**Patient Safety Incident Response Framework Plan**

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**1. Introduction**

The Patient Safety Incident Response Framework (PSIRF) represents a significant shift in the way the NHS responds to patient safety incidents and is a major step towards establishing a safety management system across the NHS. It is a key part of the [NHS patient safety strategy](https://www.england.nhs.uk/patient-safety/the-nhs-patient-safety-strategy/).

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

It promotes systematic, compassionate, and proportionate responses to patient safety incidents, anchored in the principles of openness, fair accountability, learning and continuous improvement – and with the aim of learning how to reduce risk and associated harm. In our responses to incidents, we will include discussion and active engagement with patients, families, and healthcare staff to seek their input and develop a shared understanding of what happened.

This Patient Safety Incident Response Plan (PSIRP), is part of the PSIRF and sets out how The Newcastle upon Tyne Hospitals NHS Foundation Trust intends to respond to patient safety incidents over the coming 18 months.

We will remain flexible and consider the specific circumstances in which patient safety issues and incidents occurred and the needs of those affected. There are many ways we can respond to an incident. This document covers responses conducted solely for the purpose of system learning and improvement and there is no remit to apportion blame or determine liability, preventability or cause of death.

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.

Some incidents in healthcare require a specific type of response as set out in policies or regulations. These responses include mandatory Patient Safety Incident Investigation (PSII) in some circumstances or review by, or referral to, another body or team, depending on the nature of the incident.

**2. Our services**

The Newcastle upon Tyne Hospitals NHS Foundation Trust is registered with the CQC to provide regulated activity at the following locations:

* Campus for Ageing and Vitality
* Dental Hospital
* Freeman Hospital
* International Centre for Life
* Northern Centre for Cancer Care- North Cumbria
* Royal Victoria Infirmary
* West Cumberland Hospital

Newcastle Hospitals has over 1,400 beds, around 16,000 staff, and an annual income of £1.6 billion, and offers a wide range of specialist as well as community services. The trust has a strong reputation for research and innovation and hosts the region’s clinical research network and a biomedical research centre. The Trust has been working with the Institute for Healthcare Improvement (IHI) for the last two years to develop a culture of improvement and has been building capability and capacity in this regard.

During the PSIRP drafting process we have faced a number of organisational challenges including implementing a new organisational structure, creating eight operational Clinical Boards in place of eighteen Directorates. At the time of completing the PSIRP, Clinical Boards are embedding their governance processes which provides an opportunity for standardisation.

**3. Definitions**

**Patient Safety Incident**: any unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving healthcare.

**Serious Incidents:** adverse events, where the consequences to patients, families and carers, staff or organisations are so significant or the potential for learning is so great, that a heightened level of response is justified

**Trust Priority Incident**: are patient safety incidents that are aligned to our improvement priorities and which have a robust improvement plan monitored and tracked by a trust wide quality committee, Clinical Group or Board.

**National and Regulatory Incident**: are patient safety incidents that require a specific type of response as set out in national policies or regulations. These responses will include an internal trust patient safety incident investigation (PSII) or review by or referral to another body or team, depending on the nature of the incident.

**Never Event**: are incidents that are wholly preventable because guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers. Full details of each never event can be accessed via NHS England website.

**Patient Safety Incident Investigation (PSII)**: an in-depth investigation undertaken when an incident or near-miss indicates significant patient safety risks and potential for new learning. A PSII investigation uses the Systems Engineering Initiative for Patient Safety (SEIPS) framework to understand interactions within complex systems and which can be applied to support the analysis of incidents and safety issues more broadly. Investigations 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.

**After Action Review (AAR)**: is a structured facilitated discussion of an incident, the outcome of which gives individuals involved an understanding of why the outcome differed from that expected and the learning to assist improvement. AAR generates insight from the various perspectives of a muti-disciplinary team and can be used to discuss both positive outcomes as well as incidents.

**Multi-disciplinary team (MDT) Review**: The multidisciplinary team (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; and gain insight into ‘work as done’ in a health and social care system.

**Swarm Huddle**: Swarm-based safety huddles are rapid reviews used to identify learning from patient safety incidents. Immediately after an incident, staff ‘swarm’ to the site to quickly (i.e. within 24 hours) analyse what happened and how it happened and decide what needs to be done to reduce risk of reoccurrence.

**Case Note Review**: a method used to determine whether there were any problems in the care provided to a patient within a particular service. It is undertaken routinely to learn and improve in the absence of any particular concerns about care. This is because it can help identify problems where there is no initial suggestion anything has gone wrong. It can also be done where concerns exist, such as when bereaved families/carers or staff raise concerns about care.

**Structured Judgement Review**: a case note review methodology that blends traditional, clinical-judgement based review methods with a standard format. This approach requires reviewers to make safety and quality judgements over phases of care, to make explicit written comments about care for each phase, and to score care for each phase. The result is a relatively short but rich set of information about each case in a form that can also be aggregated to produce knowledge about clinical services and systems of care.

**Clinical Governance and Risk Department (CGARD)**: Governance department within Newcastle Hospitals, responsible for patient safety, clinical effectiveness, compliance and assurance and legal services.

**Maternity and Newborn Safety Investigation Health (MNSI)**: Perinatal patient safety body under direction from the Department of Health and Social Care.

**Level 2 mortality review**: A process in which the circumstances around the care of a patient who died in hospital are systematically examined. A stage 2 review will determine the quality of care and whether the death could have been avoidable. Learning is disseminated through the appropriate clinical governance structures.

**4. Evaluation**

Prior to updating this response plan, after 18 months we will seek views and assurance on the patient safety response framework and the effectiveness of this plan.

This will ensure our future plan has further enhanced engagement on the improvement priority areas.

**5. Stakeholder engagement**

To develop the framework and plan we engaged with a range of different people. A summary of this engagement is detailed below.

|  |  |
| --- | --- |
| **Stakeholder**  | **Involvement** |
| Staff | Through incidents reported on the Trust incident reporting system (Datix). |
| Core Project Team  | The team conducted the data collection and initial analysis to socialise further. This team also triangulated the data and responded to any comments, feedback and challenges. |
| Clinical Boards  | Boards were asked to provide detailed feedback, analysis and recommendations to ensure that the proposed incident profiles aligned with the current incidents and improvement work ongoing in their areas. |
| Board Executives | The proposed incident profiles were presented to the Trust Board (executive & non-executive) for oversight and comment. |
| Trust Quality Committee | The proposed incidents profiles were reviewed across all trustwide quality committees for comment, challenge and feedback.  |
| Newcastle Improvement  | The proposed incidents profiles were reviewed for comment, challenge and feedback. Alignment with ongoing and future plans for improvement work. |
| Patient Experience Team  | Provided data based upon patient feedback, experiences and complaints to ensure that the patient voice was acknowledged and included within the thematic analysis provided. Further development work for Patient Safety Partners. |
| Legal and Claims, Learning from Deaths, Risk Register | Provided additional data and reports to enable a thematic review and triangulation with the proposed incident profiles. |
| Patient Safety Partners (PSP) | Further development work required in regard to PSP job descriptions. |

**6. Defining our patient safety incident profile**

**6.1 Situational analysis**

The Trust reviewed available incident data from the last three years, 1 January 2020 to 31 December 2022 (Figure 1). This included never events, serious incidents, harm and no harm incidents. The trends and themes from these incidents were triangulated with complaints, patient experience, mortality, claims and inquest data and risks

Data sources used:

* Greatix reports
* Patient safety incidents reported on the trust’s incident management and risk system (Datix)
* Serious incidents
* Thematic analysis of quantitative and qualitative serious incident data
* Key themes from complaints and patient advice and liaison service (PALS)
* Key themes from claims
* Themes from learning from deaths
* Review of trust wide Risk Register

**Figure1 - data reviewed**

\*excluding falls and pressure ulcers

There are existing clinical groups in Newcastle Hospitals with a focus on improvement including;

* Harm free care (falls and pressure ulcers)
* Maternity
* Infection control

In order to maximise the Trust-wide benefits of PSIRF, these existing areas with an existing improvement focus were not selected as initial priorities.

**6.2 Themes and justification for improvement priorities**

Through the review and the thematic analysis of our data, we have identified the following Trust Priority Incidents that we will focus on for the next 12-18 months.

|  |  |  |  |
| --- | --- | --- | --- |
| **Trust priority incidents**  | **Rationale**  | **Key Actions**  | **Oversight Committee/Group**  |
| **Diagnostic results**: Reported Incidents about action on abnormal results from Radiology by clinicians | Most common theme for SI.Contributory factor in litigation: delay in diagnosis/treatment,failure to act.Multifactorial issues across a number of Boards, with identified risks documented in Radiology (risk rated 16). | Priority leads for improvement will be identified and clear aims statement developed.Improvement workstreams required * E-record
 | Patient Safety Group Senior Team\*  |
| **Lost to follow up:** Reported Incidents from systemic failure to refer and or act on follow up/referral from internal request | Very common theme for SI.Contributory factor in litigation: delay in diagnosis/treatment, failure to act.Multifactorial issues across a number of specialities within Boards including Ophthalmology and Cancer (risks rated as 12). | Priority leads for improvement will be identified and clear aims statement developed.Improvement workstreams required * Development of standardised referral system
* E-record
 | Patient Safety Group Senior Team\* |
| **Anticoagulation:** Omission in medication especially low molecular weight heparin (LMWH)/ Warfarin | Medications incidents are most common patient safety incident and common SI - average around 1 in 10 SIs. Trend of incidents reported involving anticoagulation – heparin & warfarin. Recent thematic analysis has been completed with several large improvement workstreams identified. Thrombosis service staffing rated as 15 on risk register.  | Priority leads for improvement will be identified and clear aims statement developed.Improvement workstreams required * E-record
* training & support in prescribing for junior doctors
* nursing standards & handover
 | Thrombosis Working Group Medication Safety Group Patient Safety Group |

\*The senior team comprises senior nurses, clinical directors of patient safety and quality and senior members of CGARD.

**7. Types of incident**

There is an established process for triaging serious incidents within the Trust. This work is currently largely conducted by CGARD, with the exception of national (external) reviews e.g. Maternity and Newborn Safety Initiative (MNSI). It is anticipated that the serious incident triage process will change (see Appendix B) with the Serious Incident Triage Panel becoming the Response Action Review meeting.

* ***Nationally defined priorities for PSII or review by external team* –** MNSI, Learning from lives and deaths – People with a learning disability and autistic people **(**LeDer,) Screening incidents etc
* ***Nationally defined incidents requiring local PSII*** - NEs, Learning from Deaths
* ***Locally defined incidents requiring local investigation*** (priority driving local improvement work)– PSII or other method \*
* ***Locally defined emergent incidents requiring PSII*** (unexpected incident with extreme level of risk and potential for learning) \*

\*these will be differentiated through the triage process and the type of investigation required determined by the triage panel.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **2020** | **2021** | **2022** |
| **National priorities (excluding child death and LeDeR) \*** | 5 | 9 | 7 |
| **Never events** | 2 | 4 | 6 |
| **Serious incidents (excluding falls and pressure ulcers)** | 55 | 68 | 61 |
| **Locally defined SIs \*\*** | 32 | 24 | 33 |
| **Locally emergent SIs \*\*\*** | 2 | 6 | 1 |

**Table 2: Current numbers of incidents as per category**

\* from priorities outlined above in section 2

\*\*Child death review and LeDeR data was not available for analysis

\*\*\* underreported as a specific cohort of SIs reported in 2023 occurred in this period

**8. Projected workload**

Based on historical data over the course of a year:

* average 6-8 external investigations with MNSI (terms of reference unchanged to date)
* 4 - 6 other national priority/NE investigations per year
* 5 – 8 local emergent investigations with cross cutting themes.

There will be an estimated 20 local defined investigations with triage determining proportionate action focussing on improvement through the relevant clinical board, with support from the allocated CGARD/NI and clinical director links (see section 9 Responding to incidents).

The remaining incidents (fit priorities, known contributory factors, align to improvement work) that would previously have required an investigation under the SI framework will be closed by the boards and do not require investigation (See section 9 Responding to Incidents).

Based on historical data we anticipate that the majority of these investigations will be concentrated in four Clinical Boards; Womens, Cardiothoracics, Medicine and Surgery. These Boards will be targeted for enhanced support during the first 12-18 months (see section 9: Responding to incidents).

There will be a quality assurance process in place for supporting the Boards with these investigations at each stage.

**9. Responding to incidents**

The chart below outlines the Trust response to reported incidents. Each step and those responsible is described in further detail within the Trust incident management policy. To ensure resource to focus on improvement is available the response to incidents must be proportionate. The ongoing monitoring and assessment of trends and themes will provide the assurance and confidence that we are responding appropriately and proportionately to patient safety incidents. Duty of Candour must be implemented for any incident meeting the regulatory requirement.



**10. Responding to national or regulatory incidents**

Some patient safety incidents require a specific type of response as set out in national policies or regulations. These responses will include an internal trust patient safety incident investigation or review by or referral to another body or team, depending on the nature of the incident. The table below sets out the current nationally mandated responses for national incidents.

|  |  |  |
| --- | --- | --- |
| **Incident**  | **Response Assessment**  | **Response Action** |
| Incidents meeting the Never Events Criteria 2018  | Assess against any improvement plans  | Patient Safety Incident Investigation (PSII) Align with improvement plans or if trend/theme submit for trust improvement |
| Deaths thought more likely than not to be due to problems in care | Assess against any improvement plans  | Patient Safety Incident Investigation (PSII) Align with improvement plans or if trend/theme submit for trust improvement |
| Deaths of patients detained under the Mental Health Act (1983) or where the Mental Capacity Act (2005) applies | Assess against any improvement plans  | Patient Safety Incident Investigation (PSII) Align with improvement plans or if trend/theme submit for trust improvement |
| Maternity & neonatal incidents meeting Healthcare Safety Investigation Branch (HSIB) or Maternity and Neonatal Safety Investigation (MNSI) criteria | Assess against any improvement plans  | Refer to HSIB/MNSI for independent Patient Safety Incident Investigation (PSII) |
| Incidents in NHS screening programmes | Assess against any improvement plans  | Refer to local screening quality assurance service for consideration of locally-led learning response |
| Child deaths | Assess against any improvement plans  | Refer for Child Death Overview Panel review. Locally-led PSII (or other response) may be required alongside the panel review |
| Deaths of persons with learning disabilities | Assess against any improvement plans  | Refer for Learning Disability Mortality Review (LeDeR) Locally-led PSII (or other response) may be required alongside the LeDeR |
| Mental health-related homicides | Assess against any improvement plans  | Refer to the NHS England Regional Independent Investigation Team (RIIT) for consideration for an independent PSII Locally-led PSII may be required |
| Safeguarding incidents meeting criteria | Assess against any improvement plans  | Refer to local authority safeguarding lead |
| Deaths in custody | Assess against any improvement plans  | Refer to the Prison and Probation Ombudsman (PPO) or the Independent Office for Police Conduct (IOPC). |

**11. Responding to Trust priority (improvement) incidents**

|  |  |  |
| --- | --- | --- |
| **Trust Priority Incident (aligned to improvement profile** | **Response Assessment** | **Response Action** |
| **Diagnostic Results**: Reported Incidents about action on abnormal results from Radiology by clinicians | Assess the contributory factors involved in the Incident to identify whether they are well understood and aligned to existing improvement plan. Consider the potential for learning. | If contributory factors are well understood and aligned to improvement plan → provide local staff and team feedback and close the Incident. Inform patient/NoK. ORContributory factors not aligned to improvement plan and potential additional learning → consider appropriate and proportionate learning response method and feed results into relevant improvement group and teams within governance structures. |
| **Lost to follow up:** Reported Incidents from systemic failure to refer and or act on follow up/referral from internal request | As above | As above |
| **Anticoagulation:** Omission in medication especially low molecular weight heparin (LMWH)/ Warfarin | As above | As above |

**12. Responding to other reported incidents**

The following incidents include any that is not a national/regulatory response requirement or one of our identified Trust Priority Incidents. Many of these will be patient safety areas we are aware of, with known contributory factors. These should remain as incidents to monitor at this stage because there is a limited resource available to act and improve all patient safety areas.

Some incidents may occur that have a high chance of future risk to patients, staff and the organisation. These may require a proportionate response to understand the contributory factors prior to consideration on department or trust action. Safety concerns will be escalated through the appropriate governance structures and subject matter experts.

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**13. Engaging and involving patients, families and staff**

Patients and families provide a unique and meaningful insight into patient safety incidents and their involvement and contribution to a learning response can help to develop a relationship of openness and trust, leading to and understanding of how the organisation responds to safety incidents. All staff are expected to demonstrate compassionate interactions with patients and families following a safety incident.

**14. Duty of Candour and notifiable safety incidents**

If a patient safety incident is confirmed as being notifiable, then statutory Duty of Candour (DoC) will apply. This requires us to discharge verbal and written DoC as well as sharing the outcome. Patients and families will be invited to be involved as part of the learning response. For cases where DoC applies, and no investigation is required as part of the response framework, we will complete the DoC requirement through a verbal and written response. This will include the associated improvement plan and information and assurance on what approach was taken and why. The responsibility for DoC lies with the clinicians and clinical board where the incident occurred.

**15. Management and identification of Trust improvement priorities**

The process for managing new improvement work identified through incidents, risk assessment, learning from deaths, inquests, claims clinical audit and outcomes and patient feedback (such as complaints or patient surveys) must be continuous. The priority incidents and subsequent improvement plans detailed in this document have been developed from triangulated data over the last three years. These will be the focus over the next 12-18 months; however, other safety issues will continue to be identified. New safety issues will be discussed and confirmed through the Trust governance structures. The improvement priorities will undertake focused work and as part of this will identify improvement aims and improvement metrics..

**16. Cross-System learning responses**

These will generally be managed by individual organisations to facilitate the involvement of people affected and those responsible for delivery of the services. However, if Newcastle Hospitals, another Trust or the North East and North Cumbria Integrated Care Board identify that a cross-system learning response is required, a shared agreement on the lead and delivery of this response and subsequent improvement will be confirmed with the ICB.

**17. Training requirements**

The transition to PSIRF from the previous Serious Incident Framework will be a significant change in Newcastle Hospitals. The Serious Incident Framework has been used for many years (the current version since 2015) and is embedded in governance processes.

Under PSIRF, the newly formed Clinical Boards will take increasing ownership for incident investigations supported by the Clinical Governance and Risk Department and the Clinical Directors for Patient Safety and Quality. A new role of Quality and Safety lead has been created by the Boards to support this and other oversight processes. It is recognised that training for incident investigation using the systems-based approaches to learning from patient safety incidents will be an essential part of this transition.

**Table .1 PSIRF training requirements**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Topic  | Minimum Duration | Content | Clinical department Managers, Supervisors and Team leaders | Staff with specific patient safety roles (Matrons, governance leads) | Patient Safety Specialists, Trust Patient safety team and Board Representatives |
| NHS Patient safety syllabus level 1: Essentials for patient safety | e-learning20 mins | Listening to patients and raising concerns. The systems approach to safety: improving the way we work, rather than the performance of individual members of staff.Avoiding inappropriate blame when things don’t go wellCreating a just culture that prioritises safety and is open to learning about risk and safety |  |  |  |
| NHS Patient safety syllabus level 2: Access to practice | e-learning40 mins | Introduction to systems thinking and risk expertiseHuman factorsSafety culture |  |  |  |
| Incident investigation training (HSIB level 2 equivalent) | 1 day plus 1 day workshop | Human factors and ergonomicsSafety cultureLearning from incidentsProxys work as doneLocal rationalityAdaptions and work aroundsOrganisational driftPresenting evidenceAction planning and improvement. |  |  |  |