

Patient safety incident response plan

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INTRODUCTION 3

The NHS Patient Safety Strategy was published in 2019 and describes the Patient Safety Incident Response Framework (PSIRF), a replacement for the NHS Serious Incident Framework. This document is the Patient Safety Incident Response Plan (PSIRP). It provides the detail of how we will implement the requirement of the PSIRF as set out in our associated

The Serious Incident Framework provided structure and guidance on how to identify, report and investigate an incident resulting in severe harm or death. PSIRF is best considered as a learning and improvement framework with the emphasis placed on the system and culture that support continuous improvement in patient safety through how we respond to patient safety incidents.

One of the underpinning principles of PSIRF is to do fewer "investigations" but to do them better. Better means taking the time to conduct systems-based investigations by people that have been trained to do them. The NHS Patient Safety Strategy challenges us to think differently about learning and what it means for a healthcare organisation.

Carrying out investigations for the right reasons can and does identify learning. Removal of the serious incident process and threshold does not mean "do nothing", it means responding in a proportionate way to incidents and striking the right balance between investigation and learning and improvement. PSIRF recognises that under the old SI framework too much time and resource was spent investigating incidents based on a predefined threshold, such as subjective level of harm, when there may be little learning to be gained. PSIRF provides the framework to shift focus to provide a better balance between investigating and learning and improvement to improve patient safety.

A risk to successfully implementing PSIRF is continuing to investigate and review incidents as we did before, but simply giving the process a new label. The challenge is to embed an approach to investigating that forms part of the wider response to patient safety incidents whilst allowing time to learn key themes from all patient safety feedback and insights.

Compassionate engagement and a 'just culture' are the foundation of PSIRF. We need to ensure we have support structures for staff and patients involved in patient safety incidents. Part of which is the fostering of a psychologically safe culture championed by our leaders, our trust-wide strategy and our reporting systems.

We have developed our understanding and insights over the past three years, includina regular discussions engagement through our committees and group. We have also completed a detailed analysis of themes and trends arising from a range of information sources over the last 3 years, such as Incidents, complaints and concerns, GP enquiries, risk registers, coronial inquests, patient feedback (Friends & Families Test), legal claims and staff concerns. This plan provides the mechanisms of how PSIRF will be implemented at The Whittington.

There are many ways to respond to an incident. This document covers responses conducted solely for the purpose of systems- based learning and improvement.

There is no remit within this Plan or PSIRF to apportion blame or determine liability, preventability or cause of death in a response conducted for the purpose of learning and improvement. This plan augments and reinforces existing guidance and best practice in relation to 'Just Culture' and professional accountability.

It is outside the scope of PSIRF to review circumstances relating to complaints, HR matters, legal claims and inquests which must be pursued through the appropriate guidance and policies. This Plan explains the scope for a systems- based approach to learning from patient safety incidents. We will identify incidents to review through nationally and locally defined patient safety priorities. An analysis of which is explained later within this document.

Our vision: "Helping local people live longer, healthier lives" supported by our 'ICARE' values: (Innovation, Compassion, Accountability, Respect and Excellence), along with our strategic aims:

- Deliver outstanding safe, compassionate care in partnership with patients
- Empower, support and develop an engaged staff community
- Integrate care with partners and promote health and wellbeing
- Transform and deliver innovative, financially sustainable services

will sit at the heart of our implementation and delivery of this PSIRP.



We have reviewed our local system to understand the people who are involved in patient safety activities across the Trust, as well as the systems and mechanisms that support them.

Our local care system is complex with many interrelated components that are crucial to ensuring everything works. We have reviewed all patient safety activities and engaged closely with our network of key stakeholders and partner agencies who are integral to the Patient Safety agenda.



This Trust has a Corporate Directorate. The central Patient Safety Team works closely with other Corporate Teams, particularly the Patient Experience Team, Quality Improvement Team, Clinical Effectiveness Team and Legal Services Team.

There are 5 Integrated Care Service Units (ICSU's) providing clinical services across the Trust:

- Acute Patient Access, Clinical Support Services and Women's Health (ACW)
- 2. Adult Community Health Services (ACS)

- 3. Children and Young People Services (CYP)
- 4. Emergency and Integrated Medicine (EIM)
- 5. Surgery and Cancer (SC)

Core patient safety activities undertaken include:

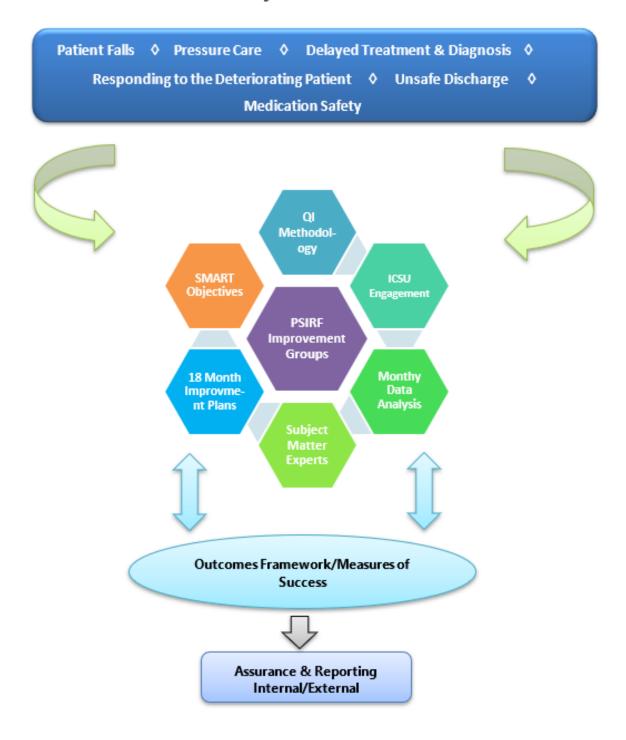
- NHS Patient Safety Strategy
- Patient Safety Programme
- Patient Safety Incident Response Framework
- Patient Safety Partners involvement
- Risk Management
- Central Alert System (CAS)
- Quality Improvement

Other activities within the Trust that provide insights to patient safety include Structured Judgement Reviews, Learning from Deaths, complaints and feedback, legal claims and inquest responses.

The operational 'work-as-done' for these patient safety activities is predominantly owned by our colleagues within the operational Integrated Care Support Unit (ICSU's). Each ICSU is supported by a small governance team who provide local expertise and advice on patient safety matters with support from the Corporate Teams and Patient Safety Specialist.

This emergent system has been built to respond to the needs of our patients, services, and structures we work in. This involves key people & teams within the Trust who are integral in facilitating our patient safety system and patient safety culture. This system is not static and will evolve and adapt further as we embark on our PSIRF journey.

Patient Safety Priorities for PSIRF



In the last three years, more than 12,000 patient safety incidents have been reported by the Trust with around 1% (1200) of these meeting the threshold for consideration as a Serious Incident under the previous Serious Incident Framework.

A significant amount of time and resource is completing consumed in serious incident investigations, ensuring action plans are completed and providing assurance of learning improvement internally and to commissioners.

It has been recognised in the PSIRF, that a disproportionate amount of time and effort is required to carrying out serious incident investigations, significantly limiting time to learn thematically from the other 99% of patient safety incidents (that do not meet the criteria as a 'serious incident').

In short, the burden of effort is placed on fewer than on fewer than 1% of all patient safety incidents.

A significant risk to successfully implementing PSIRF is continuing to investigate as many things as possible within Serious Incident Framework but simply calling them something else.

A key part of developing the new national approach is to understand the amount of patient safety activity the trust has undertaken over the last few years. This enables us to plan appropriately and ensure that we have the people, system and processes to support the new approach.

The patient safety investigation and learning related activity undertaken prior to PSIRF can be broken down as follows:

Patient Safety Activities	Activity	Definition	Av. of prev. 3 calendar years	Last calendar year
National Priorities	Incident resulting in death	Serious incident requiring investigation which met the standard investigation timeframe and resulted in patient's death.	6	3
	Never Events	Incident meeting criteria for never events framework and reported to STEIS	3	1
Local Patient Safety Activities	Serious Incident Investigations (SI's)	Serious incident requiring investigation (SIRI) which met the standard investigation timeframe.	50	19
	72 Hour reviews	Including moderate harm incidents meeting the requirement for Statutory Duty of Candour, or other incidents of concern.	173	59
	Patient Safety Incident Validation	Patient safety incidents of low/no harm requiring validation at department/ward level.	4100	5813

In order to identify our key improvement priorities we analysed 3 years of data up to 31/12/2022 relating to the following activities:

- Reported incidents (including low and noharm incidents)
- Complaints, concerns and patient feedback through the Friends and Families Test (FFT)
- Risks and risk registers
- Legal claims and inquests
- Staff and GP concerns/enquiries

From analysis of incident data, it was clear, as would be expected for an acute hospital trust, that pressure ulcers, medication transfer/discharge issues and harm related to delayed treatment were the most significant categories of incidents in the low or no-harm categories. Significant variation between ICSU's is evident, as would be expected given the diverse nature of services provided. For example pressure ulcers are a more significant issue for community services, delayed treatment nursing emergency medicine and discharge for inpatient medical and surgical wards.

Clinical incidents resulting in moderate or above harm levels presented a slightly different picture with more incidents relating to pressure ulcers, falls, delays in cancer treatment, infection control and resuscitation. As would be expected, there are considerable variations between ICSU's and specialties in terms of incident reporting profiles and numbers of incidents reported.

Legal claims and inquests provide a different perspective with failure to treat/diagnose, complications from treatment and labour/delivery issues being the most frequent categories of claims.

Data and information from complaints/concerns presented a more nuanced picture based more on perceptions of patients or relatives, such as communication issues, delays/waiting times, care needs not being met and perceptions of staff attitude.

Analysis of risk registers highlighted the key operational challenges that impact upon quality and safety of patient care. These relate primarily to system capacity to deliver services such as: staffing shortages, patient flow, medical equipment, infection control and issues relating to estate and facilities. As PSIRF requires a more holistic assessment of patient safety it is recognised that governance of the risk framework should be more closely aligned with patient safety at a strategic and operational level in future. Improvement plans and risk mitigation should be co-terminus with patient safety priorities to maximise risk reduction and minimise likelihood of incident reoccurrence.



Through the analysis of our patient safety insights, based on both the original thematic analysis and the updated incident review, there are six patient safety priorities which will be the focus on for the next two years. It is recognised that some of the themes relating to issues such as estates, staffing levels, IT system failures and patient flow would be best managed through the operational management structures, rather than the patent safety agenda.

These patient safety priorities form the foundation for how we will decide to conduct Patient Safety Incident Investigation (PSII) and learning responses, and also where no further investigation is required.

The patient safety priorities were agreed at the PSIRF Implementation Group in August 2023.

Theme	Key Theme	Key Risks from Activity
1	Patient Falls	Consistently a high number of incidents across inpatient areas and wards. Many resulting in patient harm.
2	Medication / Safety	Administration of medicines, omitted or delayed doses, high risk drugs (especially insulin and anticoagulation).
3	Responding to a deteriorating patient	NEWS & PEWS scores, fluid balance management, stepdown to ward level care.
4	Pressure related skin damage	Trust acquired or deterioration in pressure damage. There is also a key link with self-neglect and vulnerable adult/safeguarding issues in the community.
5	Delayed Treatment & Diagnosis	Particularly in relation to cancer treatment pathways, patient tracking systems and patients lost to follow up. Incorrect diagnosis.
6	Unsafe discharge	A range of concerns identified from across ICSU's particularly relating to delays in transfer, learning disability patients and discharge medications and equipment.

Deciding what to investigate through a PSII or other learning response such as an After-Action Review, SWARM or MDT review will be a flexible approach, informed by the local and national priorities. Our objective is to facilitate an approach based on decision making by those best placed to understand the incident circumstances, environment, and contributory factors, rather than centrally mandated rules and compliance with rigid procedures. <u>Under PSIRF, incidents will not be selected for further learning responses based on the level of harm, instead incidents that provide the greatest opportunity for new learning will be selected for further learning responses.</u>

Each of these priorities will have a pro-active improvement plan, utilising a Quality Improvement (QI) methodology, to support the PSIRF principle of shifting more time and resource from investigating to improvement. As part of our planning we have mapped existing QI and improvement work (see appendix 1) against these PSIRF priority themes to identify any gaps or where additional support or capacity maybe required.

At the onset, we will use existing structures to support the process of decision making. There is an established weekly executive- led incident review meeting (formally SIEAG but now called WISH – Whittington Improvement & Safety Huddle), where potential serious incidents and other emerging patient safety issues across the Trust are discussed. ICSU's have local arrangements to ensure incidents are reviewed daily and key risks and concerns identified.

Our medium to longer term aim is to support each ICSU to have more autonomy to find the most appropriate and proportionate approach to investigate and learn from incidents. This will evolve through our implementation of the PSIRF and the associated training and professional development in human factors and systems thinking. A move away from centrally mandated rules and thresholds governing what should investigated is central to the PSIRF principles.

As we transition into PSIRF, the Patient Safety Team will continue to work closely with the ICSU Quality and Risk teams to develop and support this approach. In PSIRF, the approach of investigating incidents by their level of harm will no longer apply, and we will focus on incidents that provide opportunities for new learning and quality improvement, as well as the national and local patient safety priorities as illustrated below

National guidance recommends that 3-6 learning responses (which may include PSII) per priority theme are conducted each year. When combined with patient safety incident investigations from the nationally mandated priorities this will likely result in around 15-20 investigations per year. Attempting to do more than this will impede our ability to focus more time and effort on improving patient safety and less on investigating incidents, particularly where contributory factors are well understood, and improvement work is in progress. This is the very essence of the PSIRF approach.

Patient safety incidents that must be investigated under PSIRF

The following types of incidents will still require a comprehensive PSII investigation:

- 1. Patient safety incident is a Never Event
- 2. Deaths more likely than not due to problems in care. This can be identified through an incident and/or the learning from deaths process.
- 3. Emerging National priorities for investigations (at the time of developing this plan, there are none apart from those already listed above. We will include any new priorities as they emerge).

Apart from the mandated incidents listed above, the following questions must be considered when deciding which incidents require further investigation or a learning response.

- Is the patient safety incident linked to one of the Trust's Patient Safety Priorities that were agreed as part of the situational analysis?
- Is the patient safety incident an emergent area of risk? For example, a cluster of patient safety incidents of a similar type or theme may indicate a new priority emerging. In this situation, a proactive investigation can commence, using a single or group of incidents as index cases.

Incidents that meet the statutory Duty of Candour thresholds:

There is no legal requirement 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 states we must:

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

This legal duty will not be affected by the implementation of the PSIRF, though the way we communicate and type of information we share with patients, carers or relatives may change depending on the type of learning response utilised. Additionally, there should also be more opportunities to involve patients and carers/families more closely in our learning responses with the learning tools / methods available.

Patient safety incidents that have resulted in severe harm:

These incidents would have automatically been investigated as a 'serious incident' under the Serious Incident Framework. It is crucial that these incidents are not routinely investigated using the PSII process, otherwise we will be re-creating the Serious Incident Framework. The criteria of 'providing significant opportunities for new learning' will determine whether a learning response (including PSII) is required and not the level of harm.

The routine response to an incident that results in severe harm will be to follow the Statutory Duty of Candour requirements. This will both provide insights to thematic learning and provide information about the events to share with those involved.

Event Approach Improvement Incidents meeting each baby counts criteria. Investigation Branch (HSIB) Incidents meeting maternal death criteria. Child death Initiate child death review process Respond to recommendations from Death of person with learning Reported and reviewed by Learning external referred disabilities Disabilities Mortality Review (LeDeR) agency/organisation as required. Safeguarding incidents meeting Reported to named safeguarding criteria (Babies, children, or young people on a child protection plan; looked after plan or a victim of willful neglect or domestic National Priorities Patient Safety Incident Investigations Reported to Public Health England Incidents in screening programmes Death of patients in custody/prison/probation Incidents meeting the Never Event criteria. Create local organisational recommendations and Deaths caused by treatment issues / omission. Patient Falls Pressure Care Create local organisational rust Priorities Deteriorating patient recommendations and Unsafe discharge actions feeding into Delayed treatment / patient safety priority diagnosis improvement Medication Safety programmes. Emerging areas of risk / Other incidents of concern or Locally agreed learning response or which present significant escalation for possible PSII Inform thematic analysis opportunities for new learning. to identify new patient safety risks. Manage at service level and close. No further learning response. All other incidents.

Under the PSIRF a suite of learning responses will be available to investigate different types of incidents depending on their circumstances. Central to all learning responses/investigations will be a focus on human factors and systems thinking and a move away from root causes and the actions of individuals. The PSIRF framework requires the Trust to provide additional training, education and availability of resources in relation to these new methodologies and frameworks.

A detailed training needs analysis has been completed to identify the right level of training for key staff groups such as senior leaders overseeing PSIRF; staff who will be completing investigations and learning responses; and staff who will be engaging with patients, carers and families following a patient safety incident. A programme of externally facilitated training will be delivered to all required staff prior to our transition to the PSIRF which will cover the following key modules:

Systems approach to learning from patient safety Incidents 2-day 12 hours	Systems approach to learning from patient safety incidents oversight training 1-day 6 hours	Engaging with patients, families and staff following a patient safety incident training 1 day- 6 hours
 For: All Learning Response Leads All those in PSIRF oversight Roles 	For:All those in PSIRFOversight Roles;Provider Boards	For:All Engagement LeadsAll those in PSIRF oversight roles

Additionally, all staff identified above will need to complete the NHSE, Patient Safety Syllabus level 1 and level 2 e-Learning. This is available to all staff and provides an introduction to the key principles and methodologies that are covered in more depth in the externally facilitated training.

Types of Learning Response

The Trust will initially adopt the 4 learning response methodologies below. Trained investigators will decide which incidents require a learning response and which tool is most appropriate for the circumstances of the incident on a case-by-case basis. It must be recognised that many incidents will not require any further learning response and can be dealt with at a local level or at sub committees for specific categories where there are already existing improvement plans in place, or where they relate to one of the key improvement themes & workstreams.

<u>Patient safety incident investigations (PSII's)</u> - are comprehensive investigations conducted to identify the circumstances and systemic, interconnected, causal factors that result in patient safety incidents. These are usually the most detailed and in-depth investigations, similar to 'serious incident' (SI) investigations conducted under the old framework. As detailed above, this methodology will still be required for some types of nationally mandated incidents and can be used to investigate any incidents locally where this approach is deemed the most

appropriate. For example, complex incidents where contributory factors are not well understood and the potential for new learning is high.

<u>After-Action Review (AAR)</u> - An after-action review method of evaluation usually takes the form of a facilitated discussion following an event or activity. It enables understanding of the expectations and perspectives of all those involved and it captures learning, which can then be shared more widely.

<u>SWARM huddle</u> - 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.

Multidisciplinary team (MDT) review - The MDT review supports health and social care teams to:

- identify learning from multiple patient safety incidents
- agree the key contributory factors and system gaps in patient safety incidents
- explore a safety theme, pathway, or process
- gain insight into 'work as done' in a health and social care system.

More detailed information on learning response tools can be found on the NHSE website at : https://www.england.nhs.uk/publication/patient-safety-learning-response-toolkit/

"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)

Support for patients, carers and families following an incident

We recognise the significant impact patient safety incidents can have on patients, their families, and carers. The Trust is committed to ensuring that patients and their families or carers receive all necessary support following a patient safety incident.

The patient voice is very much an integral part of our work at the Trust. Our Patient Safety Partners will be a valuable source of information and feedback to ensure the patients voice is integral to PSIRF.

As detailed above, engagement with families and patients is a central principle of the PSIRF. It also supports and augments existing guidance under the Duty of Candour requirement. In line with the PSIRF guidance the Trust will endeavor to put patient involvement at the heart of our PSIRF implementation by:

 Recruiting Patient Safety Partners into the organisation to provide insight, support and scrutiny in relation to our patient safety arrangements and agenda.

- Reviewing and updating our Duty of Candour policies and procedures to ensure they are in line with the principles of the PSIRF.
- Delivering required PSIRF training to all engagement leads on 'engaging with patients, families and staff following a patient safety incident'.
- Regularly seeking feedback through existing arrangements such as local focus groups, surveys, FFT and patient stories.
- Triangulation of patient safety data and information with data and intelligence from the Patient Experience team / agenda.
- Continually listening to our patients to understand their needs, and the best ways to involve them, in an inclusive, supportive, and collaborative manner.

As part of our new policy framework, we are developing procedures and guidance to support staff in how to discuss incidents with patients and family.



We are on a journey at the Trust to ensure it is a safe and fair place, where everyone's voice is encouraged, valued, and listened to, helping us to continually learn, inspire change and improve.

When a colleague reports an incident or is providing their insights into the care of a patient for an investigation, we will actively encourage a safe space to discuss the events, explore the system in which they work and listen openly without judgement. Our new policy, procedures and guidance will support this in practice.

We recognise that many staff will be involved with a patient safety incident at some point in their careers and this can be a distressing and traumatic experience. We have a wealth of excellent psychological, wellbeing and support services for individuals. Additionally, our managers, supervisors and leaders are committed to the Trust values of compassion and respect, to our staff as well as our patients.

The learning response methodologies, detailed above, that the Trust will employ under the new framework, will also ensure staff are fully engaged and supported throughout the process of investigation and learning.

Additionally, the Trust's associated policies and procedures in relation to Just Culture and Freedom to Speak Up, augment the principles and methodologies detailed in this plan. The implementation of the PSIRF will provide an opportunity to refresh and revisit these in an inclusive and collaborative way.

Several existing approaches to supporting staff and staff teams following an incident are already established, as detailed below.

Debrief: An unstructured, moderated discussion.

Safety huddle proactive: A planned team gathering to regroup, seek advice, talk about the day.

Safety huddle reactive: Triggered by an event to assess what can be learned.



These will continue to be promoted and facilitated within our teams and services.

Governance, oversight and assurance under PSIRF will need to shift its focus to learning, improvement and compassionate engagemnt, rather than compliance with process, targets and thresholds under the SIF. The Trusts approach will be to retain existing governance structures and committees. However, reports, terms of reference and agenda's will be reviewed and amended to reflect the new approach. It is recognised that this element of PSIRF, especially, will evolve and develop as we progress on our journey.

The **Trust Management Group** oversees the delivery of clinical services, informed by the outcomes from review meetings between ICSU's and the Executive Team.

The **Quality Governance Committee** is chaired by the Executive Medical Director. This meeting will have strategic oversight of the PSIRF. This will include assurance that improvement plans are progressing and learning responses are being conducted effectively, consideration of any emerging risks and mitigations required and any other significant activity or exceptions reported by Patient Safety Group or WISH.

The **Patient Safety Group** will have operational oversight of PSIRF including: progress and approval of PSIIs, progress with safety actions arising from learning responses, analysis of data and information relating to patient safety and improvement, identification of emerging risks, and to have supportive oversight of improvement plans for the key local priorities.

The **Patient Experience Group** chaired by the Deputy Chief Nurse and supports the Board oversight in this area.

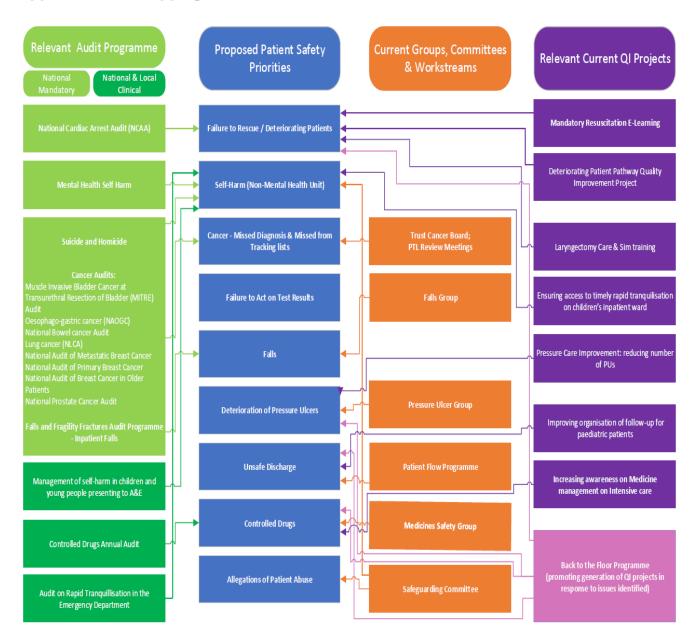
The **Medicines Safety Group** chaired by the Deputy Chief Nurse oversees all aspects of medicines safety across the Trust.

The Whittington Improvement & Safety Huddle (WISH) will review incidents and risks on a weekly basis and seek assurance from ICSU's that incidents are being managed in line with the PSIRP (see flowchart in appendix 3). The group will consider any escalations from ICSU's and the Risk and Safety Team and agree any incidents of concern that require PSII level investigation.

The **Trust Board** seeks assurance that high quality services are being delivered through its sub-committees and presentation of reports, data and information.

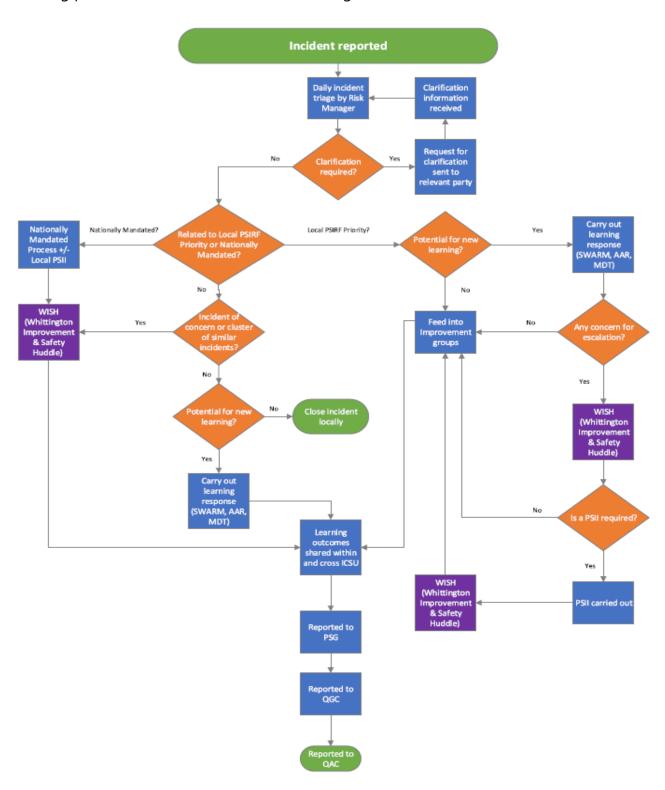
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Appendix 1: QI Mapping Results

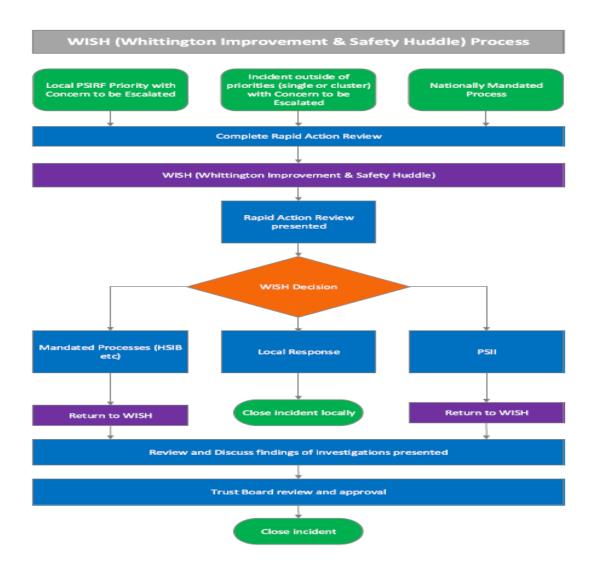


Appendix 2: Incident response Process – Integrates Care Service Units (ICSU) to Whittington Improvement & Safety Huddle (WISH)

The flowchart below illustrates the patient safety incident governance and decision-making process for review and decision making.



Appendix 3: Incident response Process – WISH



After Action Review (AAR) – A type of 'learning response' where staff involved in an incident get together for a group discussion to look at what happened in more detail and what can be learned.

Human Factors (Ergonomics) – The principles and practices of Human Factors focus on optimising human performance through better understanding the behaviour of individuals, their interactions with each other and

with their environment.

Just Culture – National NHS guidance to assist providers, when responding to incidents or adverse events, to understand when it is appropriate, and not appropriate, to hold an individual solely to account for an error or omission. https://www.england.nhs.uk/wp-content/uploads/2021/02/NHS 0932 JC Poster A3.pdf

Learning Response – replaces the term 'investigation'. A more in-depth review of an incident (or group of incidents) using a recognised methodology (for example an AAR).

Multi-disciplinary Team (MDT) Review – Another type of 'learning response', where a team of experts from different disciplines discuss an incident collectively to identify where improvements can be made.

Patient Safety Incident Investigation (PSII) – The most comprehensive and complex type of leaning response looking in detail at all aspects of a patients care. Conducted by a trained lead investigator.

Quality Improvement (QI) – A term used, mainly in the NHS, that encompasses a range of systematic methodologies aimed at continually improving the quality of care provided.

SWARM Huddle – A type of 'learning response' where staff 'swarm' to the site of an incident as quickly as possible to understand what happened and what can be done to prevent reoccurrence.

Systems Approach / Systems Thinking – a range of recognised methodologies that can be used to understand how various parts of the care 'system' interact / work together to provide safe care. For example: people, technology, the physical environment, policies and procedures etc.