The Leeds Teaching Hospitals NHS Trust

Patient safety incident response plan 2022/23

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NHS England and NHS Improvement

Contents

1. Purpose, scope, aims and objectives

1.1. Purpose

1.1.1. This Patient Safety Incident Response Plan (PSIRP) sets out how **Leeds 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.

1.2. Scope

1.2.1. There are many ways to respond to an incident. This document covers **responses conducted solely for the purpose of system learning and improvement.**

1.2.2. Patient safety incidents are any unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving healthcare.

1.2.3. 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

1.2.4. Responses covered in this Plan include:

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

1.2.5. 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, coroners 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.

1.2.6. 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

1.3. Aims and objectives

1.3.1. Table 1 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.

Table 1. Overarching aims and specific objectives of the Patient Safety Incident Response Framework

Overarching aims	Specific objectives
1. Improve the safety of the care we provide to our patients.	• Develop a climate that supports a just culture[1] and an effective learning response to patient safety incidents. • Respond to patient safety incidents purely from a patient safety perspective • Reduce the number of duplicate PSIIs into the same type of incident to reduce waste, enable more resource to be focused on effective learning and so enable more rigorous investigations that identify systemic contributory factors • Aggregate and confirm validity of

[1] A culture in which people are not punished for actions, omissions or decisions commensurate with their experience and training, but where gross negligence, wilful violations and destructive acts are not tolerated. Eurocontrol (2019) Just culture.

	learning and improvements by basing PSIIs on a small number of similar repeat incidents • Consider the safety issues that contribute to similar types of incident • Develop system improvement plans across aggregated incident response data to produce systems-based improvements • Better measurement of improvement initiatives based on learning from incident response
2. Improve the experience for patients, their families and carers wherever a patient safety incident or the need for a PSII is identified.	• Act on feedback from patients, families, carers and staff about their concerns with patient safety incident responses in the NHS. • Support and involve patients, families and carers in incident response, for better understanding of the issues and contributory factors, promoting Duty of Candour
3. Improve the use of valuable healthcare resources.	• Transfer the emphasis from quantity of investigations completed with an arbitrary deadline to a higher quality response to patient safety incidents, and the implementation of meaningful actions that lead to demonstrable change and improvement • Develop a local board-led, commissioner and integrated care system (ICS)/sustainability and transformation partnership (STP) assured architecture around response to patient safety incidents, which promotes ownership, accountability, rigour, expertise and efficacy
4. Improve the working environment for staff in relation to their experiences of	• Act on feedback from staff about their

patient safety incidents and investigations.	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

2. Resource analysis

2.1. Background

2.1.1. There are many ways an organisation can respond to a patient safety incident to learn and improve.

2.1.1. 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.

2.1.2. Different PSR techniques can be adopted depending on the intended aim and required outcome. All PSRs are conducted locally by our organisation.

2.1.3. There are four broad categories of PSRs (see Appendix B. Patient Safety Review Types for more information):

- Incident recovery
- Team reviews
- Systematic reviews
- Monitoring

2.1.4. 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.

2.1.5. While most PSIIs are conducted locally by our organisation, some are conducted independently. Independent PSIIs can be funded by our organisation or regionally/nationally.

2.1.6. Some types of patient safety incidents have been identified as national priorities and require a specific response. See Appendix A for a full list of national priorities, and what response is required to them.

2.1.7. 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.

2.1.8. Understanding our capacity to respond to incidents enables us to be strategic in proactively allocating resources to responding to patient safety incidents that are not included in the list of national priorities.

2.1.9. This section outlines our approach to understanding our available resources, it describes how we are ensuring our resources meet standards required in the National PSII standards and details how much resource we have

available to proactively plan how we will respond to key risks that fall outside national priorities.

2.1.10 How we defined our key risks is outlined in Section 3 - Risk Analysis.

2.2. Understanding patient safety incident response activity

2.2.1 A data review of LTHT Incident Management System (Datix) and other specialist teams information systems e.g. Safeguarding, was conducted for incidents reported between April 2018 and March 2021 to establish the number of investigations that took place within the categories listed below. The data includes events reported as part of the Trust complaints procedure and coroner activity.

Table 2. Average annual response activity for April 2018 to March 2021

Response type	Category	Average annual number of responses
National priorities requiring patient safety incident investigation	Patient safety incident investigation into Never Events	7
	Mortality Reviews (including Structured Judgement Reviews)	703
	Incidents **referred** (to HSIB/Regional independent investigation teams (RIITs)/Public Health England(PHE)) for independent PSII	10
	Deaths of persons with learning disabilities	25
	Adult Safeguarding incident reviews Safeguarding Provider Enquiry Reports Independent Enquiry Reports Serious Adult Case Reviews Domestic Homicide Reviews Joint Statutory Reviews Children's Safeguarding incident reviews Child Safeguarding Practice Reviews Domestic Homicide Reviews	 121 1 5 2 1 1 2 2

	Incidents in screening programmes	3
Patient safety incident investigations conducted locally	Coroner initiated patient safety incident investigations	0
	Patient/family/carer complaint-initiated patient safety incident investigations (red risk complaints)	26
	Level 3 Serious Incident investigations (Investigations under the current NHS Serious Incident Framework and reported to StEIS)	35
	Level 2 incident investigations utilising a systems framework for review	79
	Level 1 incident investigations utilising a systems framework for review	631
Patient safety reviews	Root Cause Analysis Reviews e.g. Pressure Ulcers, falls, Infection control, VTE, Blood transfusion	753
	'Stop The Line' reviews for pressure ulcer incidents	492

2.3. Patient safety incident response skills - gap analysis

2.3.1 A review of the resource and activity associated with the current Serious Incident Framework for the period 2018 - 2021 has been undertaken to determine how many PSIIs can be supported during 2022/23. This review was carried out alongside the NHS National standards for patient safety investigation to ensure that all future PSIIs are compliant with these standards.

2.3.2 In addition, a review has been completed to determine the current level of resource for Patient Safety Reviews, including pressure ulcers and falls. This supports planning of appropriate responses – using different review techniques – where PSII is not indicated.

2.3.3 This review has been led by the Serious Incident Investigations and Learning Manager with support and involvement from the Risk Management Team, Patient Safety & Quality Managers, Corporate Nursing Directorate, the Complaints Team and Operational CSUs.

2.3.14 In order to meet the requirements of the new NHS National Standards for Patient Safety Investigation we will:

- Assign an appropriately trained member of the Executive Team to oversee delivery of the PSII standards and support the sign off of all PSIIs.
- Provide Being Open training for all board members.
- Provide access to update training for current staff who provide the incident investigation oversight function on use of updated analytical tools, use of improvement science approaches and utilization of the national report template.
- Provide access to update training for existing investigators or investigation teams/staff in specific areas. This will include:
    - Application of updated analytical tools to support PSII
    - Training in identifying and addressing unconscious bias
    - Using Quality Improvement (QI) methodology and improvement science approaches
    - Report writing and use of the national PSII report template
- Identify an appropriate training provider for training new investigators of PSII's in the Trust to the standard required by PSIRF(e.g. minimum of two days). We will use a targeted approach to identify a number of investigators from a range of professional backgrounds i.e. medical, nursing, AHP, psychology.
- Produce new documentation for patients, families and staff members involved in patient safety incidents and ensure they are available on a public-facing area of our website
- Work with senior nursing staff to review the existing tools for Patient Safety Reviews (PSRs) to ensure they reflect current practice and analytical tools for the identification of all causal factors.
- Negotiate time in job plans for a core group of senior clinical staff to undertake PSII investigations every year.
- Modify existing internal training courses for staff who are required to undertake Patient Safety Reviews to include:

- Application of updated analytical tools
- Principles of PSIRF
- Using QI methodology and improvement science approaches

2.4. Resources for proactive planning

2.4.1 The current structure relies heavily on senior clinicians, employed by the trust but independent of the clinical area where the incident occurred, undertaking reviews in their allotted management time. The Risk Management Team do not have any line management responsibilities with regards investigators and thus limited influence over how investigators prioritise their time for investigations. Investigation reports have executive level sign off.

2.4.2 Resource, restructuring and training is needed to meet the requirements of the patient safety incident investigation standards and the PSIRF.

2.4.3 Senior management level planning to address the above is underway and expected to take twelve to 24 months to rollout and fully embed. The planning and restructuring exercise will:

- Enhance patient safety management and leadership support
- Enhance resource and skills to conduct alternative patient safety reviews
- Enhance patient safety investigation with a lead and supporting investigator, subject matter experts, administrative support, patient and family liaison, and executive level oversight and support
- Enable each investigator to:
  - receive systems-based patient safety incident investigation training.
  - be dedicated to one PSII at any time

Table 3. Proactive response planning: overview of estimated resource allocation for patient safety incidents that fall outside national priorities

Response type	Category	Total number of responses	Hours
PSII	Locally defined PSIIs	16	**Minimum 60 hours per investigation for:** • 1 lead investigator • 1 support investigator **Up to 30 hours per investigation for:** • subject matter expertise • family liaison

			Plus **Up to 30 hours per investigation for:** • investigation oversight and support • administration support • interview and statement time of staff involved in the incident board committee approval and sign off
	Unanticipated incidents	7	**Minimum 60 hours per investigation for:** • 1 lead investigator • 1 support investigator **Up to 30 hours per investigation for:** • subject matter expertise • family liaison ***Plus*** **Up to 30 hours per investigation for:** • investigation oversight and support • administration support • interview and statement time of staff involved in the incident board committee approval and sign off
PSRs	All types	2,016	Maximum eighteen hours per response review

3. Risk analysis

3.1. Risk stakeholders and data inputs

3.1.1 The patient safety incident risks for this organisation have been profiled using organisational data between the years 2018 to 2021 from;

- patient safety incident reports
- complaints
- legal claims
- Coroners findings including prevention of future death notifications and cause for concern notifications
- mortality thematic reviews, and;
- staff survey results.

3.1.2 Incident types, recurrence and severity were explored, together with careful consideration of safety improvement opportunities and knowledge, together with plans and interventions already in place.

3.1.3 A range of staff, including leads for each of the above data collection systems, were consulted and a prioritised list of incidents for the year ahead was agreed.

3.1.4 The review also highlighted areas which required the collation of further intelligence to inform subsequent plans.

3.1.5 In the years ahead, the trust will seek data and insight from stakeholders to inform potential future categories for local patient safety incident investigation and system improvement.

3.1.6 Key stakeholders have been consulted throughout the process to agree the identified priorities and LTHT Patient Safety Incident Response Plan including:

- Commissioners
- Members of staff
- Trust Board and delegated committees
- Members of the Partner Programme
- Patients, families and carers
- NHS England/Improvement national patient safety team

3.2. Local patient safety risk profile

3.2.1 Table 4 lists the local patient safety risks that fall within the national priority areas (See Appendix A for more details).

Table 4. Local patient safety risks that fall within national priorities

	National priority	Incident type	Specialty
1	Never Events	All	All
2	Learning from Deaths	Where a patient death is thought more likely than not to be due to problems in care	All
3	Safeguarding Incidents	All	All
4	Deaths of persons with learning disabilities	All	All
5	Incidents in Screening Programmes	All	All

Table 5. Criteria for defining top local patient safety risks

Criteria	Considerations
Potential for harm	• People: physical, psychological, loss of trust (patients, family, caregivers) • Service delivery: impact on quality and delivery of healthcare services; impact on capacity • Public confidence: including political attention and media coverage
Likelihood of occurrence	• Persistence of the risk • Frequency • Potential to escalate

3.2.2 The current local top ten patient safety risks for LTHT as identified via the analysis described in section 3.1 are presented in table 6 below.

Table 6. Top local patient safety risks

	Incident type	Description	Specialty	Response Type
1	Pressure Ulcers & Tissue Damage	All categories of pressure ulcer and tissue damage as a result of hospital stay	All	Stop The Line and RCA See also Table 8 for thematic review
2	Slip, Trip & Fall	Patient falls that lead to injury	All	Stop The Line and RCA
3	Medication	Prescribing incidents concerning Enoxaparin occurring at LGI	All	Patient Safety Incident Investigation
4	Appointments, Admission, Transfer & Discharge	Incidents regarding issues with movement of patients particularly delays to follow-up	All	After Action Review
5	Obstetrics	Postpartum Hemorrhage in excess of 1.5L requiring return to theatre or activation of major hemorrhage protocol	Women's CSU	Patient Safety Incident Investigation
6	Diagnostic Services	Incidents reported from our Radiology service with regards to imaging of patients and sharing of results	Radiology CSU	After Action Review
7	Treatment	Delays to treat the deteriorating patient	All	Thematic review of failure to recognize the deteriorating patient (review of 20 incidents)
8	Communication	Enhanced care plans which are ineffective or not followed to prevent harm to patients including Mental Health (excluding patient falls)	All	Patient Safety Incident Investigation
9	Infection	All instances of healthcare acquired infections and issues with infection control procedures	All	HCAI RCA, Outbreak reviews
10	Health Records, Consent & Confidentiality	Incidents relating to health records and consent issues	All	Case Note Review

3.3. Locally defined responses

Table 7. Criteria for selecting risks for PSII response

Criteria	Considerations
Potential for learning and improvement	• Increased knowledge: potential to generate new information, novel insights, or bridge a gap in current understanding • Likelihood of influencing: healthcare systems, professional practice, safety culture. • Feasibility: practicality of conducting an appropriately rigorous PSII • Value: extent of overlap with other improvement work[2]; adequacy of past actions
Systemic risk	• Complexity of interactions between different parts of the healthcare system

3.3.1 Based on the analysis and selection criteria described above, local priorities for PSII have been set by this organisation for the period 01 January 2022 to 31 December 2022.

3.3.2 The priorities have been agreed with our commissioning organisation, NHS Leeds Clinical Commissioning Group, and the national patient safety team at NHS England and Improvement. Priorities are listed in table 8 below.

3.3.3 Each PSII will be conducted separately, in full and to a high standard, by a team whose lead investigator is appropriately trained (see PSIRF Part C: governance arrangements for training requirements).

3.3.4 Findings from investigations conducted from the same narrowly specified incident type will be analysed for commonalities and opportunities for system improvement.

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Table 8. Planned Patient Safety Incident Investigation responses for top local patient safety risks

	Incident type	Description	Response type	Number of responses (if PSII)
1	Pressure Ulcer	Thematic review of deterioration of MASD to category 2 pressure ulcer (review of 20 incidents)	Thematic review	--
2	Medication	Prescribing incidents concerning Enoxaparin occurring at LGI	PSII	4
3	Obstetric Incident	Postpartum Hemorrhage in excess of 1.5L requiring transfer to theatre or activation of major hemorrhage protocol	PSII	4
4	Treatment	Thematic review of failure to recognize the deteriorating patient (review of 20 incidents)	Thematic review	--
5	Communication	Enhanced care plans which are ineffective or not followed to prevent harm to patients including Mental Health (excluding patient falls)	PSII	6

3.4. Approach to local PSII selection

3.4.1 The LTHT Datix incident reporting system will be utilised to alert the Trust Incident Management Team to when incidents are recorded matching the types identified for PSII.

Incident Type	Description	Sampling technique
Pressure Ulcers	• Thematic review of deterioration of MASD to category 2 pressure ulcer (review of 20 incidents) • Currently monitored by Pressure Ulcer Improvement Collaborative and Tissue Viability Team	Five incidents meeting the necessary criteria, chosen from a spread across clinical specialties, from each of the preceding four calendar quarters. Quarter 1

Medication	• Prescribing incidents concerning Enoxaparin occurring at Leeds General Infirmary • Currently monitored by Medicines Safety Group	One incident per calendar quarter. • 1 severe harm • 2 moderate harm • 1 no/low ham
Obstetrics / Maternity	• Postpartum Hemorrhage in excess of 1.5L requiring return to theatre or activation of major hemorrhage protocol • Currently monitored by Obstetric Improvement Collaborative	One incident per calendar quarter from Women's CSU. • 1 severe harm • 2 moderate harm • 1 no/low harm
Treatment	• Thematic review of failure to recognize the deteriorating patient (review of 20 incidents) • Currently monitored by the Deteriorating Patient Improvement Collaborative	Five incidents meeting the necessary criteria, chosen from a spread across clinical specialties and harm levels, from each of the preceding four quarters. Quarter 2
Communication	• Enhanced care plans which are ineffective or not followed to prevent harm to patients including Mental Health (excluding patient falls) • Currently monitored by the De-escalation Improvement Collaborative	One incident every two calendar months across a range of harm levels and clinical specialties • 2 severe harm • 2 moderate harm • 2 no/low harm

3.5. Timescales for PSIIs

3.5.1. 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.

3.5.2. PSIIs will ordinarily be completed within one to three months of their start date.

3.5.3. In exceptional circumstances, a longer timeframe may be required for completion of a PSII. In this case, any extended timeframe will be agreed

between the Leeds Teaching Hospitals NHS Trust and the patient/family/carer.

3.5.4. No PSII should take longer than six months. 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.

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

4. Aggregating learning from incident responses

4.1. Findings from PSIIs and PSRs provide key insights and learning opportunities, but they are not the end of the story.

4.2. Findings will be translated into effective improvement design and implementation.

4.3. Quality Improvement Collaboratives and specialist working groups will oversee collation and execution of System Improvement Plans (see section 9).

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

4.5. All other recommendation development will consider aggregated findings across all or a subset of responses into a single risk.

4.6. To aggregate learning, findings from each individual response linked to a specific risk will be collated to identify common contributory factors and any common interconnections or associations upon which effective improvements can be designed. Associated recommendations and monitoring arrangements will be summarised in a System Improvement Plan.

4.7. Consideration will be given to the timeframe taken to complete a System Improvement Plan and the impact of extended timescales on those involved in the incident.

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

5. Roles and responsibilities

5.1 This organisation describes 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

5.2 All Staff

All staff have a responsibility to highlight any risk issues which would warrant further investigation. 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.

5.3 Incident Reviewers

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.

5.4 **Being Open Leads**

- Responsible for ensuring the organisation's legal duty of candour is discharged for appropriate incidents.
- Identify those affected by patient safety incidents and their support needs by being the 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.
- Work with the patient safety team and other services to prepare and inform the development of different support services.

5.5 **CSU Clinical Directors**

Clinical Directors have a responsibility to:

- Encourage the reporting of all patient safety incidents and ensure all staff in their department/division/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.
- Ensure that they and their staff periodically review the PSIRF and the organisation's PSIRP to check that expectations are clearly understood.
- 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).

5.6 **Patient Safety Partner**

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 PSRIF Programme Board, Quality Improvement Steering Group, QI Collaboratives 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 8.

5.7 **Risk Management Department**

- The senior Risk Management Team will meet on a weekly basis to review reported incidents and ensure that PSIIs are undertaken for all incidents that require this level of response (as directed by the organisation's PSIRP).

- Develop and maintain the local risk management systems and relevant incident reporting systems (including StEIS and its replacement once introduced) to support the recording and sharing of patient safety incidents and monitoring of incident response processes.
- Leads the development and review of the organisation's PSIRP.
- Ensures the organisation has procedures that support the management of patient safety incidents in line with the organisation's PSIRP (including convening review and PSII teams as required and appointing trained named contacts to support those affected).
- Establishes procedures to monitor/review PSII progress and the delivery of improvements.
- Works 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.
- Supports and advises 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.

5.8 **Patient safety incident investigators**

- Patient safety incident investigators will have been trained over a minimum of two days in systems-based PSII.
- Ensure that PSIIs are undertaken in-line with the national PSII standards.
- Ensure that they are competent to undertake the PSII assigned to them and if not, request it is reassigned.
- Undertake PSIIs and PSII-related duties in line with latest national guidance and training.
- Provide liaison with patients and families subject to a patient safety incident investigation

5.9 **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). Patient safety reviewers 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.

5.10 **Medical Examiner**

The medical examiner's key role is to:

- provide greater safeguards for the public by ensuring proper scrutiny of all non-coronial deaths
- ensure the appropriate direction of deaths to the coroner
- provide a better service for the bereaved and an opportunity for them to raise any concerns to a doctor not involved in the care of the deceased
- improve the quality of death certification
- improve the quality of mortality data

Whilst medical examiners are NHS employees, they have separate professional accountability and their independence, which is vital to the scrutiny they provide, is overseen by the national medical examiner.

Medical examiners scrutinise all deaths to:

- agree the proposed medical cause of death and ensure the overall accuracy of the medical certification of the cause of death
- identify problems in treatment or care and, as necessary, report to the trust's clinical governance process
- discuss the cause of death with the bereaved and listen to any concerns
- ensure the referral of deaths to the coroner as required by the law; this includes deaths where there are concerns that failure in care contributed to death or where the bereaved raise significant concerns about the care provided to their relative
- liaise with, and assist, the coroner with medical information
- educate and provide advice to other clinicians about death registration and the coronial process

5.10 **Quality & Safety Assurance Group (QSAG)**

The Quality and Safety Assurance Group (QSAG) has responsibility for reviewing the incident management function. QSAG reports to the Quality Assurance Committee and provides assurance on reports/evidence received. Where there are concerns about the robustness of actions identified, or the progress on implementation, the Chair of QSAG will seek assurances from CSUs that risks are being adequately addressed. Where there are remaining concerns these will be escalated to the Quality Assurance Committee.

5.11 **Quality Assurance Committee (QAC)**

The Quality Assurance Committee has responsibility for reviewing completed reports and system improvement plans for effectiveness. The Committee will receive a report at each meeting of the organisation's progress against this PSIRP.

5.12 **Chief Medical Officer - Executive lead for supporting and overseeing implementation of the PSIRF**

The Chief Medical Officer has delegated responsibility for Risk Management and has the organisational lead for ensuring that there are adequate arrangements in place for patient safety incident investigations and reviews and for monitoring, reviewing and updating these arrangements. In addition, that there is adequate assurance to demonstrate learning is being shared and changes to practice as a result of patient safety incident investigations and reviews are implemented across the Trust.

5.13 **Chief Executive**

The Chief Executive is responsible for the provision of appropriate policies and procedures for all aspects of health and safety (Health and Safety at Work Act 1974). As part of this role the Chief Executive has overall responsibility for ensuring there are effective risk management systems and processes in the Trust to enable the organisation to meet its statutory obligations relating to the health and safety of patients, staff and visitors. The Chief Executive is ultimately responsible for ensuring that all investigations are dealt with effectively and appropriately.

5.14 **Trust Board**

The Trust Board has a responsibility to ensure that it receives assurance that this plan is being implemented, that lessons are being learnt, and areas of vulnerability are improving. This will be achieved through reporting processes as well as receiving assurance via the Quality Assurance Committee and the Audit 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.

6. Patient Safety Incident reporting arrangements

6.1 Local reporting of patient safety incidents (PSIs)

6.1.1 The full details of the Patient Safety Incident reporting arrangements are detailed within the Trust Incident Reporting Procedure (PR080). The procedure provides a structure for reporting incidents at Leeds Teaching Hospitals NHS Trust, including external notification requirements.

6.1.2 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.

6.1.3 A record of the incident or near miss should be contemporaneoulsy and objectively reported in the patient's clinical records.

6.1.4 All incidents reported as causing moderate, severe, catastrophic harm will be discussed at the Trust weekly risk management meeting to determine if further information is required and advise on type of investigation required.

6.1.5 Incidents requiring consideration as a potential patient safety incident investigation (PSII) will be reviewed and discussed at the Trust weekly quality meeting to determine type of investigation required. Incidents which meet the criteria for a PSII will be reported onto the Strategic Executive Information System (StEIS) or its successor system.

6.2 National reporting of patient safety incidents (PSIs)

6.2.1 The trust undertakes its external reporting and notification requirements in line with national guidance available at appendix 6 of the patient safety incident response framework (PSIRF - 2020). NHS England » Patient Safety Incident Response Framework. Some of the key national reporting activities are:

6.2.2 The trust currently reports patient safety incidents to the national reporting and learning system (NRLS) through weekly data uploads.

6.2.3 In line with the PSIRF, reporting incidents previously defined as ‘serious incidents’ to the national ‘StEIS’ database will cease and StEIS and, at a date to be determined nationally, the replacement system will be used to report and monitor all patient safety incidents including those identified as requiring a patient safety incident investigation.

6.2.4 Management and monitoring of individual investigations, previously the responsibility of the local commissioning organisation, will be the responsibility of the Trust Board.

6.2.5 Reporting PSIs and PSIIs to the new ‘learning from patent safety events’ system will follow when this replaces the NRLS and further guidance is issued.

6.2.6 Statutory Care Quality Commission notification requirements will be met by reporting incidents to the national reporting and learning system (NRLS) and its successor system. One notable exception is the death of a patient detained under the Mental Health Act which, in line with national guidance, will be reported directly to the CQC.

7. Procedures to support patients, families and carers affected by PSIs

7.1 Patient and Family Liaison

7.1.1 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. The Being Open Procedure (PR081 - 346) sets out the responsibilities of 'Being Open Leads'

7.1.2 'Being Open Leads' are senior members of the clinical and nursing teams nominated to be the key contact for communication with patients, families and carers during a patient safety incident review.

7.1.3 It is the Being Open Lead who 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.

7.1.4 For the Patient Safety Incident Investigations identified in this PSIRP (Table 8) family liaison will be undertaken directly by the PSII team. For all other types of Patient Safety Review family liaison it is the responsibility of the nominated Being Open Lead.

7.2 Local support

7.2.1 The Patient Advice and Liaison Service at Leeds Teaching Hospitals NHS Trust is a free and confidential service to support patients and their families

7.2.2 The PALS team act independently of clinical teams when managing patient and family concerns. The PALS service will liaise with staff, managers and, where appropriate, with other relevant organisations to negotiate immediate and prompt solutions.

Leeds Teaching Hospitals Patient Advice and Liaison Service (PALS)

7.2.3 The trust is firmly committed to continuously improving the care and the services provided. There will be occasions when actions do not meet the expectations of patients, service users, family members or carers. On these occasions the trust aims to achieve a satisfactory resolution to concerns, comments and complaints and to learn from them to reduce the likelihood of recurrence.

7.2.4 Trust staff are empowered to resolve concerns immediately and informally, where this is possible. People with a concern, comment, complaint or compliment about care or any aspect of the trust services are encouraged to speak with a member of the care team.

7.2.5 Should the care team be unable to resolve the concern then the patient advice and liaison service can provide support and advice to patients, families, carers and friends.

PALS can help and support with:

- advice and information
- comments and suggestions
- compliments and thanks
- informal complaints
- advice about how to make a formal complaint

If the PALS team is unable to answer the questions raised, the team will provide advice in terms of organisations which can be approached to assist.

- telephone: 0113 2066261
- textphone: 07468753025 (if you are D/deaf or speech impaired)
- email: patientexperience.leedsth@nhs.net

7.3 National sources of support

- National guidance for NHS trusts engaging with bereaved families

- 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 Leeds provides information to help make a complaint, including sample letters.

  Address: Healthwatch Leeds. Ground Floor, The Old Fire Station, Gipton Approach, Gipton, Leeds, LS9 6NL6
  Tel: 0113 898 0035
  Textphone: 07551 122289
  Email: info@healthwatchleeds.co.uk

- 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.

8. Procedures to support staff affected by PSIs

8.1 The national and local arrangements for supporting staff following Patient Safety Incidents

8.1.1 Leeds Teaching Hospitals NHS Trust 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 in to 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.

8.1.2 Trust Risk Management Team - The Trust Risk Management Team 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.

8.1.3 Psychological Interventions for Trust Staff - There are a variety of psychological interventions available for staff at LTHT. Contact details for all these services are detailed within a centrally updated list accessed from this webpage.

8.1.4 Occupational Health Service

8.1.5 Schwartz Rounds - Schwartz Rounds provide a structured forum and safe space where staff come together to discuss the emotional and social impact of working in healthcare. You can join the conversation, share your experience or simply listen to their stories. Sessions are themed and a place can be booked by emailing leedsth-tr.OLCourseBookings@nhs.net.

8.1.6 Freedom To Speak Up Guardian - A confidential service for staff if they have concerns about the organisation's response to a patient safety incident.

8.1.7 Second Victim - A website resource for healthcare staff and managers involved in patient safety incidents.

8.2 Support from Patient Safety Incident Investigators

8.2.1 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 or a one-to-one conversation with the incident review team.

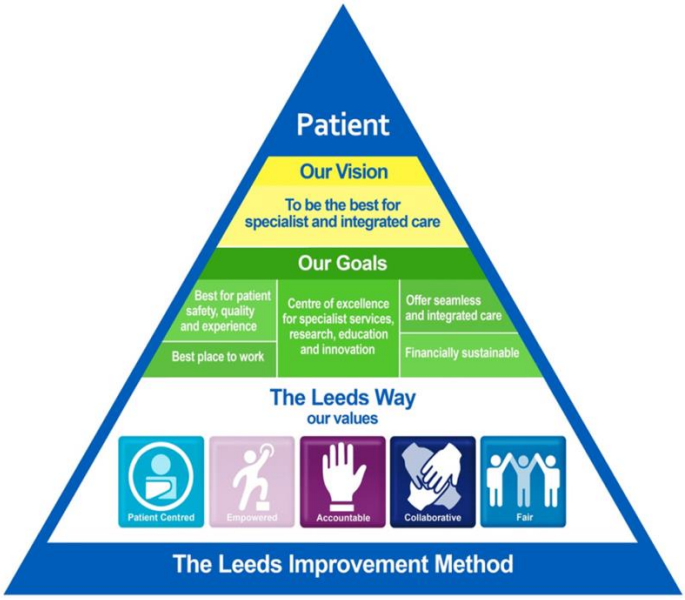
8.2.2 Review teams will agree with staff the timescales for feedback of progress and findings in accordance with the type of review method being utilised.

8.2.3 All contact with staff will involve the collection of their account of the events and also their views and opinions on how systems can be improved.

9. Mechanisms to develop and support improvements following PSIIs

9.1 The Leeds Improvement Method is the way we do business across the Trust, constantly evaluating our work processes and making changes to improve services for patients and the working environment for staff. The Strategic triangle below shows how our vision, values and goals link together to enable us to provide the best possible care for our patients. All of this is underpinned by the Leeds Improvement Method, spreading a consistent approach to continuous improvement or (Kaizen).

9.2 Our processes for improvement are described in our Quality Improvement Strategy and Clinical Quality Strategy. The recommendations from our Patient Safety Investigations and Patient Safety Reviews will flow through these processes linking them in directly to the Trusts Quality Improvement work.



9.3 At the conclusion of a Patient Safety Incident Investigation (PSII) the final report will be submitted to the Quality & Safety Assurance Group for discussion and agreement of the system improvement plan. The improvement plan will be agreed in collaboration with existing Trust quality improvement frameworks including the Quality Improvement Steering Group, Kaisen Promotion Office (Trust improvement methodology team) and the Quality Improvement Collaboratives. The Trust-wide Lessons Learned Group will also be informed to facilitate cascade of relevant information across the organisation through various mediums including the lessons learned bulletin, quality and safety matters bulletins and video.

9.4 Improvement plans will be shared with the relevant Quality Improvement Collaborative to enable delivery of actions, monitoring and evaluation of improvement outcomes. The Quality Improvement Collaboratives provide update reports on progress to the Quality Improvement Steering Group.

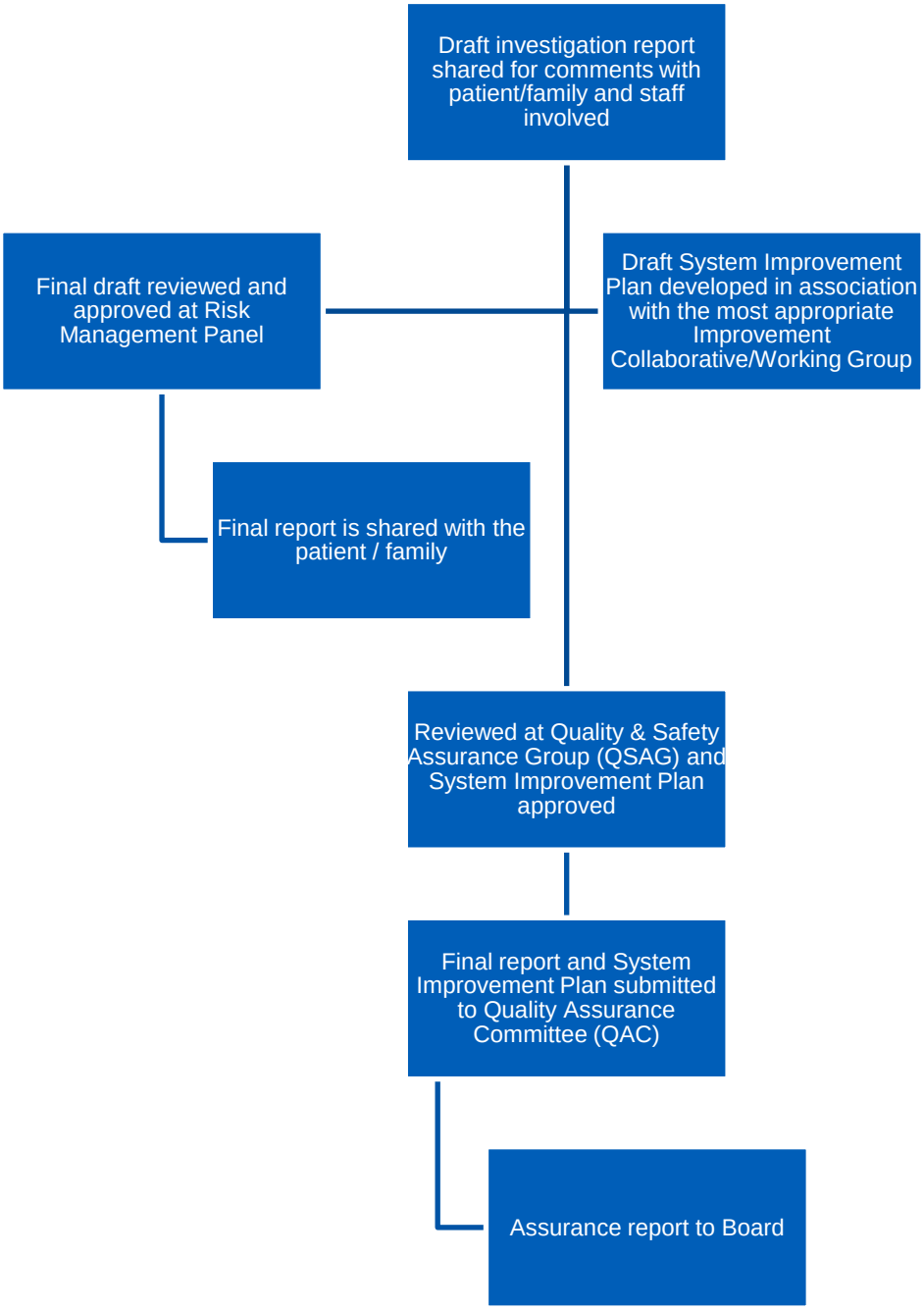
9.5 The Quality Improvement Steering Group will have oversight and undertake monitoring of all improvement plans created following a PSII. The Quality Improvement Steering Group reports to the Trust Quality, Safety and Assurance Group. The group promote a positive culture of continuous learning and improvement using Leeds Improvement Methodology to facilitate Trust-wide learning and improvement.

9.6 Monitoring through the use of 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.

9.7 Current Improvement Collaboratives:

- Care of patients with Acute Kidney Injury (AKI)
- Care of Patients with Sepsis
- Deteriorating Patients
- Reduction in the Incidence of Falls
- Reduction in the Number of Pressure Ulcers
- Scaling up Improvement: Safety Huddles
- Reduction in Harm - Maternity Care
- Improving Care for Patients with Parkinson's
- Reducing HCAI
- De-escalation

Organisation structure for the sign-off of reports and improvement plans



10. Monitoring outcomes of PSIIs and PSRs

10.1. Regular update reports will be created for Committee and Board 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 against the PSIRP
- 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

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

Leeds Teaching Hospitals Patient Liaison and Advice Service.

11.2 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 a services provided by Leeds Teaching Hospitals will be taken seriously and will be managed in a way that reflects the Leeds Way Values (patient-centred, fair, collaborative, accountable and empowering).

11.2 Leeds Teaching Hospitals NHS Trust encourages service users to raise any concerns they may have immediately and at the time they occur by speaking to a member of staff. The Trust's complaints policy focuses specifically on those concerns or complaints that require management through the Patient Advice and Liaison Service (PALS) and the Complaints Team.

11.3 The Trust's Complaint Policy (PC086) sets out the principles and processes involved when any person wishes to raise a concern or complaint. This includes the need for the Trust to provide an apology and an opportunity for learning when complaints are responded to, where this is relevant.

11.4 If you wish to raise a concern or complaint, please contact the PALS team for advice in one of the following ways:

- telephone: 0113 2066261
- textphone: 07468753025 (if you are D/deaf or speech impaired)
- email: patientexperience.leedsth@nhs.net
- download a complaint form

11.5 The PALS team will support you to decide how the issues you are raising will be managed

12. Appendix A: National priorities

12.1. National priorities requiring a response

12.1.1. National priorities are set by the PSIRF and other national initiatives for the period 2020 to 2021. These priorities require a PSII to be conducted by the organisation.

12.1.2. 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. Further detail is provided below.

Incidents that meet the criteria set in the Never Events list 2018

12.1.3. 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;

12.1.4. 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 LfD plan or following reported concerns about care or service delivery.

12.1.5. 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 Health Act.

12.1.6. 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.

12.2. National priorities to be referred to another team

12.2.1. The national priorities for referral to other bodies or teams for review or PSII (described in the PSIRF) for the period 2020 to 2021 are as follows, further details are provided 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:

12.2.2. Incidents which meet the 'Each Baby Counts' and maternal deaths criteria detailed in Appendix 4 of the PSIRF must be referred to the Healthcare Safety Investigation Branch (HSIB) for investigation (https://www.hsib.org.uk/maternity/)

12.2.3. 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

12.2.4. 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

12.2.5. These must be discussed with the relevant NHS England and NHS Improvement regional independent investigation team (RIIT)

Child deaths

12.2.6. For further information, see: *Child death review statutory and operational guidance*

12.2.7. Incidents must be referred to child death panels for investigation

Deaths of persons with learning disabilities

12.2.8. Incidents must be reported and reviewed in line with the Learning Disabilities Mortality Review (LeDeR) programme

Safeguarding incidents:

12.2.9. 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

12.2.10. For further information see: **incidents in screening programmes**

12.2.11. 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

12.2.12. 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.

13. Appendix B: Patient Safety Reviews

PSR type	Methods	Objective
Incident recovery Immediate measures taken to: • Address serious discomfort, injury or threat to life • Respond to concerns raised by the affected patient, family, or carer • Determine the likelihood and severity of an identified risk	Immediate actions	To take urgent measures to address serious and imminent: • discomfort, injury, or threat to life • damage to equipment or the environment.
	Risk assessment	To assess the likelihood and severity of identified hazards in order that risks can be determined, prioritised, and control measures applied
	Timeline mapping	To provide a detailed documentary account of what happened in the style of a 'chronology'
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	Case	To determine whether there were any problems with

To determine: • The circumstances and care leading up to and surrounding the incident • Whether there were any problems with the care provided to the patient	record/note review (e.g., Structured Judgement Review)	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.)
	Mortality 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 reviews	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 Inquiry	

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This publication can be made available in a number of other formats on request.

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