed in discussion with the ICB.

14. Complaints

Any complaints relating to this guidance, or its implementation can be raised informally with the Patient Safety Lead Nurse, initially, who will aim to resolve any concerns as appropriate.

Formal complaints from patients or families can be lodged through the Trust's complaints procedure at <http://nww.staffintranet.lhch.nhs.uk/media/2558/complaints-policy-v36.pdf>. At the earliest opportunity speak to the manager of the ward, matron, department, or doctor in charge of your care to let them know what you are not happy with. They will do all they can to resolve the issues that you raise.

or by contacting the Patient and Family Support Team below:

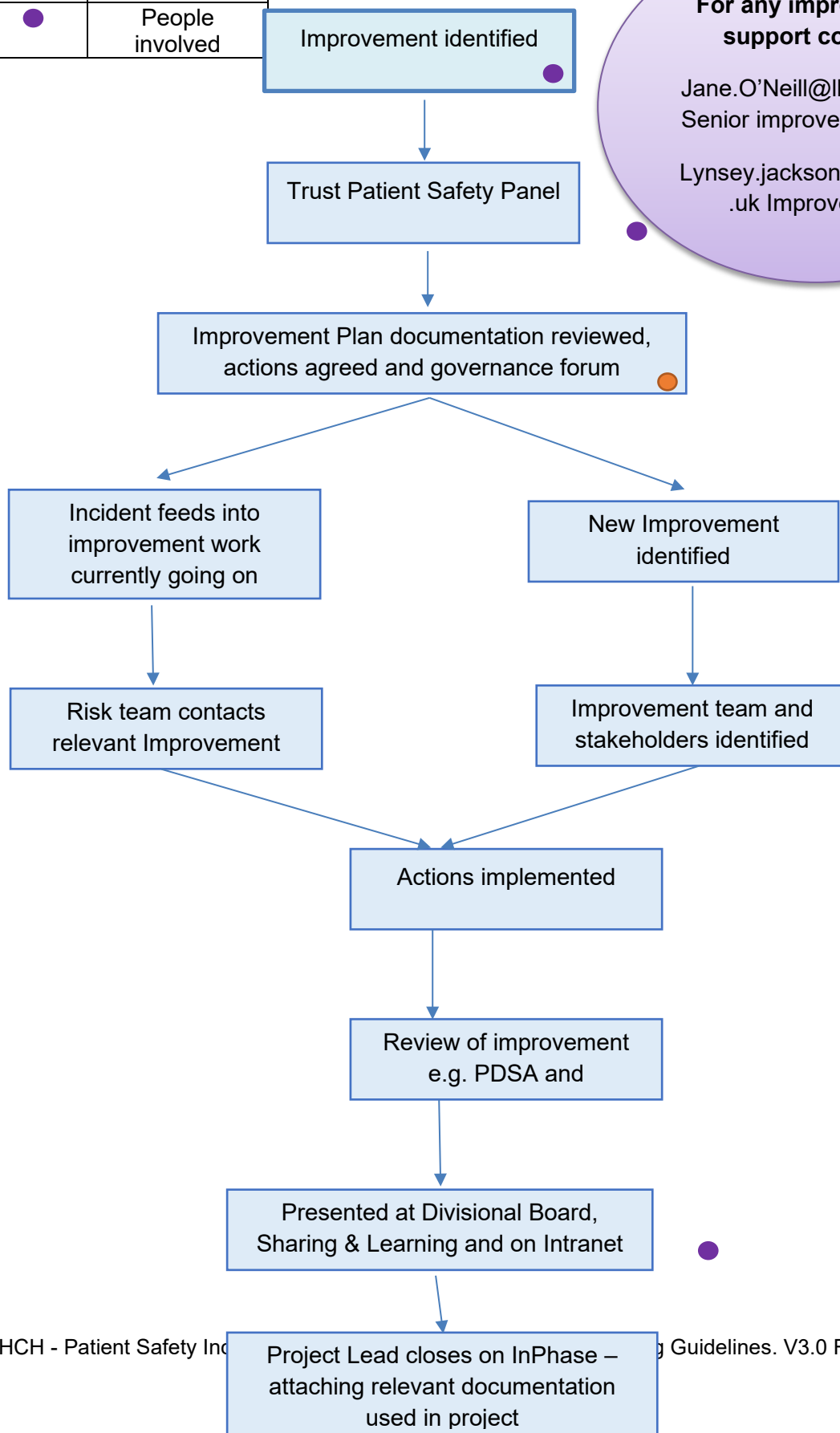
Laura Allwood
Patient and Family Support Manager
Liverpool Heart and Chest Hospital NHS Foundation Trust
☎ 0151 600 1257
✉ laura.allwood@lhch.nhs.uk

1. Appendices

Appendix 1

	Process step
●	Document
●	People involved

Improvement Process



For any improvement support contact:

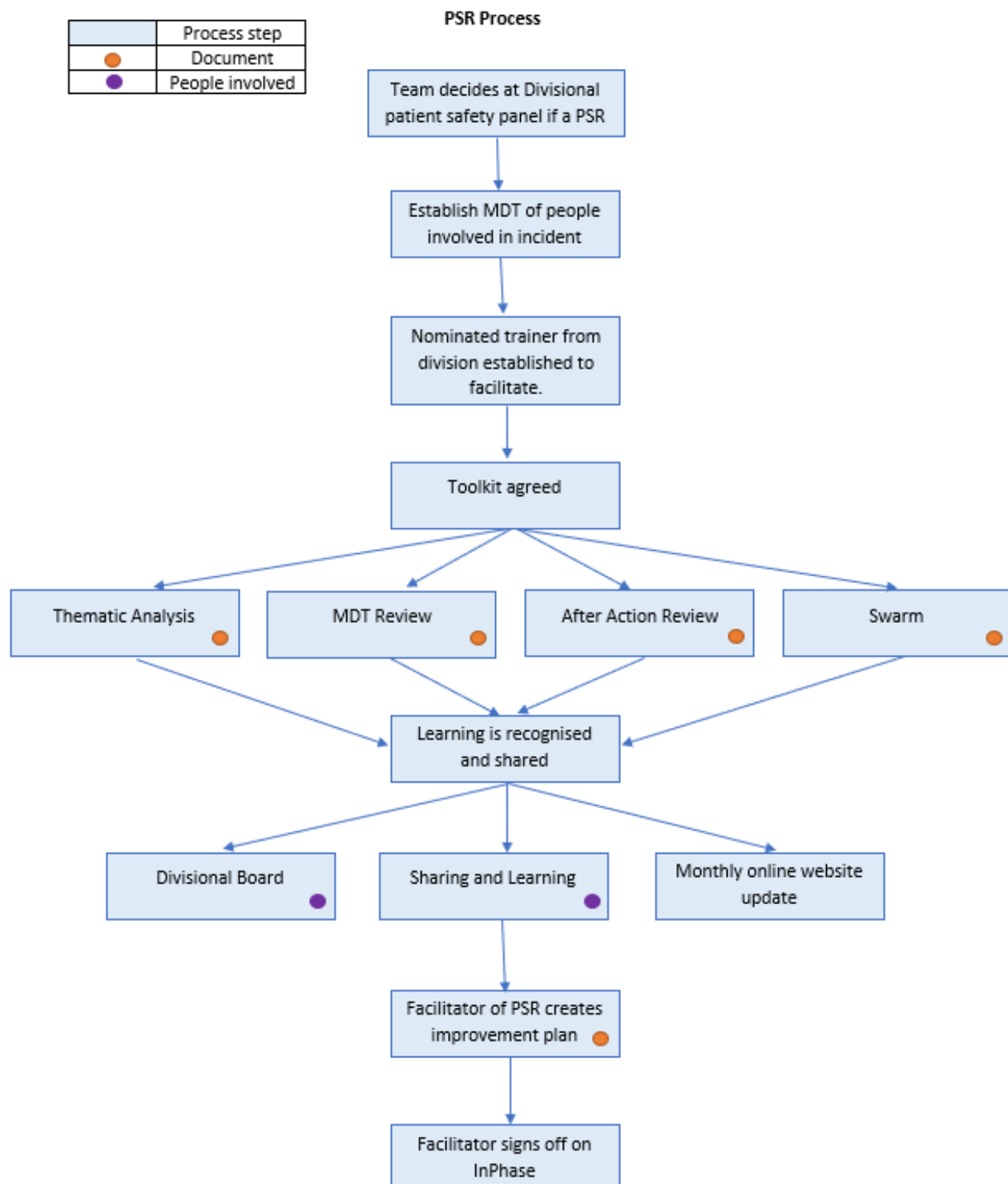
Jane.O'Neill@lhch.nhs.uk
Senior improvement Lead

Lynsey.jackson@lhch.nhs.uk
Improvement

Feedback to governance forum

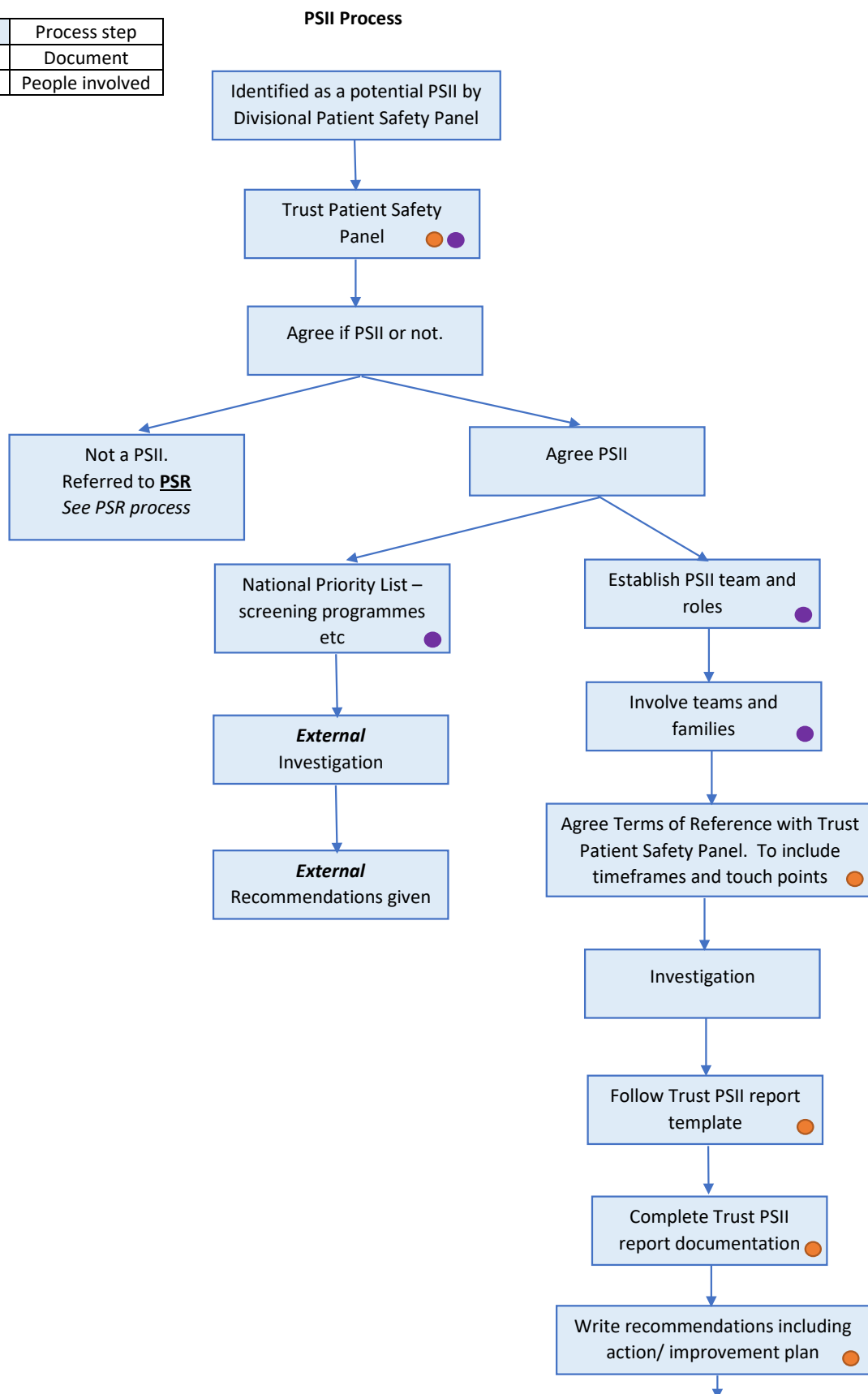
Appendix 2

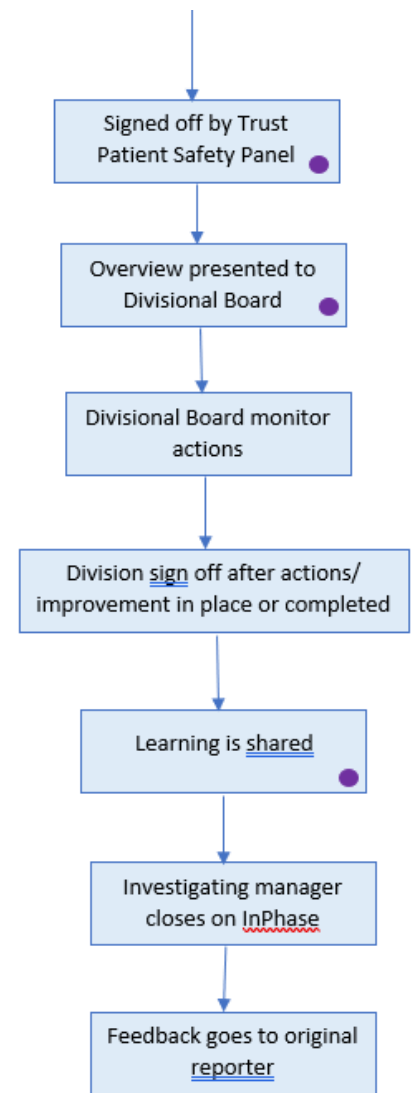
PSR process Map



Appendix 3

	Process step
●	Document
●	People involved





Incident Reporting Guideline

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1. Guideline Statement

The Trust is committed to providing a safe environment for its patients, staff and visitors and to delivering high standards of care. Central to the Trust's ethos is putting patients, families and carers at the centre of everything we do.

It acknowledges that sometimes, in the course of providing healthcare and associated functions, incidents can occur, some of which may have serious consequences for a patient, their carers/ families, staff and the public. It is very important that we learn from incidents and to ensure identify through the investigation process any learning to improve the care we provide.

Responding appropriately when things go wrong is a key part of the way the Trust can learn and continually improve the safety of the services provided to our patients and to support staff to achieve this. The Trust recognises that in complex healthcare settings, unintended or undesirable outcomes will arise, but when they do it is important that incidents are identified correctly, investigated thoroughly and most importantly triggers actions which will prevent future harm.

This guidance is for all staff and includes the principles of Being Open and Duty of Candour. When incidents occur, we need to ensure we are open, honest and transparent. Duty of Candour includes ensuring that any patient who experiences moderate/severe harm during the provision of healthcare is provided with an apology and an explanation of what happened. Full guidance can be found at: CQC Regulation 20 Duty of Candour <https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-20-duty-candour>

2. Purpose of the guidance

The purpose of this guidance is to ensure all incidents are reported appropriately in proportionate to their level of severity.

This guidance defines the roles and responsibilities of staff in relation to the processes for reporting incidents

This guidance is intended to ensure that:

- Staff work in an open, honest and transparent way where patients and families are put at the centre of the process.
- Incidents are managed effectively and immediate action / learning takes place.
- Learning responses are conducted in a timely manner and are of high quality.
- Staff follow the correct procedure when an incident arises.
- Incident reviews are completed with the patient and family in mind / involvement of the patient and family.
- Staff are supported following an incident.

3. Roles, Responsibilities and Duties

Chief Executive and Executive Board

- Ensures the Trust has adequate systems for the reporting of all incidents and near misses
- The Chief Executive and Board provide the strategic leadership to promote and develop the Trust's safety culture. This includes responsibility for effective risk management within the Trust and to ensure the organisation complies with its statutory obligations.

Director of Risk and Governance

- Has the Executive Lead for Risk Management
- Ensures organisational learning occurs following the investigation into reported incidents and near misses.
- Implementation of this guidance

Patient Safety Specialist

- Will be the point of contact for medical staff who are identified as investigation personnel
- Will support the risk management team in ensuring all timeframes for completion of investigation reports are adhered to

Patient Safety Lead Nurse/Head of Risk Management

- Will support the Director of Risk and Improvement in ensuring the guidance is implemented
- Will act in an advisory capacity to the Risk Management Team with regards to the grading of incidents
- Will ensure the investigation process is followed by the Divisions in regard to completion and appropriate review
- Will ensure the Trust Board are appraised incidents resulting in moderate, severe harm or death
- Will assist the Divisions in the discharge of their duties when identifying and investigating incidents within the timescales for investigating and reporting of those incidents.

Trust Patient Safety Panel

- The Group will be responsible for identifying a learning response lead/team in the event of a major patient safety event or in the event of identification of an incident relating to the Trust National priorities, to conduct a Patient Safety Incident Investigation (PSII).
- The Group will ensure the learning response lead/team commence engagement with those affected as part of the investigation.
- The Group will oversee all PSII's, ensuring a terms of reference is set for each investigation.

- Those integral to the investigation should be consulted when developing the terms of reference. This includes all people with a significant interest in the outcome and questions to be addressed by the investigation.
- Ensure that there is a robust quality assurance process in place for the approval of PSII's prior to the report being shared, once completed.
- Ensure all PSII's are fully investigated, and areas of improvement describe broader systems issues.
- Ensure safety action development is submitted and are auditable and the action owners and timescales set are appropriate.
- Learning Disabilities Mortality Reviews (LEDER) to be presented, noting whether a response is required and managing and monitoring of the responses.
- Claims to be presented, noting whether immediate response is required or any immediate concerns.

Divisional Triumvirate/ Clinical Leads

Divisional Heads of Operations' (DHOO's), Divisional Directors of Nursing (DDONS), Associate Medical Directors (AMD) and clinical leads in each service are responsible for the implementation of this guidance in their service area which ensures:

- The Service meets its obligations as described within this guidance, which includes the Duty of Candour and the requirement to involve the patient, their family / carer in the process of investigation.
- That appropriate and effective incident reporting processes are in place within the designated area.
- All staff within their work environment to include all bank and agency staff, are made aware and given guidance on the incident reporting process.
- Action is taken to contain an incident when identified in order to minimise harm.
- Identified actions from incidents are acted upon in a timely manner as per the timeframes within the action plan
- Themes and trends from incidents are acted upon and learning is shared within their division
- In situations where significant risks have been identified and where local control measures are considered to be potentially inadequate, these risks are escalated via the risk identification process.
- Effective and timely communication with staff and patients, their carers and family and the provision of appropriate support.

All staff

All staff will follow the procedure outlined in this guidance which includes:

- Attending to people's immediate needs following an incident and maintaining / re-establishing a safe care environment
- Being familiar with and implement the procedure for reporting incidents
- Ensuring effective incident management by completing a web-based incident report form on Inphase when either directly involved in an incident or injured as a result of an incident.
- Reporting all incidents including near misses within their span of duty.

- Co-operating with all reviews or investigations that the Trust undertakes. This is in line with various NHS and Professional Codes of Conduct and Trust policy.
- Will ensure that all nosocomial infections are reported as incidents

Risk Management Team

- To ensure all reported incidents and near misses are recorded, assigned a manager
- Reviewing incidents and trends on an organisation wide basis
- Ensure monthly reports extracted from the Inphase system detailing all reported incidents and near misses within clinical areas or departments are forwarded to Divisional Head of Operations, Associate Medical Directors, Divisional Directors of Nursing and Heads of Departments.
- Maintain a contemporaneous record of all incident reviews performed within the Trust
- Report relevant incidents to monitoring organisations as required (i.e. Monitor, Care Quality Commission)

Freedom to Speak Up Guardian

The Freedom to Speak Up Guardian is responsible for supporting staff when they have a concern so that they feel able to raise matters freely and safely in relation to patient safety, treatment or standards of care. This role is key in helping to increase the profile of raising concerns in the Trust and the Guardian can provide confidential advice and support to staff in relation to concerns they have. The Guardian provides support to ensure that employee concerns have been fully explored to the satisfaction of the employee and that staff members have been responded to appropriately.

4. Risk Definitions

Incident: Any event whether planned or unplanned that has given or may give rise to actual or possible personal injury, to patient dissatisfaction, or to property loss or damage.

Near Miss: A near miss is an unexpected or unplanned event that could have resulted in loss, damage, injury or ill health.

Patient Safety Incident: A patient safety incident is any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS care (NPSA 2011). This includes:

- Incidents that you have been involved in.
- Incidents that you may have witnessed.
- Incidents that caused no harm or minimal harm.
- Incidents with a more serious outcome.
- Prevented patient safety incidents (known as 'near misses').

Never Events - A **Never Event** is defined as a serious and largely preventable patient safety incident, which should not occur if the available preventative measures have been implemented.

A Never Event may or will result in severe harm or death to a patient and/or the public.

A comprehensive list of never events including definitions can be found at www.dh.gov.uk

RIDDOR (Reporting of Injuries, Diseases and Dangerous Occurrences Regulations) puts duties on employers, the self-employed and people in control of work premises (the Responsible Person) to report certain serious workplace accidents, occupational diseases and specified dangerous occurrences (near misses).

The following injuries are reportable under RIDDOR when they result from a work-related accident:

- The death of any person (Regulation 6)
- Specified Injuries to workers (Regulation 4)
- Injuries to workers which result in their incapacitation for more than 7 days (Regulation 4)
- Injuries to non-workers which result in them being taken directly to hospital for treatment, or specified injuries to non-workers which occur on hospital premises. (Regulation 5).

Safeguarding incidents

Any safeguarding incident will be led automatically by the Safeguarding Lead nurse for the organisation.

5. Involving the patient and their family / carers

Patient safety incidents can have devastating emotional and physical consequences for their families and carers. However recent reports (Care Quality Commission (CQC); Learning, Accountability and Candour, 2016) have found that involvement of families and carers in serious incident investigations within the NHS has been very limited. In their latest review of unexpected deaths the CQC (2016) highlight that many families or carers described poor experience of investigations and said that they were not consistently treated with respect, sensitivity and honesty.

The needs of the family and carers affected by the serious incident must be the key focus of the Trust's investigation and response. Patients and their families / carers and victims' families must be involved and supported throughout the investigation process. This involves listening to their concerns, being involved in the investigation, to have their concerns accurately reflected in the report and for this to be done so in a timely and open manner. This principal links to the Trust's requirements under the 'Duty of Candour (CQC 2015) namely openness, transparency and honesty.

At the start of an investigation, families / carers will routinely be asked if they want to be involved in the review. At this point the level and type of involvement will be established, who will link with the family / carers, the questions they would like to ask and how they would like the outcome of the Trust internal investigation reported back to them.

Duty of Candour

The CQC (2015) outlines the Trust's responsibilities under the Duty of Candour as a provider of health care. The aim of Regulation 20 (CQC 2015) 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 and carers in the investigation of incidents. For further guidance please refer to the Trust's 'Duty of Candour (Being Open)' Policy.

6. Process for the reporting of all Incidents and Near Misses

This Trust welcomes knowledge of adverse events as an opportunity to learn for the benefit of our patients and staff. Unless there is clear evidence of flagrant malpractice, a complete disregard for the safety of others, malicious intent to harm, theft or fraud, disciplinary policies will not be used for investigatory purposes.

All incidents should be reported to a line manager as soon as they have occurred. Brief details of the incident should be included within the healthcare record. The safety of staff and patients will be priority

- An online incident form must be completed at the earliest possible time
- All sections of the incident form must be completed
- Once the incident is logged, the assigned investigation manager (such as Ward Manager) is automatically alerted via email and it is the responsibility of the investigation manager to review all reported incidents assigned to them within 7 days. This is to enable the identification of any cause as well as any remedial actions that need to be taken to prevent similar incidents from occurring.
- Incidents will be investigated with actions applied (if applicable) and closed within **28 days** of it being reported. Any incident likely to take longer than 28 days to investigate and close should be discussed with the Patient Safety and Emergency Planning Lead Nurse
- The Patient Safety and Emergency Planning Lead Nurse will help staff to determine which process for investigation will be followed

Learning from Patient Safety Events (LFPSE)

In 2023, NHSE/I introduced a service called Learning from Patient Safety Events (LFPSE) to replace the aging National Reporting and Learning Service (NRLS). Organisations were required to ensure their incident reporting systems were aligned to the LFPSE in order that all incidents reported were automatically reported to LFPSE

Recording patient safety events and levels of harm

Guidance has been produced for users of the LFPSE service and can be found here

<https://www.england.nhs.uk/long-read/policy-guidance-on-recording-patient-safety-events-and-levels-of-harm/>

Extract taken from the guidance.

Recording the appropriate level of harm associated with a patient safety incident is important so that:

- we have an accurate description of the event and its impact on the patient, based on the best information at the time
- there is consistency and comparability within the organisation's own data
- the [national patient safety team](#) can use the recorded information to analyse, triage and learn from consistent and high-quality data
- other policies such of Duty of Candour can be enacted appropriately.

Incident recording is mandatory in certain circumstances (see [the LFPSE FAQs for further details](#)) and very much encouraged in all others. If in doubt, it is always better to record a patient safety incident using the available information and best judgement, and LFPSE is designed to support record updates as and when new information becomes available. There are [certain mandatory reporting requirements set out in CQC regulations](#), but ultimately determining when an incident has occurred, the extent to which that incident has caused harm, and the level of harm caused, are all judgements.

To support these judgements, this policy guide sets out the definitions of Incident and Good Care event types, level of harm, and answers some frequently asked questions relating to the recording of incidents.

Definitions – event types

The full definitions of the patient safety event types in this guide are:

Patient Safety Incident – Something unexpected or unintended has happened, or failed to happen, that could have or did lead to patient harm.

What does this mean? – This event type encompasses all patient safety incidents, including “near misses”. Select this option if you know that something did not go as intended or expected – whether an act or an omission – and as a direct result the incident could have or did harm one or more patients.

Good Care – An example of good care that can be learned from

What does this mean? – Positive learning opportunities. Select this option if you want to share experiences or learning from things that have gone well whilst delivering care.

Definitions – harm grading

In the NHS, degree of harm recording relates to the actual impact on a patient from the particular incident being reported

A new addition in this policy guide and in relation to patient safety incident data in the LFPSE service relates to specific capture of information on psychological harm. Previously in the NHS, harm grading included psychological harm as well as physical harm within one measure.

Previous harm grades	New physical harm grades	New psychological harm grades
No Harm	No physical harm	No psychological harm
Low harm	Low physical harm	Low psychological harm
Moderate harm	Moderate physical harm	Moderate psychological harm
Severe harm	Severe physical harm	Severe psychological harm
Death	Fatal	n/a

The full definitions of the harm gradings are as follows:

Physical harm

No physical harm

No physical harm

Low physical harm

Low physical harm is when **all of the following** apply:

- minimal harm occurred – patient(s) required extra observation or minor treatment
- did not or is unlikely to need further healthcare beyond a single GP, community healthcare professional, emergency department or clinic visit
- did not or is unlikely to need further treatment beyond dressing changes or short courses of oral medication
- did not or is unlikely to affect that patient's independence
- did not or is unlikely to affect the success of treatment for existing health conditions.

Moderate physical harm

Moderate harm is when **at least one** of the following apply:

- has needed or is likely to need healthcare beyond a single GP, community healthcare professional, emergency department or clinic visit, and beyond dressing changes or short courses of medication, but less than 2 weeks additional inpatient care and/or less than 6 months of further treatment, and did not need immediate life-saving intervention
- has limited or is likely to limit the patient's independence, but for less than 6 months
- has affected or is likely to affect the success of treatment, but without meeting the criteria for reduced life expectancy or accelerated disability described under severe harm.

Severe physical harm

Severe harm is when **at least one** of the following apply:

- permanent harm/permanent alteration of the physiology
- needed immediate life-saving clinical intervention
- is likely to have reduced the patient's life expectancy
- needed or is likely to need additional inpatient care of more than 2 weeks and/or more than 6 months of further treatment
- has, or is likely to have, exacerbated or hastened permanent or long term (greater than 6 months) disability, of their existing health conditions
- has limited or is likely to limit the patient's independence for 6 months or more.

Fatal (previously documented as 'Death' in NRLS)

You should select this option if, at the time of reporting, the patient has died and the incident that you are recording may have contributed to the death, including stillbirth or pregnancy loss. You will have the option later to estimate to what extent it is considered a patient safety incident contributed to the death.

Psychological harm

Please note that when recording psychological harm, you are not required to make a formal diagnosis; your answer should be an assessment based on the information you have at the point of recording and can be changed if further information becomes available.

No psychological harm

Being involved in any patient safety incident is not pleasant, but please select 'no harm' if you are not aware of any specific psychological harm that meets the description of 'low psychological harm' or worse. Pain should be recorded under physical harm rather than psychological harm.

Low psychological harm

Low psychological harm is when **at least one** of the following apply:

- distress that did not or is unlikely to need extra treatment beyond a single GP, community healthcare professional, emergency department or clinic visit
- distress that did not or is unlikely to affect the patient's normal activities for more than a few days
- distress that did not or is unlikely to result in a new mental health diagnosis or a significant deterioration in an existing mental health condition

Moderate psychological harm

Moderate psychological harm is when **at least one** of the following apply:

- distress that did or is likely to need a course of treatment that extends for less than six months
- distress that did or is likely to affect the patient's normal activities for more than a few days but is unlikely to affect the patient's ability to live independently for more than six months
- distress that did or is likely to result in a new mental health diagnosis, or a significant deterioration in an existing mental health condition, but where recovery is expected within six months

Severe psychological harm

Severe psychological harm is when **at least one** of the following apply:

- distress that did or is likely to need a course of treatment that continues for more than six months
- distress that did or is likely to affect the patient's normal activities or ability to live independently for more than six months
- distress that did or is likely to result in a new mental health diagnosis, or a significant deterioration in an existing mental health condition, and recovery is not expected within six months

Assigning of incidents

Levels of severity of harm	No Harm / Low • prevented • not prevented	Minor harm	Moderate – short term harm	Severe/Fatal
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No/Low harm incidents - Ward/Department Managers/ Matrons

The majority of incidents will be no/low harm; however, the circumstances of the incident may require it being assigned to a senior member of staff such as Head of Nursing or DHOO. In this circumstance, the process for a severe/death incident should be followed as per PSIRF guidance with a meeting being convened. The outcome of the discussion should be recorded on InPhase as part of the incident management

Moderate incidents – Divisional Directors of Nursing

Severe/Fatal incidents - Divisional Head of Operations (DHOO), Divisional Directors of Nursing Medical Director, Associate Medical Director or Executive Director – when notified that the level of harm is severe or fatal will arrange a meeting with relevant staff to discuss.

7. Learning the lessons

Process for involving and communicating with internal and external stakeholders to share safety lessons

Adequate and timely feedback is key to ensuring lessons are learned and applied into everyday practice.

The Trust will use the following methods to ensure this:

- Incidents will be investigated where agreed and learning responses undertaken, with the lessons learned being discussed via the Divisional Meetings, weekly patient safety learning meeting, and the appropriate assurance committee and the learning forums
- Medical Audit days/Team brief will be used as a means of disseminating lessons learnt.
- The Integrated Incident Complaints and Claims report will be produced twice yearly, collating information from the previous 6 months. This will be sent to the Risk Management and Corporate Governance Committee, Trust Board and the Divisional meetings.

8. Issues of staff performance identified as part of the incident investigation

On occasions, as part of the initial management review or within the process of the incident investigation, poor staff performance or misconduct may be identified.

When this is the case, the disciplinary investigation and report will be a separate process and conducted independently of the incident investigation. The disciplinary investigation can be conducted at the same time.

It is important that when deciding if a disciplinary process should proceed, the lead for the investigation must refer to the NHS England's (2025) 'Being Fair Tool' guidance as it will assist in the decision making.

9. Incidents that involve other agencies

NHS Patients from Wales

When incidents involve NHS patients from Wales receiving care in English provider organisations, the commissioner of these patients care in Wales must be informed. This will be the local health board, unless it is specialist care being provided in which case Health Commission Wales must be informed.

Specific Managers across the Trust have duties to report to external agencies when required as listed below. When this reporting takes place, an incident reporting form should be completed and forwarded to the Risk Management Department, so the external reporting can be logged.

In the case of a death, resulting from an incident, the coroner must be informed. This is done by a telephone call from the responsible member of medical staff.

Health and Safety Incidents

The Governance Systems Analyst, on advice from the Health and Safety Advisor will contact the Health and Safety Executive with regard to Reporting Injuries, Diseases and Dangerous Occurrences (RIDDOR) by completion of the electronic reporting form available on the HSE website.

Incidents involving Fire

Fires involving death or injury must also be reported to the Health and Safety Executive under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR) .

Estates Incidents

The Estates Manager will report more serious incidents involving death, injury, large-scale evacuation or damage on a large scale relating to buildings and plant immediately to the Department of Health, Estates and Facilities Management Directorate

Infection Control Incidents

The Trust Catering Manager will report incidents involving food to the Food Standards Agency by telephone. Additionally, any incidents of food poisoning or suspected food poisoning will be reported to the Environmental Health Service by telephone.

The Trusts Consultant Microbiologist will report incidents involving Salmonella and Legionnaires to Environmental Health

All nosocomial infections must be incident reported. All nosocomial deaths must be reported as an SI.

Medical Device Incidents

The Manager of the Trusts Medical Engineering Department will report incidents relating to medical devices to the Medical and Healthcare Products Regulatory Agency (MHRA) on-line.

Clinical Negligence

For Clinical Negligence or other incidents resulting in a claim, the Risk Management Team will inform NHS Resolution

Reportable Drug incidents

The Trusts Chief Pharmacist will report Incidents involving faulty drug products to the Medical and Healthcare Products Regulatory Agency (MHRA) Defective Medicines Report Centre by telephone or e-mail using the regional quality control cascade system.

The Trusts Chief Pharmacist will report incidents involving adverse reaction to drugs via the yellow card scheme: Medicines Control Agency – Committee for Safety of Medicines. This will be done by completing and posting a yellow card to the MHRA.

Radiotherapy Incidents

The Trusts Clinical Lead for Nuclear Medicine, Radiotherapy or Radiology will ensure that radiation incidents which are required to be reported under the Ionising Radiation (Medical Exposure) Regulations 2000 are reported by the Radiation Protection Supervisor to the Department of Health. This is done by letter.

Infection Prevention

The Trusts Infection Control Team will report infectious disease outbreaks to Merseyside and Cheshire Health Protection Unit by phone.

Blood Transfusion

The Trusts Blood Transfusion Team will report all Serious Hazards of Transfusion (SHOT) via the Serious Adverse Blood Reactions and Events (S.A.B.R.E.) on-line system

General Data Protection Regulation

Incidents classified as personal data breaches will be reported, managed and investigated in line with the national NHS 'Checklist Guidance for Reporting, Managing and Investigating Information Governance and Cyber Security Serious Incidents Requiring Investigation'. This is in addition to the local requirements set out in this policy. Any incidents classified as high risk personal data breaches must also be reported in line with data protection legislation to the relevant Supervisory Authority within the legal timescales.

10. Key Stakeholders / Contacts

Organisation/Contact	Contact details	Reporting requirements
Chief Executive	Internal-1366	
Medical Director	Internal -1706	
Director of Nursing	Internal -1631	
Head of Risk Management	Internal -1051	
Deputy Director of Nursing	Internal - 1653	
Liverpool Place	in Office hours switchboard 0151 296 7476	To report adverse incidents via STEIS as in guidelines. Please contact DDON/Head of Risk Management
Health and Safety Executive	www.hse.gov.uk	Report as under RIDDOR
Hill Dickinson – Trust Solicitors	0151 600 8000	For advice on any legal issues
Medicines and Healthcare products Regulatory agency (MHRA),	020 3080 6000	Voluntary user reporting of Incidents involving medical devices
Needle stick injury	Contact via LHCH switch Team Prevent	Following a sharps injury
NHS Resolution Clinical – team leader	020 7811 2700	Any claim or incident /complaint that may result in a claim
RIDDOR	0845 300 9923 www.hse.gov.uk	Refer to RIDDOR Guide in resource folders
Serious Hazards of Transfusion	Manchester Blood Service Plymouth Grove Manchester M13 9LL email: shot@nbs.nhs.uk tel: 0161 251 4208	Voluntary user reporting of Incidents involving blood transfusion

Neighbouring Trusts	Listed in the stakeholder data source on the intranet miscellaneous section and available at switchboard	If the incident crosses the boundaries of care or ongoing support of patients or high media interest expected
Local GP's	Listed in the stakeholder data source on the intranet miscellaneous section	If the incident crosses the boundaries of care or ongoing support of patients or high media interest expected
Liverpool City Council	0151 233 3000/1300 362170	If the incident crosses the boundaries of care or high media interest expected
Merseyside Police	0151 709 6010	Incidents where criminal activity suspected
Coroner	Mon-Fri 08:00 to 17:30 0151 233 4701 Out of hours Pager 07669178252 0151 709 6010 [via police]	
Mersey Regional Ambulance Service NHS Trust	0151 260 5220	If the incident crosses the boundaries of care or ongoing support of patients or high media interest expected
Department of Health	0207 210 4850	
Care Quality Commission	0300 0616161	Care Quality Commission is an independent body, set up to promote and drive improvement in the quality of healthcare and public health
Environmental health	Refer to Infection Prevention Team	Incidents relating to environment for example food hygiene or Legionella.
Social Services	Via LHCH switchboard	If the incident crosses the boundaries of care or ongoing support of patients

Endorsed by:

Name of Lead Clinician/Manager or Committee Chair	Position of Endorser or Name of Endorsing Committee	Date

Record of Changes to Document - Issue number: 3.1

Changes approved in this document:

Date:

Section Number	Amendment (<i>shown in bold italics</i>)	Deletion	Addition	Reason
Front Page	Exec Lead	Sue Pemberton	Joan Matthews	Role change
Incident Reporting Guideline	Additional supporting document	N/A	The inclusion of the Incident Reporting document as a Guideline	The Incident Reporting Policy has now retired (as PSIRF is now implemented)
Page 12	Number of Patient Safety Partners	3	2	Renewal of contract
Page 9	Being Fair Tool	Just Culture Guide	Being Fair Tool	NHSE update