Patient Safety Incident Response Policy

Version No: 1

Document Summary:

This patient safety incident response plan sets out how MWL will respond to patient safety incidents reported by staff and patients, their families, and carers as part of work to continually improve the quality and safety of the care we provide from October 1st.

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Document Control

Section 1 – Document Information	
Title	Patient Safety Incident Response Policy
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New policy - This Patient Safety Incident Response Policy sets out how MWL (Mersey and West Lancashire Teaching Hospitals NHS Trust) will respond to patient safety incidents reported by staff and patients, their families, and carers as part of work to continually improve the quality and safety of the care we provide.	
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Section 4 – Approval			
Document Approved	☑ Approved ☐ Approved with minor amendments		
Assurance provided by Author & Chair	☐ Minutes of Meeting ☑ Email with Chairs approval		
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Contents

1 Introduction

This Patient Safety Incident Response Policy sets out how MWL (Mersey and West Lancashire Teaching Hospitals NHS Trust) will respond to patient safety incidents reported by staff and patients, their families, and carers as part of work to continually improve the quality and safety of the care we provide.

The Serious Incident Framework is being replaced by the Patient Safety Incident Response Framework (PSIRF). The PSIRF replaces the Serious Incident Framework (SIF, 2015) and makes no distinction between 'patient safety incidents' and Serious Incidents.

The NHS Patient Safety Strategy 2019 describes the Patient Safety Incident Response Framework (PSIRF) as "a foundation for change" and as such, it challenges us to think and respond differently when a patient safety incident occurs.

PSIRF promotes a proportionate approach to responding to patient safety incidents by ensuring resources allocated to learning are balanced with those needed to deliver improvement. This would mean serious incidents will not be reported on Strategic Executive Information System (StEIS), and the level of investigation will be determined locally dependent on potential learning. It is advised in the framework, that detailed investigations are only undertaken on key priorities and potential for system improvement, rather than resultant harm grading.

Under the new PSIRF framework, each organisation internally determines the type of incidents to be investigated, based upon local risks, trends and priorities for highest impact and learning opportunities and this Patient Safety Incident Response Policy outlines these responses.

2 Scope

Patient safety incidents are any unintended or unexpected incident which could have, or did, lead to harm for one or more patient's receiving healthcare and there are numerous ways to respond to an these.

This document covers responses conducted solely for the purpose of system learning and improvement. 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.

Responses covered in this Plan include:

- Patient Safety Incident Investigations (PSIIs)
- Patient Safety Reviews (PSRs) - Please see Appendix B for details

Other types of response exist to deal with specific issues or concerns. Examples of such responses include complaints management, claims handling, human resources investigations into employment concerns, professional standards investigations, coroner's inquests, or criminal investigations. The principle aims of each of these responses differ from the aims of a patient safety response and are outside the scope of this Plan. To be effective in meeting their specific intended purposes, responses that are not conducted for patient safety learning and improvement are separate entities and will be appropriately referred as follows:

- Human resource (employee relations) teams for professional conduct/competence issues and if appropriate, for referral to professional regulators
- Legal teams for clinical negligence claims
- Medical examiners and if appropriate local coroners for issues related to the cause of a death the police for concerns about criminal activity.

3 Definitions

Definition	Meaning
Patient Safety Incident Response Framework	A new NHS framework replacing the Serious Incident Framework (2015)
Patient Safety Incident	Any event or circumstance that could have or did lead to unintended or unexpected harm to a patient and is related to patient treatment or care.
Patient Safety Panel (Whiston/St Helens sites)	Executive Panel where decision to investigate an incident is made
Serious Incident Review Group (SIRG) (Southport/Ormskirk sites)	Executive Panel where decision to investigate an incident is made
Care Group Governance Team (Whiston/St Helens sites)	Local Governance team consisting of: • Head of Nursing and Quality • Matron (Matron, Quality, Governance and Risk) • Assistant Director for Patient Safety (Consultant) – Medical and Surgical Care Groups only
Clinical Business Unit Governance team (Southport and Ormskirk sites)	Local Governance team consisting of: • Associate Director of Nursing and AHP's • Matron • Patient Safety Manager
Patient Safety Incident investigation	Patient Safety Incident Investigations are conducted to identify the circumstances and systemic, interconnected causal factors that result in patient safety incidents. Investigations analyse the system in which we work by collecting and analysing evidence, to identify systems-based contributory factors.
Patient Safety Review	Patient Safety Reviews (PSRs) include several techniques to identify areas for improvement, immediate safety actions and to respond to any concerns raised by the affected patients, family, or carers. Different PSR techniques can be adopted depending on the intended aim and required outcome.

4 Aims and Objectives

The table below describes the four strategic aims of the Patient Safety Incident Response Framework (PSIRF) upon which this plan is based and sets out how these overarching aims will be achieved through specific objectives.

PSIRF 4 Key Aims	MWLObjectives
Compassionate engagement and involvement of those affected by patient safety incidents	• Continue to embed a climate that supports a just culture[1]. • Act on feedback from staff about their concerns with patient safety incident responses in the NHS. • Act on feedback from patients, families, carers, and staff about their concerns with patient safety incident responses in the NHS. • Support and involve staff in patient safety incident response, for better understanding of the issues and contributory factors. • Support and involve patients, families and carers involved in patient safety incident and promote rigorous Duty of Candour
Application of a range of system-based approaches to learning from patient safety incidents	• Use a wide range of tools to conduct Patient Safety Reviews (PSRs) • Consider the safety issues that contribute to similar types of incidents. • Aggregate and confirm validity of learning and improvements by basing PSIIs on a small number of similar repeat incidents
Considered and proportionate responses to patient safety incidents and safety issues	• Transfer the emphasis from quantity of investigations completed to a higher quality response to patient safety incidents which in turn will lead meaningful and measurable improvements. • Implement system that will ensure that Patient Safety Incident Investigations are commissioned on a case of need for learning. • Reduce the number of duplicate investigations to reduce waste and enable more resource to be focused on effective learning and improved investigations.
Supportive oversight focused on strengthening response system functioning and improvement.	• Develop system improvement plans across based on aggregated incident response data to produce systems-based improvements. • Better measurement of improvement initiatives based on learning from incident responses. • Ensure robust governance processes are in place around response to patient safety incidents, which promotes ownership, accountability, rigour, expertise and efficacy

[1] The fair treatment of staff supports a culture of fairness, openness and learning in the NHS by making staff feel confident to speak up when things go wrong, rather than fearing blame (NHS, 2020)

5 Our Services

A review of local systems was conducted to understand the people who are involved in patient safety activities across MWL, as well as the systems and mechanisms that support them.

The Trust provides acute and community healthcare service at Southport and Formby District General Hospital, Ormskirk District General Hospital, Whiston Hospital, St Helens Hospital and Newton Hospital. This includes adults' and children's accident and emergency services, intensive care, and a range of medical and surgical specialities.
In addition, the Trust hosts the Mid-Mersey Neurological Rehabilitation Unit at St Helens Hospital. The Trust provides the Mid-Mersey Hyper-Acute Stroke Unit (HASU) and the Mersey Regional Burns and Plastic Surgery Unit, Northwest Regional Spinal Injuries Centre at Southport Hospital and provides specialist care for patients from across the Northwest of England, North Wales and the Isle of Man. Women's and children's services, including maternity, are provided at both Whiston Hospital and Ormskirk Hospital. The Trust also provides an Urgent Treatment Centre (UTC) at the Millennium Centre in St Helens, and Marshalls Cross Medical Centre (primary care services) and intermediate care and community services at Newton Hospital. In addition, the Trust delivers a range of community services, including adult community nursing (for St Helens), Contraception and Sexual Health Services (CaSH), frailty, falls, Healthy Heart, continence, chronic obstructive pulmonary disease (COPD) services and intravenous (IV) therapy, plus outpatient and diagnostic services from a range of other community premises.

Our vision to provide 5-star patient care remains the Trust's primary objective so that patients and their carers receive services that are safe, person-centred, and responsive, aiming for positive outcomes every time. This mission and vision are integral to the delivery of safe care and has been the underpinning ethos of the development of the Patient Safety Incident Response Plan along with the Trusts values of:

- Kind & Compassionate
- Respectful & Considerate
- Listening & Learning
- Friendly & Welcoming
- Open & Honest

MWL is a complex system with many interrelated components that are crucial to ensuring services are safe and effective. This Trust currently has 4 Care groups: (Medicine, Surgery, Community and Clinical Support Services) at Whiston and St Helens sites and 4 at Southport and Ormskirk sites (Medicine, Planned Care, Women's and Children and Specialist Servies).

The Quality and Risk Team and Integrated Governance team, work alongside the Care Groups and Clinical Business Units. The Quality and Risk/Integrated Governance team comprises of Patient Safety Team, Safeguarding team, Complaint and Legal services Team, the Patient Inclusion and Experience Team, the Quality Improvement Team and the Corporate Nursing Team.

Other key stakeholders include:

- Cheshire and Mersey ICB
- Specialist Commissioner
- NHS England
- St. Helens Council
- Healthwatch

Core patient safety activities undertaken at MWL include:

- The Learning from Death Program
- Incident reporting and Investigation
- Human Factors and Investigation Teaching Programs
- Daily Incident Review meetings (Southport and Ormskirk sites)
- Weekly Incident Review Meeting
- Weekly Patient Safety Panels/Serious Incident Review Group
- Risk Management Training
- Learning from complaints and claims
- Specialty Mortality meetings
- Simulation Training Programs
- Falls Rapid Improvement Program
- Deteriorating Patient Project
- Participation in CRAB program in Medicine and Surgery

Other activities within the Trust that provide insights to patient safety include the management of complaints, claims and inquests.

The operational ‘work-as-done’ for these patient safety activities is predominantly owned by our front-line clinical team with expert support from the Care Group Governance Teams and the Patient Safety Team. They are additionally supported through by educational and corporate teams.

This system has been designed to ensure that the Trust is able to respond to patient safety incidents in a timely manner and allows learning to be identified and rapidly disseminated.

6 Our patient safety incident response plan

6.1 How we will respond to patient safety incidents

As we come together as one Trust we will define a single trust process - however, as an interim we will be following designated local processes which will ultimately still achieve the same goal.

Whiston, St Helens and Newton Sites
All staff will report all incidents and near misses via the Trust electronic incident management system, Datix. (The full details of the Patient Safety Incident reporting arrangements are detailed within the Site based Incident Reporting Policy)

All Incident report forms will be reviewed by the appropriate line manager within 5 working days of reporting and incident of concern will be escalated to the PST and Care Group Governance Team.

The Care Group Governance Team (CGGT) will discuss any incidents graded as moderate or above or any incidents of concern at their weekly Patient Safety Ongoing Concern Review (PSOCR) with the Patient Safety Team and agree next steps, any additional info required and whether there is a requirement for escalation to Incident Review Group (IRG). All incidents of moderate harm or above must be escalated along with any incident identified under the local and national priorities. For incidents nor escalated to IRG the Group will agree the level of investigation required.

Incident Review group will review all incidents of concern escalated by PSOCR and agree next steps, any additional info required and whether there is a requirement for escalation to Patient Safety Panel (PSP). All incidents of severe harm or above must be escalated along with any incident identified under the local and national priorities. For incidents nor escalated to PSP the Group will agree the level of investigation required and Duty of Candour requirements.

Patient Safety Panel will review all incidents of concern escalated by IRG and agree next steps, any additional info required and whether there is a requirement for escalation to Patient Safety Panel (PSP). PSP will agree the level of investigation required and Duty of Candour requirements.

Management and monitoring of individual investigations will be the responsibility of the Trust Board and delegated to the PST and GGCT.

Statutory Care Quality Commission notification requirements will be met by reporting incidents to the national Learning from Patient Safety Events (LFPSE) and its successor system. Except for any deaths of a patients detained under the Mental Health Act which, in line with national guidance, will be reported directly to the CQC.

The process for supporting staff will be described in detail in the associate policies, particularly in new policies that describe Patient Safety Incident Investigations, Patient Safety Incident Responses and involving patients and staff in discussions about incidents, learning and improvement.

Southport an Ormskirk Sites
All staff will report all incidents and near misses via the Trust electronic incident management system, Datix. (The full details of the Patient Safety Incident reporting arrangements are detailed within the site-based Incident Management Framework)

All Incident report forms will be reviewed by the appropriate handler and will be reviewed daily in the 'Daily Incident Meeting' where further review or allocation will be made.

The Clinical Business Unit Patient Safety team will discuss any incidents graded as moderate or above or any incidents of concern at their weekly Patient Safety Meeting and review with the Integrated Governance team to agree next steps. All incidents of moderate harm or above must be escalated along with any incident identified under the local and national priorities.

Incidents that meet the criteria of moderate and above, and or needing harm review will be escalated to the Harm Free Care group (Pressure ulcers, unsafe discharge, and falls) or the Serious Incident Review Group (SIRG) with associated 5-day rapid review completed. All incidents of severe harm or above must be escalated along with any incident identified under the local and national priorities. For incidents not escalated to PSP the Group will agree the level of investigation required and Duty of Candour requirements.

Incidents that are escalated from HFC and SIRG to the Patient Safety Panel will be reviewed and the panel will agree next steps, any additional info required and whether there is a requirement for escalation. If any of these incidents meet the criteria for PSII these will be escalated through the Patient Safety Panel.

Management and monitoring of individual investigations will be the responsibility of the Trust Board and delegated to the Patient Safety Panel.

Statutory Care Quality Commission notification requirements will be met by reporting incidents to the national Learning from Patient Safety Events (LFPSE) and its successor system. Except for any deaths of a patients detained under the Mental Health Act which, in line with national guidance, will be reported directly to the CQC.

6.2 Investigations

Patient safety investigations are conducted to identify the circumstances and systemic, interconnected causal factors that result in patient safety incidents. Investigations analyse the system in which we work by collecting and analysing evidence, to identify systems-based contributory factors. Safety recommendations are created from this evidence-based analysis, to target systems-based improvement.

There are number of review tools that can be used to support Incident Investigation and for the purposes of PSIRF these will be referred to as Patient Safety Incident Investigations (PSII) and Patient Safety Reviews (PSRs).

6.2.1 PSII

A patient safety incident investigation (PSII) is undertaken when an incident or near-miss indicates significant patient safety risks and potential for new learning and meets the national and local criteria. Patient Safety Incident Investigations (PSIIs) are distinct from PSRs and include a range of techniques (such as interviews and observations) to systematically identify the circumstances surrounding incidents.

While most PSIIs are conducted centrally by our organisation, some are conducted independently. Independent PSIIs can be funded by our organisation or regionally/nationally. Deciding what to investigate through a Patient Safety Incident Investigation (PSII) process will be a flexible approach, informed by the local and national priorities. Our objective is to facilitate an approach that involves decision making an executive led Patient Safety Panel to commission investigations and receive findings and recommendations.

PSII are detailed investigation are detailed resource intensive investigation that use a system engineering approach and are intended to explore decisions or actions as they relate to the situation. The method is based on the premise that actions or decisions are consequences, not causes, and is guided by the principle that people are well intentioned and strive to do the best they can. The goal is to understand why an action and/or decision was deemed appropriate by those involved at the time.

6.2.1 Patient Safety Reviews

Patient Safety Reviews (PSRs) include several techniques to identify areas for improvement, immediate safety actions and to respond to any concerns raised by the affected patient, family, or carer. Different PSR techniques can be adopted depending on the intended aim and required outcome. All PSRs will be conducted locally.

Patient Safety Reviews Fall into 3 categories of PSRs (see Appendix B - Patient Safety Review Types for more information):

- Team reviews
- Systematic reviews
- Monitoring

7 Review and Investigation Requirements

7.1 National Requirements

7.1.1 National Priorities requiring external Investigation

This table lists the patient safety risks that fall within the national priority areas (See Appendix A for more details).

National Priorities		
Event	Approach	Improvement
Mental health-related homicides	Referred to the NHS England Regional Independent Investigation Team (RIIT) for consideration for an independent PSII Locally led PSII may be required	
Maternity and neonatal incidents meeting Healthcare Safety Investigation Branch (HSIB) criteria or Special Healthcare Authority (SpHA) criteria when in place	Refer to HSIB or SpHA for independent PSII	Respond to recommendations from external referred
Child Death	Refer for Child Death Overview Panel Review Locally-led PSII (or other response) may be required alongside the panel review – organisations should liaise with the panel	

Deaths of persons with learning disabilities	Refer for Learning Disability Mortality Review (LeDeR) Locally led PSII (or other response) may be required alongside the LeDeR	agency/organisation as required.
Incident in screening programs	Incidents in NHS screening programmes	
Safeguarding incidents meeting criteria	Refer to local authority safeguarding lead	
Deaths in custody (e.g., police custody, in prison, etc) where health provision is delivered by the NHS	Any death in prison or police custody will be referred (by the relevant organisation) to the Prison and Probation Ombudsman (PPO) or the Independent Office for Police Conduct (IOPC) to carry out the relevant investigations Healthcare organisations must fully support these investigations where required to do so	

7.1.2 National Priorities requiring Local Investigation

There are three categories of national priorities requiring local PSII:

Events where a Locally Led PSII is mandated		
Event	Approach	Improvement
Deaths thought more likely than not due to problems in care (incidents meeting the learning from deaths criteria for PSII)	Locally led PSII	Create local organisational recommendations and actions
Deaths of patients detained under the Mental Health Act (1983) or where the Mental Capacity Act (2005) applies, where there is reason to think that the death may be linked to problems in care (incidents meeting the learning from deaths criteria)	Locally led PSII	
Incidents meeting the Never Events criteria 2018, or its replacement.	Locally led PSII	

7.2 Local Requirements

7.2.1 Key Priorities

From an analysis of the data described in section 6 the Trust has identified 5 areas of concern that fall under following key priorities.

These patient safety priorities form the foundation for how we will decide to conduct Patient Safety Incident Investigation (PSII) and patient safety reviews and incidents falling under these key priorities will always be considered will always be considered for a Patient Safety Incident Investigation.

Incident Type	Description	Action
Care of the deteriorating patient	Incidents where the identification of a deteriorating patient has lead to significant impact on patient outcome	For consideration for a full PSII
Unsafe discharges	Discharges from hospital that have been deemed unsafe and impacted on the patient outcome	For consideration for a full PSII
Misdiagnosis	Missed or delayed diagnosis that has impacted on patient outcomes, with potential for significant learning.	For consideration for a full PSII
Medication	Medication incident that has significantly impacted on patient outcomes	For consideration for a full PSII
Pressure ulcers (Southport an Ormskirk Sites Only)	Hospital Acquired Category 3 pressure ulcers and above, with potential for significant learning	For consideration for a full PSII

Slips, trips, and falls (Southport and Ormskirk Sites Only)	Inpatient fall leading to fracture of hip bone, with potential for significant learning	For consideration for a full PSII
Areas of emerging risk	Based on trend or analysis from the patient safety group, PSII will be conducted on specific areas of risk that have been identified	For consideration for a full PSII

Events where a Locally Led PSII is mandated		
Event	Approach	Improvement
Patient Safety Key Priority Cases: • Delay in Cancer Diagnosis or treatment • Medication • Responding well to clinically changing condition • Discharge • Emergent area of risk	Consideration of a Locally led PSII	Create local organisational recommendations and actions

7.2.2 Falls / Infection Prevention / Tissue Viability Incidents (Whiston, St Helens and Newton Sites only)

Despite the high number of falls, tissue viability and infection control incident reported in the Trust these types of incidents will not be routinely investigated as a PSII as part of the Key Priorities under PSIRF. This because there are already a robust and effective improvement programs supporting learning from these types of incidents. Key incidents will be subject to a Learning Review (a type of Patient Safety Review as described in section 7.1 and Appendix 2). Information from these reviews will be aggregated every 6 months and the finding from the aggregation will inform the Improvement Action Plans. Where emergent risks are identified, incidents will be escalated to Patient Safety Panel to ascertain if a PSII is required.

Falls / Infection Control / Tissue Viability Incidents		
Event	Approach	Improvement
Falls / Infection Control / Tissue Viability Incidents	PSR – Fall / IPC / TV Learning Review	Create local organisational recommendations and actions and actions from Thematic analysis

7.2.3 Maternity and Neonatal Incidents

Any incident meeting the HSIB or SUDIC requirements for investigation will be referred to HSIB / CDOP as per section 7.1.1.
Incidents meeting the requirement for MBRRACE will be reviewed via the MBRRACE process. MBRRACE will then notify the Trust which case require PMRT review.
All other maternity incidents will follow the Trust incident reporting process and may require PSII dependant on any emergent risk or never event as per section 7.
Maternity / Neonatal PSIIs will be led by the central investigation team but will always include subject matter experts as appropriate. External experts will be sough if required.

Maternity Incidents		
Event	Approach	Improvement
Maternity / Neonates	PSR / PMRT / HSIB / CDOP	Create local organisational recommendations and actions and actions from Thematic analysis

7.2.4 Other Patient Safety Incidents

All incident not fitting into the categories detailed above will be managed as follows:

Events where a Locally Led PSII is mandated		
Event	Approach	Improvement
Incident resulting in moderate or severe harm to patient	Locally led PSR	Create local organisational recommendations and actions
No/Low Harm Patient Safety Incident	• Review of incident locally which will be recorded on the Trust Incident reporting System. • Thematic analysis by specialist team	Create local organisational recommendations and actions from Thematic analysis

7.1 Aggregating review / learning from incident responses

Findings from PSII and PSR will be aggregated and identified learning will be translated into effective improvement design and implementation. Quality Improvement Programs and specialist working groups will oversee collation and execution of Improvement Plans (see section 11).

If a single review reveals significant risk(s) that require(s) immediate safety actions to improve patient safety, these actions will be made as soon as possible.

System Improvement Plans will be shared with those involved in the incident including patients, families, carers, and staff.

7.2 Timescales for PSIIs

Where a PSII is required (as defined in this Plan for both local and national priorities), the investigation will start as soon as possible after the patient safety incident is identified.

PSIIs will ordinarily be completed within 60 working days of their start date but in exceptional circumstances, a longer timeframe may be required for completion of a PSII. In this case, any extended timeframe will be agreed between MWL and the affected patients, family, or carers.

No PSII should take longer than 120 working days. A balance will be drawn between conducting a thorough PSII, the impact that extended timescales can have on those involved in the incident, and the risk that delayed findings may adversely affect safety or require further checks to ensure they remain relevant.

Where the processes of external bodies delay access to information for longer than 120 working days, a completed PSII can be reviewed to determine whether new information indicates the need for further investigative activity.

7.3 Involvement of patients, families and carers following incidents

We recognise the significant impact patient safety incidents can have on patients, their families and carers. The Trust is committed to creating a culture of openness with patients, families and carers particularly when clinical outcomes are not as expected or planned. For each incident requiring a PSII and incidents meeting the Duty of Candour Statutory requirements a Being Open Lead will be allocated.

Being Open Leads will normally be the Lead Investigator for the PSII or PSR. There may be an occasion where the statutory Duty of Candour lead and will be the key contact for communication with patients, families, and carers during an investigation.

The Being Open Lead is responsible for:

- Meeting with patient, families and carers involved in a patient safety incident to explain what has happened, the investigation taking place and provision of contact detail.
- Hearing the patient/family account of the incident from their perspective and gathering any questions they would like the review to answer.
- Ensuring that the patient has been provided with appropriate on-going support.

- Arranging for transfer of care where the patient (and/or carer) requests this
- Documenting the details of all discussions with the patient (and/or carer), copies of letters relating to the patient safety review ensuring this documentation is uploaded to the relevant incident record on Datix.
- Keeping in close communication with the patient, family and/or carer as per their wishes. Contact will also take place following the conclusion of the investigation to share the findings, lessons learned, and actions being taken.

Other sources of support are:

- Learning from deaths – information for families explains what happens after a bereavement (including when a death is referred to a coroner) and how families and carers should comment on care received.
- The NHS Complaints Advocacy Service can help navigate the NHS complaints system, attend meetings, and review information given during the complaints process.
- Healthwatch which provides information to help make a complaint, including sample letters.
- Parliamentary and Health Service Ombudsman makes the final decisions on complaints patients, families and carers deem not to have been resolved fairly by the NHS in England, government departments and other public organisations.
- Citizens Advice Bureau provides UK citizens with information about healthcare rights, including how to make a complaint about care received.

The process for supporting staff will be described in detail in the associate policies, particularly in new policies that describe Patient Safety Incident Investigations, Patient Safety Incident Responses and involving patients and staff in discussions about incidents, learning and improvement.

7.4 Duty of Candour

There is no legal duty to investigate a patient safety incident. Once an incident that meets the Statutory Duty of Candour threshold has been identified, the legal duty, as described in Regulation 20 says we must:

- Tell the person/people involved (including family where appropriate) that the safety incident has taken place.
- Apologise. For example, “we are very sorry that this happened”.
- Provide a true account of what happened, explaining whatever you know at that point. Explain what else you are going to do to understand the events. For example, review the facts and develop a brief timeline of events.
- Follow up by providing this information, and the apology, in writing, and providing an update. For example, talking them through the timeline.

- Keep a secure written record of all meetings and communications.

Duty of Candour should be applied for any incident meeting the Duty of Candour criteria as per the Being Open Policy

All patient safety incidents leading to moderate harm or above and all incidents for which a patient safety incident investigation is undertaken trigger the Duty of Candour.

7.5 Involvement and support for staff following incidents.

MWL is committed to the principles of the NHS Just Culture Guide for ensuring the fair, open and transparent treatment of staff who are involved in patient safety incidents. We have embedded these principles into our procedures for the review of incidents. The Trust recognises the significant impact being involved in a patient safety incident can have on staff and will ensure staff receive the support they need to positively contribute to the review of the incident and continue working whilst this takes place.

The Patient Safety Team and Care Group/Clinical Business Unit Governance Teams will advise, and signpost staff involved in patient safety incidents to the most appropriate information about the patient safety incident review process and further support functions.

Available resources include:

- Psychological Support for Trust Staff accessible via the Occupational Health Service
- Freedom To Speak Up Guardian - A confidential service for staff if they have concerns about the organisation's response to a patient safety incident.
- Second Victim - A website resource for healthcare staff and managers involved in patient safety incidents.
- Support will also be provided by Patient Safety investigators.

All staff with knowledge of the events being reviewed are encouraged to actively participate in the learning response. That may be through submitting written information, joining a debrief meeting, after action review or a safety huddle or a one-to-one conversation with the incident review team.

The process for supporting staff will be described in detail in the associate policies, particularly in new policies that describe Patient Safety Incident Investigations, Patient Safety Incident Responses and involving patients and staff in discussions about incidents, learning and improvement.

7.6 Inequalities

Some patients are less safe than others in a healthcare setting and the PSIRF provides a mechanism to directly address these unfair and avoidable differences in risk of harm from healthcare:

- The PSIRF's more flexible approach makes it easier to address concerns specific to health inequalities; it provides the opportunity to learn from patient safety incidents that did not meet the definition of a 'Serious Incident'.
- The Tools developed by MWL as part of our patient safety incident response toolkit prompt consideration of inequalities during the learning response process including the development safety actions.
- The Trust will use the guidance provided in "Engaging and involving patients, families and staff following a patient safety incident" to assist in engaging those with different needs.
- The PSIRF endorses a system-based approach (instead of a 'person focused' approach) and is explicit about the training and skill development required to support such an approach. This will support the development of a just culture and reduce the ethnicity gap in rates of disciplinary action across the NHS workforce.
- Learning will be identified from PSRs which will support improvement of inequalities.
- PSRs will be aggregated in terms of protected characteristics and appropriate action will be identified based on these.
- If an emerging theme is identified as part of this aggregation then a PSII would be consider as per section 7.

8 Review Process, and Roles and Responsibilities under PSIRF

MWL has defined clear roles and responsibilities in relation to its response to patient safety incidents, including investigator responsibilities and upholding national standards relating to patient safety incidents.

8.1 All Staff

All staff (including bank, agency, locum and volunteers) has the responsibility to report all incidents and near misses via the Trust electronic incident management system, Datix. (The full details of the Patient Safety Incident reporting arrangements are detailed within the Trust Incident Reporting Policy).

Staff should be fully open and co-operative with any patient safety review process. All staff are required to be aware of and comply with this patient safety incident response plan. Information regarding the reporting and management of incidents is provided for new staff at corporate induction. Information for existing staff is available on the Risk Management pages of the Trust intranet.

8.2 Incident (Datix) Reviewers

All Incident report forms will be reviewed by the appropriate line manager within 5 working days of reporting.

Where possible incident will be graded and any incident of concern of will be escalated to the PST and Care Group Governance Team.

Incident of concern include:

- Incidents of moderate harm or above
- Incident where the harm is not yet understood but may be moderate or above.
- Incident where if that type of incident were to recur it would pose a is significant risk to other patients.

All incidents that have not been escalated as incident of concern should be closed within 20 working days.

Incidents escalated as ongoing concerns should be closed within 60 working days.

8.3 Care Group Governance Team (CGGT)

All Incident report forms will be reviewed by a member of the care group governance team with within 5 working days of reporting. CGGT to discuss any incidents graded as moderate or above or any incidents of concerns at their weekly Patient Safety Ongoing Concern Review (PSOCR) with the Patient Safety Team and agree next steps and whether requirement for escalation to IRG.

CGGT are responsible for ensuring the organisation's legal duty of candour is discharged for appropriate incidents by:

- Identify those affected by patient safety incidents or moderate harm or above and their support needs by providing single point of contact.
- Provide them with timely and accessible information and advice.
- Facilitate their access to relevant support services.
- Obtain information from review/PSR teams to help set expectations.

8.4 Patient Safety Team (PST)/Integrated Governance team

The Patient Safety Team/ Integrated Governance Team will:

- Ensure all incidents of concern are discussed at the Trust weekly Incident Review Group to determine if further information is required, advise on type of investigation required and if required escalation to PSP.
- Maintain the local risk management systems and relevant incident reporting systems to support the recording and sharing of patient safety incidents and monitoring of incident response processes.
- Monitor/review PSII progress and the delivery of improvements.

- Work with the executive lead to address identified weaknesses/areas for improvement in the organisation's response to patient safety incidents, including gaps in resource including skills/training.
- Support and advise staff involved in the patient safety incident response.
- Ensure staff members involved in the management of patient safety incidents have access to the requisite knowledge, skills and tools to undertake patient safety reviews to the required national standards.
- Provide training for investigator undertaking PSII and PSRs
- Provide bi-monthly reports on patient safety incident investigations within the Trust and to Patient Safety Council and the Board.

8.5 PSR Investigators

Incidents must be investigated and reported using the appropriate tools and techniques for the type of Patient Safety Review (PSR) required. The reviewer(s) should have completed the appropriate training for the review technique to be used. The review should be fair and thorough using the methods taught on the appropriate training courses.

PSR Investigators will fulfil the role of family liaison officer with patients, families and carers where Duty of Candour applies.

All staff of band 7 / consultant grade or above may be asked to complete a PSR and act as family liaison having completed the appropriate training.

8.6 Patient safety incident investigators

Patient safety incident investigators will have been trained over a minimum of two days in systems based PSII.

They will ensure that PSIIs are undertaken in-line with the national PSII standards, national guidance, and training.

PSII Investigators will fulfil the role of family liaison officer with patients, families, and carers.

8.7 Divisional Medical Directors / Senior Nursing Team

Divisional Medical Directors / Directorate Managers have a responsibility to:

- Encourage the reporting of all patient safety incidents and ensure all staff in their department/care group /area are competent in using the reporting systems and have time to record and share information.
- Ensure that incidents are reported and managed in line with internal and external requirements.
- Provide protected time for training in patient safety disciplines to support skill development across the wider staff group.

- Provide protected time for participation in reviews/PSIIs as required.
- Work with the patient safety team and others to ensure those affected by patient safety incidents have access to the support they need.
- Support development and delivery of actions in response to patient safety reviews/PSIIs that relate to their area of responsibility (including taking corrective action to achieve the desired outcomes).

8.8 Patient Safety Partners

As part of our commitment to working with members of the public we have a partner programme in place. This is where members of the public join our Quality and Safety Improvement work. Those who Partner with us have expectations as part of their contribution to the PSIRF:

- Partners will undertake the training required to the national standard for their role as specified in the National Patient Safety Syllabus as well as other relevant training.
- Participate in investigation oversight groups and be active members of the PSP and other work streams with the aim of helping us design safer systems of care and prioritise risk.
- Encourage Patients, Families and Carers to play an active role in their safety.
- Contribute to action plans following investigation, particularly around actions that address the needs of patients.
- Contribute to staff patient safety training.

The organisation commits to protecting our partners from emotional harm which may arise from their work with us therefore, they are able to access the support detailed for Staff in section 6.10.

8.9 Clinicians/Specialist Advisors

Incident reviewers may need to involve specialist advisors to assist in their review (e.g., Safeguarding, Health and Safety, Medical Physics, Pharmacy, Radiation Protection Advisor, Clinicians with experience in a particular medical or surgical technique). PSII and PSR Investigators are responsible for determining when specialist advice is required, and specialist advisors have a duty to provide support and advice as and when required. This may be in the form of attendance at multi-disciplinary investigation meetings, provision of a written report/opinion, review of recommendations.

8.10 Patient Safety Panel

PSP will review any incident escalated to the panel by IRG and agree the level of investigation required and confirm Duty of Candour requirements.

Executive led PSP will sign off any PSII reports and agree any improvement plans agreed as part of the PSII

PSP will sign any Aggregated reviews and agree any improvement plans agreed as part of the Aggregated review.

Improvement plans will be monitored to completion by PSP.

8.11 Incident Review Group

Has responsibility for reviewing the incident management function and will review all incidents of concern as escalated by PSOCR and agree which of these require escalation to PSP. For incidents not escalated to PSP they will agree the level of investigation required and confirm Duty of Candour requirements

Incident review group will also monitor within the reporting process that Incident reports in Datix are managed within the agree timeframe.

8.12 Trust Board

The Trust Board has a responsibility to ensure that it receives assurance that this plan is being implemented, that lessons are being learned, and areas of vulnerability are improving. This will be achieved through reporting processes as well as receiving assurance via the Quality Committee. The Trust Board receives a bi-monthly report on patient safety incident investigations within the Trust and monitors the lessons learned from these. Where concerns are identified relating to the robustness of lessons learned or actions planned the Trust Board will seek assurances that these concerns are being acted upon.

9 Mechanisms to develop and support improvements following PSIIs

At the conclusion of a Patient Safety Incident Investigation (PSII) the final report will be submitted to the PSP for discussion and agreement of the system improvement plan.

The Patient Safety Council or identified Improvement Group will have oversight and undertake monitoring of all improvement plans created following a PSII. The Patient Safety Council reports to the Trust Quality Committee.

Monitoring using audit should be undertaken when improvement plans are complete to ensure that changes are embedded and continue to deliver the desired outcomes. When changes have led to measurable improvements then these will be shared and implemented with other areas of the organisation and peer organisations

Where learning is identified that may be applicable across the Cheshire and Merseyside NHS Health system the Trust with work with the ICB to ensure cross system improvements.

Any themes identified will be discussed via appropriate Cheshire and Merseyside Healthcare Partnership fora.

Any collaboration will be included and monitored as part of each PSR and aggregated review action plan as per the incident reporting policy.

Learning will be feedback to Patient Experience council and Commissioning Quality forums which include patient representation.

10 Monitoring Outcome of PSII and PSRs

Regular update reports will be created for Patient Safety Council review and assurance. Contents may vary, but will likely include aggregated data on:

- Patient safety incident reporting
- Findings from PSIIs
- Findings from PSR reviews
- Progress on System Improvement Plans
- Results of surveys and/or feedback from patients/families/carers on their experiences of the organisation's response to patient safety incidents
- Results of surveys and/or feedback from staff on their experiences of the organisation's response to patient safety incidents.

11 Complaints and appeals in relation to PSII and PSRs

Local and national arrangements for complaints and appeals relating to the organisation's response to patient safety incidents are available via:

- Named family liaison officer.
  or
- MWL Patient Liaison and Advice Service.

The Trust fully upholds the NHS Constitution, aspiring to put the patient at the heart of everything it does. Any concerns or complaints raised about the Patient Safety Review or Investigation process by MWL will be taken seriously and will be managed in a way that reflects the MWL Values.

MWL encourages the affected patient, family, or carer to raise any concerns they may have in regard to a Patient Safety Review or Investigation at the time they occur by speaking to the Family Liaison officer or any other member of staff.

All attempts will be made to resolve any such issues via the Patient Safety Review or Investigation process.

If the affected patient, family, or carer remains dissatisfied and we are unable to resolve their concerns via the Patient Safety Review or Investigation process then this should be escalated to the executive team for a decision regarding next steps. Relevant person should be offered the opportunity to make a formal complaint at this stage.

12 Equality Analysis Form

The screening assessment must be carried out on all policies, procedures, organisational changes, service changes, cost improvement programmes and transformation projects at the earliest stage in the planning process to ascertain whether a full equality analysis is required. This assessment must be attached to all procedural documents prior to their submission to the appropriate approving body. A separate copy of the assessment must be forwarded to the Patient Inclusion and Experience Lead for monitoring purposes. Cheryl.farmer@sthk.nhs.uk. If this screening assessment indicates that discrimination could potentially be introduced, then seek advice from the Patient Inclusion and Experience Lead. A full equality analysis must be considered on any cost improvement schemes, organisational changes or service changes which could have an impact on patients or staff.

Equality Analysis				
Title of Document/proposal /service/cost improvement plan etc.:	Patient Safety Incident Response Plan			
Date of Assessment	01/06/2023	**Name of Person completing assessment /job title:**	Nadine Higgins	
Lead Executive Director	Director of Nursing, Midwifery & Governance		Patient Safety Manager	
Does the proposal, service or document affect one group more or less favourably than other group(s) based on their:		**Yes / No**	**Justification/evidence and data source**	
1	Age	No	Click here to enter text.	
2	Disability (including learning disability, physical, sensory or mental impairment)	No	Click here to enter text.	
3	Gender reassignment	No	Click here to enter text.	
4	Marriage or civil partnership	No	Click here to enter text.	
5	Pregnancy or maternity	No	Click here to enter text.	
6	Race	No	Click here to enter text.	
7	Religion or belief	No	Click here to enter text.	
8	Sex	No	Click here to enter text.	
9	Sexual Orientation	No	Click here to enter text.	
Human Rights – are there any issues which might affect a person's human rights?		**Yes / No**	**Justification/evidence and data source**	
1	Right to life	No	Click here to enter text.	
2	Right to freedom from degrading or humiliating treatment	No	Click here to enter text.	
3	Right to privacy or family life	No	Click here to enter text.	
4	Any other of the human rights?	No	Click here to enter text.	
Lead of Service Review & Approval				
Service Manager completing review & approval	Rajesh Karimbath			

Appendix 1 National Priorities

12.1 National Priorities Requiring a Trust Response

There are three categories of national priorities requiring local PSII: incidents that meet the criteria set in the Never Events list (2018); incidents that meet Learning from Death criteria; and Death or long-term severe injury of a person in state care or detained under the Mental Health Act.

Incidents that meet the criteria set in the Never Events list 2018
Patient safety incidents that are wholly preventable where guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and have been implemented by healthcare providers.

Incidents that meet the 'Learning from Deaths' criteria
Deaths clinically assessed as more likely than not due to problems in care - using a recognised method of case note review, conducted by a clinical specialist not involved in the patient's care, and conducted either as part of a local Learning from Deaths plan or following reported concerns about care or service delivery.

Examples include:

- deaths of persons with mental illness whose care required case record review as per the Royal College of Psychiatrist's mortality review tool and which have been determined by case record review to be more likely than not due to problems in care
- deaths of persons with learning disabilities where there is reason to believe that the death could have been contributed to by one or more patient safety incidents/problems in the healthcare provided by the NHS. In these circumstances a PSII must be conducted in addition to the LeDeR review
- deaths of patients in custody, in prison or on probation where there is reason to believe that the death could have been contributed to by one or more patient safety incidents/problems in the healthcare provided by the NHS

Death or long-term severe injury of a person in state care or detained under the Mental

Examples include suicide, self-harm or assault resulting in the death or long-term severe injury of a person in state care or detained under the Mental Health Act.

12.1 National Priorities to be referred to another team for investigation

The national priorities for referral to other bodies or teams for review or PSII (are detailed below:

- Maternity and neonatal incidents
- Mental health related homicides by persons in receipt of mental health services or within six months of their discharge
- Child deaths
- Deaths of persons with learning disabilities
- Safeguarding incidents
- Incidents in screening programmes
- Deaths of patients in custody, in prison or on probation

Maternity and neonatal incidents:
Incidents which meet the 'Each Baby Counts' and maternal deaths criteria detailed in must be referred to the Healthcare Safety Investigation Branch (HSIB) for investigation (https://www.hsib.org.uk/maternity/)

All cases of severe brain injury (in line with the criteria used by the Each Baby Counts programme) must also be referred to NHS Resolution's Early Notification Scheme

All perinatal and maternal deaths must be referred to MBRRACE

Mental health-related homicides by persons in receipt of mental health services or within six months of their discharge
These must be discussed with the relevant NHS England and NHS Improvement regional independent investigation team (RIIT)

Child deaths
For further information, see: *Child death review statutory and operational guidance.* Incidents must be referred to child death panels for investigation

Deaths of persons with learning disabilities
Incidents must be reported and reviewed in line with the Learning Disabilities Mortality Review (LeDeR) programme

Safeguarding incidents:
Incidents must be reported to the local organisation's named professional/safeguarding lead manager and director of nursing for review/multi-professional investigation

Incidents in screening programmes

Incidents must be reported to Public Health England (PHE) in the first instance for advice on reporting and investigation (PHE's regional Screening Quality Assurance Service (SQAS) and commissioners of the service)

Deaths of patients in custody, in prison or on probation
Where healthcare is/was NHS funded and delivered through an NHS contract, incidents must be reported to the Prison and Probation Ombudsman (PPO), and services required to be registered by the Care Quality Commission (CQC) must also notify CQC of the death. Organisations should contribute to PPO investigations when approached.

Appendix 2 PSRs

PSR Type	Method	Objective
Team reviews Post-incident review as a team to: • Identify areas for improvement • Celebrate success • Understand the expectations and perspectives of all those involved • Agree actions • Enhance teamwork through communication and collaborative problem solving	Debrief	An unstructured, moderated discussion The simplest and most informal method to gain understanding and insight soon after an incident (debriefs held immediately after an incident are known as 'hot' debriefs).
	Safety huddle	Proactive: a planned team gathering to regroup, seek collective advice, or talk about the day, shift, next few hours. Allows for on-the-spot assessment, reassessment, and consideration of whether there is a need to adjust plans. Reactive: triggered by an event to assess what can be learned or done differently. Focused on process-oriented reflection to find actionable solutions
	After action review	A 'cold' structured debrief facilitated by an AAR facilitator. AARs are based around four overarching questions: 1. What is expected to happen? 2. What happened? 3. Why was there a difference between what was expected and what happened? 4. What are the lessons that can be learnt?
Systematic Reviews To determine:	Case record/note review (e.g., Datix review Timeline or	To determine whether there were any problems with the care provided to a patient by a service. (To routinely identify the prevalence of issues; or when bereaved families/carers or staff raise concerns about care.)

• The circumstances and care leading up to and surrounding the incident • Whether there were any problems with the care provided to the patient	Rapid Review)	
	Mortality Review (Structured Judgement Review)	A systematic review of a series of case records using a structured or semi-structured methodology to identify any problems in care and draw learning or conclusions that inform action needed to improve care, within a setting or for a specific patient group, particularly in relation to deceased patients
	Specialised Learning Review	For example, falls, pressure ulcers, IPC reviews
Monitoring	Audit	Regular review to improve the quality of care by evaluating delivered care against standards Can be observational or include documentation review (or both)
	Survey	
	Appreciative Enquiry	