East Midlands
School Of Anaesthesia

Anaesthetic Resident Doctor Guide To The Investigative Process Following A Patient Safety Incident (PSI)

Introduction

The Patient Safety Incident Response Framework (PSIRF) is the national approach to managing patient safety incidents within NHS organisations. It replaces the previous Serious Incident Framework 2015 and focuses on a systems-based, proportionate response to patient safety incidents. The framework aims to enhance learning from incidents to improve patient care rather than solely attributing blame.

The key principles of the PSRIF are:

1. Compassionate engagement and involvement of those affected by patient safety incidents
2. Application of a range of system-based approaches to learning from these incidents
3. Considered and proportionate responses to incidents
4. Supportive oversight focused on strengthening response system functioning and improvement

Patient Safety Incidents and Their Reporting

A patient safety incident is any unintended or unexpected event that could have or did lead to harm for one or more patients. Under PSIRF, incidents are reported through the organisation's internal reporting system, such as **Datix or Ulysses**, ensuring prompt documentation of the incident's details. Reports should include:

1. Date, time, and location of the incident.
2. Description of the event.
3. People involved.
4. Immediate actions taken.
5. Any contributory factors.

It is essential to report incidents as soon as possible, ensuring that accurate and comprehensive information is captured.

Additional Sources of Reporting a Patient Safety Incident:
In addition to internal reporting systems, patient safety incidents can be identified through various other channels:

- **Patient Complaints:** Concerns raised by patients or their families may highlight potential safety issues requiring investigation.
- **Retrospective Case Reviews:** Audit and analysis of past medical records can reveal patterns of harm or near-misses.
- **Morbidity and Mortality (M&M) Meetings:** Regular reviews of adverse outcomes in anaesthesia practice can help identify systemic issues.

- **Safety Huddles and Team Debriefs:** Discussions following critical events can surface important safety concerns.
- **Whistleblowing:** Staff can report concerns anonymously through dedicated channels, such as the Freedom to Speak Up Guardian.
- **Incident Trend Analysis:** Data analytics and thematic reviews of multiple cases can highlight recurrent risks in anaesthesia practice.

Criteria for Investigation Under PSIRF

Not all reported patient safety incidents will lead to a full investigation. Instead, PSIRF uses a risk-based approach to determine the need for an investigation. The following factors influence whether an investigation is initiated:

1. **Severity of harm:** Incidents resulting in significant harm or death are more likely to be investigated.
2. **Recurrence risk:** Incidents that indicate a recurring system issue will be prioritised.
3. **Potential for learning:** Events that offer insight into systemic failures will be investigated.
4. **Regulatory and legal considerations:** Certain incidents, such as Never Events, must be reported to external bodies.

Investigation Process

A patient safety incident investigation (PSII) is undertaken when an incident or near-miss indicates significant patient safety risks and potential for new learning. Terms used before to describe these incidents were serious incident, serious untoward incident, near miss events or significant events.

When an investigation is initiated under PSIRF, it follows a structured approach:

1. **Initial Assessment (Within 5 Working Days)**
   - Incident is reviewed by patient safety leads and senior clinicians.
   - Decision made on the appropriate response (full investigation, thematic review, local review, etc.).

2. **Investigation Planning (Within 15 Working Days)**
   - Establishment of an investigation team.
   - Identification of key witnesses and data sources.
   - Agreement on the scope and methodology of the investigation.

3. **Data Collection and Analysis (Typically 6-8 Weeks)**

- Review of medical records, policies, and procedures.
- Staff interviews and debriefs.

- Analysis of contributing factors using recognised methodologies (e.g., Systems Engineering Initiative for Patient Safety (SEIPS) or Human Factors Analysis).

4. **Report Compilation and Review (Within 12 Weeks of Initiation)**
   - Summary of findings and contributory factors.
   - Recommendations for system improvements.
   - Development of an action plan to mitigate future risks.

External Agency Involvement

Certain incidents require external reporting and oversight. The following types of patient safety incidents typically require escalation to an external agency:

- **Serious Harm or Death:** Incidents resulting in significant patient harm or mortality, particularly those where systemic failures are suspected.
- **Never Events:** Defined by NHS England, these serious, preventable patient safety incidents must be reported.
- **Maternal and Neonatal Incidents:** Any significant adverse events occurring in maternity or neonatal care must be reported to MNSI.
- **Suspected Criminal Activity:** Any incident involving potential criminal behavior, such as neglect or malpractice, may require reporting to the police or regulatory bodies.
- **Regulatory Breaches:** Incidents indicating non-compliance with healthcare regulations require reporting to the CQC.
- **Whistleblowing Allegations:** Concerns raised by staff regarding unsafe practices that could compromise patient safety.
- **Coroner's Cases:** Any patient death where cause of death is unclear, unexpected, or related to medical intervention may require referral to the Coroner's Office.

Reporting Agencies and Their Roles

- **Health Services Safety Investigations Body (HSSIB):** Investigates complex or high-risk cases involving systemic patient safety risks with the aim of improving future healthcare delivery.
- **Care Quality Commission (CQC):** If the incident suggests regulatory breaches.
- **NHS England/NHS Improvement:** For mandated reporting, including Never Events.
- **Coroner's Office:** If the incident contributed to a patient's death, requiring an inquest.

- **Maternity and Newborn Safety Investigations (MNSI):** Conducts independent investigations into maternity and neonatal incidents to improve the quality and safety of maternity care.

Possible Outcomes of an Investigation

Following an investigation, outcomes may include:

- **System and process improvements:** Implementation of changes to clinical pathways, equipment, or protocols.
- **Training and education:** Enhanced learning sessions or competency checks for staff.
- **Policy revisions:** Updates to guidelines and procedures to prevent recurrence.
- **Staff support and learning:** Feedback sessions for involved staff with a focus on professional development rather than blame.
- **Regulatory compliance actions:** Where required, organisations may need to report their action plan to external agencies.
- **Referral to Professional Regulatory Bodies:** If concerns arise regarding an individual clinician's practice, the case may be referred to the General Medical Council (GMC) for professional review and potential fitness-to-practice hearings.
- **Police Involvement:** If an incident suggests potential criminal activity, such as gross negligence, fraud, or deliberate harm, it may be referred to the police for further investigation.
- **Legal Proceedings and Court Cases:** If negligence, malpractice, or serious misconduct is identified, the case may lead to civil litigation or criminal prosecution, depending on the nature of the incident. Families and patients may seek legal redress through the courts.
- **Coroner's Inquest:** If a patient death is involved, particularly if the cause of death is unclear, unexpected, or potentially due to medical intervention, the case may be subject to an inquest led by the Coroner's Office.
- **Employment Disciplinary Action:** In cases where misconduct or failure to follow safety protocols is identified, the healthcare professional may face internal disciplinary procedures, which could result in suspension, retraining, or dismissal. Following an investigation, outcomes may include:
- **System and process improvements:** Implementation of changes to clinical pathways, equipment, or protocols.
- **Training and education:** Enhanced learning sessions or competency checks for staff.
- **Policy revisions:** Updates to guidelines and procedures to prevent recurrence.
- **Staff support and learning:** Feedback sessions for involved staff with a focus on professional development rather than blame.
- **Regulatory compliance actions:** Where required, organisations may need to report their action plan to external agencies.

Conclusion

This document provides a broad overview of the patient safety incident process under PSIRF, outlining the key stages following an incident report.

It is intended as a general guide rather than an exhaustive explanation, as each case will evolve based on its specific circumstances.

More detailed information can be explored as needed, and resident doctors should seek guidance when required. Support is readily available through patient safety teams, senior colleagues, and professional bodies to assist in navigating these processes effectively.