Patient safety incident response plan 2021/23

London Ambulance Service NHS Trust

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 London Ambulance Service NHS Trust (the Trust) will seek to learn from patient safety incidents reported by staff and patients, their families and carers as part of our work to continually improve the quality and safety of the care we provide.

1.1.2 This plan will help us measurably improve the efficacy of our local patient safety incident investigations (PSIIs) by:

a. Refocusing PSII towards a systems approach[1] and the rigorous identification of interconnected causal factors and systems issues.

b. Focusing on addressing these causal factors and the use of improvement science[2] to prevent or continuously and measurably reduce repeat patient safety risks and incidents.

c. Transferring the emphasis from the quantity to the quality of PSIIs such that it increases our stakeholders' (notably patients, families, carers and staff) confidence in the improvement of patient safety through learning from incidents.

d. Demonstrating the added value from the above approach.

1.2 Scope

1.2.1 A PSIRP is a requirement of each provider or group/network of providers delivering NHS-funded care.

1.2.2 This document should be read alongside the introductory Patient Safety Incident Response Framework (PSIRF) 2020, which sets out the requirement for this plan to be developed.

[1] The approach is broken down into units to make it easier to understand the complexity, interactive nature and interdependence of the various external and internal factors.

[2] "Improvement science is about finding out how to improve and make changes in the most effective way. It is about systematically examining the methods and factors that best work to facilitate quality improvement." Health Foundation (2011) https://www.health.org.uk/publications/improvement-science.

1.2.3 We have developed the planning aspects of this PSIRP with the assistance and approval of our local commissioner(s) including the North West London Clinical Commissioning Group and the North East London Clinical Commissioning Group covering our NEL Integrated Urgent Care Service. The involvement with these key groups/individuals was to also enable cascade of the development through established communication channels to all STPs/ICS across London.

1.2.4 The aim of this approach is to continually improve. As such this document will be reviewed annually and approved by the Trust and local commissioners.

1.3 Strategic aims

1.3.1 Improve the safety of the care we provide to our patients, and improve our patients', their families' and carers' experience of it.

1.3.2 Further develop systems of care to continually improve their quality and efficiency.

1.3.3 Improve the experience for patients, their families and carers wherever a patient safety incident or the need for a PSII is identified.

1.3.4 Improve the use of valuable healthcare resources.

1.3.5 Improve the working environment for staff in relation to their experiences of patient safety incidents and investigations.

1.4 Strategic objectives

1.4.1 Act on feedback from patients, families, carers and staff about the current problems with patient safety incident response and PSIIs in the NHS.

1.4.2 Develop a climate that supports a just culture[3] and an effective learning response to patient safety incidents.

1.4.3 Develop a local board-led with commissioners and integrated care system (ICS)/sustainability and transformation partnership (STP) assured architecture

[3] 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.

around PSII and alternative responses to patient safety incidents, which promotes ownership, rigour, expertise and efficacy.

1.4.4 Make more effective use of current resources by transferring the emphasis from the quantity of investigations to a higher quality, more proportionate response to patient safety incidents, as a whole. The aim is to:

- make PSIIs more rigorous and, with this, identify causal factors and system-based improvements
- engage patients, families, carers and staff in PSII and other responses to incidents, for better understanding of the issues and causal factors
- develop and implement improvements more effectively
- explore means of effective and sustainable spread of improvements which have proved demonstrably effective locally.

2. Situational analysis – national

2.1 Many millions of people are treated safely and successfully each year by the NHS in England, but evidence tells us that in complex healthcare systems things will and do go wrong, no matter how dedicated and professional the staff.

2.2 When things go wrong, patients are at risk of harm and many others may be affected. The emotional and physical consequences for patients and their families can be devastating. For the staff involved, incidents can be distressing and members of the clinical teams to which they belong can become demoralised and disaffected. Safety incidents also incur costs through lost time, additional treatment and litigation. Overwhelmingly these incidents are caused by system design issues, not mistakes by individuals.

2.3 Historically, the NHS has required organisations to investigate each incident report that meets a certain outcome threshold or 'trigger list'. When this approach was developed it was not clear that:

a. Luck often determines whether an undesired circumstance translates into a near miss or a severe harm incident.[4] As a result, focusing most patient safety investigation efforts on incidents with the most severe outcome does not necessarily provide the most effective route to 'organisational learning'.[5]

b. There is no clear need to investigate every incident report to identify the common causes and improvement actions required to reduce the risk of similar incidents occurring. To emphasise this point, it has been highlighted that in-depth analysis of a small number of incidents brings greater dividends than a cursory examination of a large number.[20]

2.4 An increased openness to report patient safety issues has also led to an ever-growing number of incidents being referred for investigation. NHS organisations are now struggling to meet the number of requests for investigation into similar types of incident with the level of rigour and quality required. Available resources have

[4] Health and Safety Executive (2014) Investigating accidents and incidents: A workbook for employers, unions, safety representatives and safety professionals.

[5] Vincent C, Adams S, Chapman A et al (1999) *A protocol for the investigation and analysis of clinical incidents*.

become inundated by the investigation process itself – leaving little capacity to carry out the very safety improvement work the NHS originally set out to achieve.[6,7,8,9,10]

2.5 In addition, the remit for patient safety incident investigation (PSII) has become unhelpfully broad and mixed over time. This originates from an attempt to be more efficient by addressing the many and varied needs of different types of investigation in a single approach. Sadly, the very nature and needs of some types of investigation (e.g. professional conduct or fitness to practise; establishing liability or avoidability; or establishing cause of death) have frustrated the original patient safety aim and blocked the system learning the NHS set out to achieve.

2.6 Many other high-profile organisations now identify and describe their rationale for deciding which incidents to investigate from a learning and improvement perspective. While some industry leaders describe taking a risk-based approach to safety investigation (e.g. the Rail Accident Investigation Branch and Air Transport Safety Board), others list the parameters that help their decision-making processes (the police, Parliamentary Health Service Ombudsman and Healthcare Safety Investigation Branch).

2.7 We need to remove the barriers in healthcare that have frustrated the success of learning and improvement following a PSII (eg mixed investigation remits, lack of dedicated time, limited investigation skills). We also need to increase the opportunity for continuous improvement by:

a. improving the quality of future PSIIs
b. conducting PSIIs purely from a patient safety perspective
c. reducing the number of PSIIs into the same type of incident
d. aggregating and confirming the validity of learning and improvements by basing PSIIs on a small number of similar repeat incidents.

6 Public Administration Select Committee (2015) *Investigating clinical incidents in the NHS. Sixth report of session 2014–15*.
7 Parliamentary and Health Service Ombudsman (2015) *A review into the quality of NHS complaints investigations where serious or avoidable harm has been alleged*.
8 Care Quality Commission (2016) *Learning from serious incidents in NHS acute hospitals. A review of the quality of investigation reports*.
9 NHS Improvement (2018) *The future of NHS patient safety investigation*.
10 NHS Improvement (2018) *The future of NHS patient safety investigation: engagement feedback*.

2.8 This approach will allow NHS organisations to consider the safety issues that are common to similar types of incident and, on the basis of the risk and learning opportunities they present, demonstrate that these are:

a. being explored and addressed as a priority in current PSII work or
b. the subject of current improvement work that can be shown to result in progress or
c. listed for PSII work to be scheduled in the future.

2.10 As part of this approach, incidents requiring other types of investigation and decision-making, which lie outside the scope of this work, will be appropriately referred as follows:

a. professional conduct/competence – referred to human resource teams
b. establishing liability/avoidability – referred to claims or legal teams
c. cause of death – referred to the coroner's office
d. criminal - referred to the police

2.11 In some cases where a PSII for system learning is not indicated, another response may be required. Options that meet the needs of the situation more appropriately should be considered; these are listed in Section 5.

3. Situational analysis – local

3.1 Results of a review of activity and resources

3.1.1 Patient safety incident investigation (PSII) activity: Jan 2017 to Dec 2019:

	2017/18	2018/19	2019/20	Ave
Never Events	0	0	0	0
Serious Incident investigations*	87	85	130	101
Other RCA investigations (internal/departmental level investigations)**	13	30	2	15
			TOTAL	116

* This includes the number of coroner investigations notified to the Trust which were reported as serious incidents

** Includes internal RCAs and directorate level investigations, but not routine Datix incident reports

3.1.2 Estimate of current Serious Incident (SI) resources: 2019 (a snapshot, baseline measure):

For SI investigations	Grade(s)	Hours/year	~£/year
Patient safety team hours dedicated to SI-level PSIIs	8a (2) 7 6	150/52= 7,800	£193,881.000
Risk management team hours dedicated to SI-level PSIIs	-	-	-
Complaints team resources dedicated to SI-level PSIIs	8(b) 8(a) 7 6	20/52=1040	£31,200
Patient Advice and Liaison Service (PALS) team resources dedicated to SI-level PSIIs	6	10/52= 520	£10,400
Duty of Candour/'being open' resource (if not included above) dedicated to SI-level PSIIs	8b	7/52= 364	£214.97
SI-related PSII panels	Director 8d (4) 8c (3) 8b (3) 8a (3)	2/52= 104	£53,078.48

For SI investigations	Grade(s)	Hours/year	~£/year
SI leads/Supervisors	8b 8(a) 7		
SI-related PSII subject matter experts	-	-	-
Staff involvement in SI-level PSIIs	-	-	-
SI-related PSII reviewers	Included in SI-Level PSII leads		
Board/executive team sign-off of SI-level investigations	CQO CMO		
Solution/improvement identification, design and development costs (action planning) – resulting from SI-level investigations (if not included above)	-	-	-
Solution/improvement implementation costs – resulting from SI-related investigations	-	-	-
Solution/improvement monitoring/review – resulting from SI-level investigations (if not included above)	-	-	-
PSII trainer time/training fees (for SI-level courses)	Included in patient safety team figures		

3.1.3 The patient safety incident risks for the Trust has been profiled using organisational data from recent patient safety incident reports, complaints, freedom to speak up reports, SIs, mortality reviews, case note reviews, staff survey results, claims and risk assessments. Resources mined for this data include:

a. staff survey explorer tool results:
   - https://www.nhsstaffsurveys.com/Page/1058/Survey-Documents/Survey-Documents/

b. organisation patient safety reports:
   - https://report.nrls.nhs.uk/ExplorerTool/Report/Default
   - https://improvement.nhs.uk/resources/organisation-patient-safety-incident-reports-27-march-2019/

3.2 Conclusions from review of the local patient safety incident profile

3.2.1 The current top 8 local priorities/risk register are:

	Incident type	Specialty
1	Delays	Trust wide
2	Call handling and dispatch	EOC/IUC
3	Civility (Behaviour and Attitude)	Trust wide
4	Clinical Assessment	Trust wide
5	Medicine Management	Trust wide
6	Delayed Defibrillation	Ambulance Services
7	IT Infrastructure	Trust Wide
8	Medical Equipment	Ambulance Services/Logistics

3.3 Gap analysis

3.3.1 In line with the national PSII standards the following resources have been identified to enable delivery of the potential investigation programme, that is:

a. National priorities:

- Never Events
- 'Learning from Deaths'-related incidents (identified via structured judgement review to be more likely than not due to problems in care)
- unexpected incidents which signify an extreme level of risk for the patients, families and carers, staff or organisations, and where the potential for learning and improvement is so great (within or across a healthcare service/pathway) that they warrant the use of additional resources to mount a comprehensive PSII response.

b. Local priorities identified in 3.3.1 above.

c. Excluding incident types that are already part of an active improvement plan that is being monitored to determine efficacy and for which incremental improvement can be demonstrated.

3.3.2 The table below outlines the different stages of the investigation process and the resource required for each patient safety incident investigation. The exact resources required will depend on the specific incident, and therefore the resources stated are estimations. It also provides an indication on the differing resource requirements for the relevant staff groups.

Investigation Stage	Responsibility	Estimated Resource (HRs)
1. Plan the investigation		
a. Appoint investigators who are trained, competent, have secure protected time and sufficient support. b. Inform and engage with the patient/family and staff involved in agreeing scope.	QIL Team Investigation Supervisor and/or Lead	
2. **Gather and map the information** (**WHAT** Happened**)**		
c. Identify the WHO, WHERE and WHEN of the incident. d. Identify WHAT happened e. Map the incident timeline from the HCR, incident report and/or complaint letter. f. Add further detail and achieve mutual understanding via meetings/interviews with the patient/family and staff involved	Lead Investigator/ Investigation Supervisor	
3. Identify Problems (HOW it happened and variations from what was expected to happen)		
g. Identify and reference good practice requirements (work as imagined) h. Identify the key problems arising	Lead Investigator/ Investigation Supervisor /Subject Matter Expert	
4. **Analyse contributory and causal factors** (**WHY** these key problems arose)		
i. Observe and discuss how work is routinely done (work as done) j. Search for contributory and causal factors for each key problem (deep-seated reasons WHY)	Lead Investigator/ Investigation Supervisor	
5. **Write Investigation Report-** with clarity, openness and in full consultation with patient/family and staff		
k. Write investigation report	Lead Investigator/ Investigation Supervisor	
6. Develop Recommendations and Action Plan		
l. Identify and develop strong systemic improvements (using HF principles) m. Develop action plan. n. Review effectiveness of actions/improvements in reducing or preventing repeat incidents	Lead Investigator/ Investigation Supervisor QIL Team/Safety Investigation Assurance and Learning Group	

3.4 Strategic plan

3.4.1 The PSIRF Task and Finish group along with the PSIRF Steering Group have developed a strategic plan to address the above findings. Consultation on the Trust's prioritisation plan has been undertaken internally via the Trusts Safety Investigation Assurance and Learning Group, the Quality Oversight Group, the Quality Assurance Committee, Trust Board and externally with Trust's Clinical Commissioning Group (CCG).

a. A patient safety incidents register has been developed identifying those which present the greatest risk (severity, likelihood, concern, and cost) and the greatest opportunity for new knowledge and improvement. This register will be reviewed periodically to ensure the Trust's plan remains up to date.

b. Based on analysis of current and committed resources the Trust has planned to undertake 65 system-based patient safety incident investigations during 12 months. In total 25 investigations will be undertaken following incidents related to agreed priority areas to enable meaningful thematic analysis.

c. Based on historic incident reporting data it is anticipated that 40 will be 'national priority' patient safety incident investigations during the 12 month period.

d. The Trust has therefore identified 5 priority areas for "local priority" patient safety incident investigations for the next 12 months. The 5 priority areas are outlined within section 4.6.1 of this document.

e. Based on historic incident reporting data, the Trust will undertake PSIIs on priority incidents reported across a range of severities/outcomes, including at least one incident reported to have resulted in near miss/no or low harm.

f. All subsequent incidents falling into each priority area will be reviewed by one of the alternate measures outlined in Table 1. The exception being if it is felt that there is potential for significant new learning then a full patient safety incident investigation will be undertaken.

g. It has been agreed that incidents regarding resource availability, civility, medical equipment, delayed defibrillation and IT infrastructure have or require active improvement delivery plans in place based on learning identified from previous patient safety incident investigations. This

includes the recent COVID19 wave 1 review and the current review being undertaken for COVID19 wave 2 within the Trust.

h. If an incident does occur which has the potential for significant new learning then these incidents can be declared a PSII via the emergent are of high risk investigation route.

i. Delivery of these improvement plans will be monitored by the Quality Improvement and Learning team, and via the Safety Investigation Assurance and Learning Group (SIALG). A combination of both process and outcome metrics will be utilised to measure their effectiveness once fully complete.

j. Clinical effectiveness processes such as clinical audits, national reviews and Learning from Death data will continue to be monitored to ensure any new patient safety risks are identified and acted upon in a timely manner. This data will also be used to inform the Trust's patient safety incident risk profile.

k. Different review techniques will be utilised for all incidents that fall outside the patient safety investigation plan, but require action or new insight, this is described in section 5 of this document.

l. The summary PSIRP will be available on the Trust's website making it accessible to Patients, Families and wider stakeholders.

3.5.2 For each comprehensive PSII the Trust will:

a. Ensure each PSII is conducted separately, in full and to a high standard, by a team whose investigation supervisors is an experienced Band 8 and above who has received a minimum of two days' training.
b. Undertake PSII in line with the national PSII standards and conduct PSIIs as per the plan and in line with national good practice for PSII.
c. Use the national standard template to report the findings of the PSIIs.
d. Identify common, interconnected, deep-seated causal factors (not high-level themes or problems).

3.5.3 For each group of PSIIs dedicated to a similar/narrow focus incident type the Trust will:

a. Design strong/effective improvements to sustainably address common interconnected causal factors.
b. Develop an action plan for implementation of the planned improvements.
c. Monitor implementation of the improvements.
d. Monitor effectiveness of the improvements over time.

3.5.4 The Trust will also monitor the quality of PSII findings and progress against this PSIRP. This will include consideration and evidence required to answer the following questions:

a. Are the actions likely to achieve improvement?
b. Is there evidence of improvement?

4. Selection of incidents for patient safety incident investigation

4.1 Aim of a patient safety incident investigation (PSII)

4.1.1 PSIIs are conducted for systems learning and safety improvement. This is achieved by identifying the circumstances surrounding incidents and the systems-focused, interconnected causal factors that may appear to be precursors to patient safety incidents. These factors must then be targeted using strong (effective) system improvements to prevent or continuously and measurably reduce repeat patient safety risks and incidents.

4.1.2 There is no remit in PSII to apportion blame or determine liability, preventability or cause of death.

4.1.3 There are several other types of investigation which, unlike PSIIs, may be conducted for or around individuals. Examples include complaints, claims, human resource, professional regulation, coronial or criminal investigations. As the aims of each of these investigations differ, they need to continue to be conducted as separate entities to be effective in meeting their specific intended purposes.

4.2 Selection of patient safety incidents for PSII

4.2.1 In view of the above, the selection of incidents for PSII is based on the:

a. actual and potential impact of the incident's outcome (harm to people, service quality, public confidence, products, funds, etc.)
b. likelihood of recurrence (including scale, scope and spread)
c. potential for new learning in terms of:
    - enhanced knowledge and understanding of the underlying factors
    - improved efficiency and effectiveness (control potential)
    - opportunity to influence wider system improvement.

4.3 Timescales for patient safety PSII

4.3.1 Where a PSII for learning is indicated, the investigation must be started as soon as possible after the patient safety incident is identified.

4.3.2 PSIIs should ordinarily be completed within one to three months of their start date.

4.3.3 In exceptional circumstances, a longer timeframe may be required for completion of the PSII. In this case, any extended timeframe should be agreed between the healthcare organisation and the patient/family/carer.

4.3.4 No local PSII should take longer than six months. A balance must be drawn between conducting a thorough PSII, the impact that extended timescales can have on those involved in the incident, and the risk that delayed findings may adversely affect safety or require further checks to ensure they remain relevant. (Where the processes of external bodies delay access to some information for longer than six months, a completed PSII can be reviewed to determine whether new information indicates the need for further investigative activity.)

4.4 Nationally-defined priorities to be referred for PSII or review by another team

4.4.1 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:

a. **maternity and neonatal incidents:**

- 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/)
- all cases of severe brain injury (in line with the criteria used by the Each Baby Counts programme) must also be referred to NHS Resolution's Early Notification Scheme
- all perinatal and maternal deaths must be referred to MBRRACE

b. **mental health-related homicides by persons in receipt of mental health services or within six months of their discharge** must be discussed with the

relevant NHS England and NHS Improvement regional independent investigation team (RIIT)

c. **child deaths** (*Child death review statutory and operational guidance*):

- incidents must be referred to child death panels for investigation

d. **deaths of persons with learning disabilities:**

- incidents must be reported and reviewed in line with the Learning Disabilities Mortality Review (LeDeR) programme

g. **safeguarding incidents:**

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

e. **incidents in screening programmes:**

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

h. **deaths of patients in custody, in prison or on probation** where healthcare is/was NHS funded and delivered through an NHS contract:

- incidents must be reported to the Prison and Probation Ombudsman (PPO), and services required to be registered by the Care Quality Commission (CQC) must also notify CQC of the death. Organisations should contribute to PPO investigations when approached.

4.5 Nationally-defined incidents requiring local PSII

4.5.1 Nationally-defined incidents for local PSII are set by the PSIRF and other national initiatives for the period 2020 to 2021. These are:

a. **incidents that meet the criteria set in the** Never Events list 2018

b. **incidents that meet the** 'Learning from Deaths' criteria; that is, deaths clinically assessed as more likely than not due to problems in care.

4.6 Locally-defined incidents requiring local PSII

4.6.1 Based on the local situational analysis and review of the local incident reporting profile, local priorities for PSII have been set by the Trust for the period of 12 months.

a. **Locally-defined emergent patient safety incidents requiring PSII.** An unexpected patient safety incident which signifies an extreme level of risk for patients, families and carers, staff or organisations, and where the potential for new learning and improvement is so great (within or across a healthcare service/pathway) that it warrants the use of extra resources to mount a comprehensive PSII response.

b. **Locally-predefined patient safety incidents requiring investigation.** Key patient safety incidents for PSII have been identified through analysis of local data and intelligence from the past three years, and agreed with the commissioning organisations as a local priority in line with the following guidance:

- **Criteria for selection of incidents for PSII:**

  a. actual and potential impact of outcome of the incident (harm to people, service quality, public confidence, products, funds, etc.)

  b. likelihood of recurrence (including scale, scope and spread)

  c. potential for learning in terms of:

  - enhanced knowledge and understanding
  - improved efficiency and effectiveness (control potential)
  - opportunity for influence on wider systems improvement.

4.6.2 A local priority of incidents for PSIIs is detailed in the table below. Each incident type has been allocated a set number of PSIIs which will be conducted in the set 12 month period.

4.6.3 A PSII will be declared where the criteria (listed above) is met as well as taking into account any similarly PSIIs already being investigated and the area in which the incident occurred. This will ensure that PSII are selected for incidents occurring across the Trust as well as allowing actions from previous PSIIs to be implemented.

	Incident type Specific risk (or incident subtype) identified through risk assessment process and described with the support of patient safety teams, executive team, patient groups and clinical commissioning groups		Number of PSIIs	Planned response for specific incident type - selected based on risk assessment and particularly on potential for new learning or insight
1	Call handling	Errors in 999 call handling which has led to a patient receiving a delayed response attributed to probable harm	**6**	3 PSIIs will be undertaken into each specific incident type to identify key common interlined causal factors
		Errors in 111/IUC call handling which has led to a patient receiving a delayed response attributed to probable harm		
2	Face to Face Clinical Assessment	Clinical assessment which led to a patient being managed down an incorrect pathway	**9**	3 PSIIs will be undertaken into each specific incident type to identify key common interlinked causal factors.
		Face to face assessment which resulted in an incorrect decision to not convey the patient. The non-conveyance is attributed to probable harm.		
		Face to face assessment which resulted in the conveyance to hospital but not to definitive care; where there was clear indication for the patient to have been conveyed to a specialist centre.		
3	Enhanced Telephone Clinical Assessment	Enhanced telephone clinical assessment incorrectly resulting in home management advice. The management of the patient down this pathway resulted in probably harm.	**3**	3 PSIIs will be undertaken to identify key common interlinked causal factors.
4	Clinical Assessment of Spinal Injuries	Clinical assessment which led to a patient not receiving immobilisation where it was clinically indicated	**3**	3 PSIIs will be undertaken to identify key common interlinked causal factors.
5	Medicine management	Medication error	**4**	4 PSIIs will be undertaken to identify key common interlinked causal factors.
		Errors occurring during the preparation or administration of medicines with or without the presence of patient harm		

4.6.4 The following process will be followed by the Trust to review incidents under the Patient Safety Incident Response Framework:

a. All incidents with the severity of moderate harm and above will be discussed with the Quality Improvement and Learning team who will review the incidents against the framework and agree a planned approach for each incident. This will include reviewing and planning appropriate review techniques for incidents outlined in section 5. Priorities for 'being open' conversations and Duty of Candour include:

- all patient safety incidents leading to moderate harm or above
- all incidents for which an investigation is undertaken.

b. The Quality Improvement and Learning team will meet weekly with the Executive leads to discuss and agree the planned approach for these incidents.

c. The Quality Improvement and Learning team will ensure agreed PSII's will be logged on the Strategic Executive Information System (StEIS).

d. A 72 hour reports will be completed for every PSII declared for investigation. The report will contain the known facts relating to the incident and be sent to the CCG within the 72 hours following the identification of the PSII. The purpose of the 72 hour report is to recognise and mitigate immediate risks at an early stage of the investigation.

e. The Trust will used the national developed designated PSII template. The template will be shared will all LI's by their supporting supervisor.

f. Some incidents may trigger a specific type of multi-agency review and/or PSII to ensure system wide learning. The Trust will co-ordinate and lead cross-system PSIIs through their internal systems and teams. Where required, the Trust will engage early with commissioning teams and/or relevant teams within the wider sustainability and transformation partnership (STP), ICS or local maternity system (LMS) to support the co-ordination of a cross-system PSII within a local system.

g. Datix is the electronic system utilised by the Trust to report and record incidents. The Trust's incident reporting policy is 25 working days to review, investigate and close all clinical and non-clinical incidents. Exceptions to this being those declared as PSII's. Each declared PSII will be recorded in Datix and assigned an identification number. The Datix record will hold all relevant documents, progress notes, internal communications and the final report. It will be the responsibility of the supervisors to ensure the records are accurate and up to date.

h. The Executive Team Members will review and approve all final PSII reports. Any feedback required from the Executive Panel will be communicated to the relevant SI supervisor for review and amendment. The three nominated Executive Leads are:
    - Chief Paramedic & Quality Officer
    - Medical Director
    - Chief Operating Officer

i. Once the report has been approved by the Executive Team Members the ongoing management of PSIIs including action completion, Trust wide learning and monitoring of ongoing compliance with completed actions/changes will be undertaken via the Trust's Safety Investigation Learning and Assurance Group (SILAG).

4.7 Thematic analysis following the completion of a small number individual investigations of similar patient safety incidents

4.7.1 Once a number of PSIIs have been completed, a valuable and thorough way of accomplishing thematic analysis of PSII findings is to select a few (three to six) recent and very similar incidents and investigate each individually with skill and rigour to determine the interconnected contributory and causal factors.

4.7.2 The findings from each individual investigation are then collated, compared and contrasted to identify common causal factors and any common interconnections or associations upon which effective improvements can be designed.

4.7.3 Importantly, investigation of recent incidents allows more accurate information gathering from properly specified, good quality PSIIs, and detailed analysis of the system as it currently stands.

4.8 Patient safety improvement plans underway

4.8.1 The findings from incident reviews, PSIIs or other related activities must be translated into effective and sustainable action that reduces the risk to patients. For this to happen, organisations must be able to apply knowledge of the science of patient safety and improvement to identify:

- where improvements are needed
- what changes need to be made
- how changes will be implemented
- how to determine if those changes have the desired impact (and if they do not, how they could be adapted).

4.8.2 The Trust uses the standardised approach to improvement via the Quality, Service Improvement Re-design (QSIR) programme to ensure staff have the tools they need to sustain improvement.

4.8.3 A number of strategic programmes and projects as well as locally designed patient safety improvement plans are underway across the Trust. These relate to full plans, rather than individual actions, designed and prescribed to address known issues

with all of them incorporating previous PSIIs, review, audit or risk assessment findings (e.g. national suicide prevention plan).

4.8.4 The below is an overview of these Trust's programmes, projects and current quality improvement plans:

	Strategic Programmes and Projects improvement plan	Specialty	Monitoring Committee/Group
1	IT Infrastructure	Integrated Patient Care Services/IM&T/Ambulance Services	Programme Monitoring Board (PMB)
	***Local* patient safety incident improvement plans titles**	**Specialty**	**Monitoring Committee/Group**
1	Delayed Defibrillation	Ambulance Services	SIALG/QOG/QAC
2	Missing Equipment	Ambulance Service/Fleet and Logistics	SIALG/QOG/QAC
3	Nature of Call (NoC)	Ambulance Services	SIALG/QOG/QAC

4.8.5 It is important to take a proactive approach and be dynamic to patient safety risks to achieve continuous improvement. The Trust's main role in developing this plan was to involve key stakeholders across the clinical and quality agenda. This was to ensure and address common interconnected contributory factors. As a result, the below two themes were identified (with work commenced) for improvement projects/improvement plans in the 12 month period:

	Patient safety incident improvement plan/projects	Specialty	Monitoring Committee/Group
1	Delays in high demand – including improvements identified from the thematic COVID19 review in wave 1 & the thematic review currently being undertaken for wave 2.	Trust wide	SIALG/QOG/QAC
3	Civility (Behaviour and Attitude) a proactive approach to understand this theme via patient safety issues as well as complaints and patient feedback.	Trustwide	SIALG/QOG/QAC

5. Selection of incidents for review

5.1. Some patient safety incidents will not require PSII but may benefit from a different type of examination to gain further insight or address queries from the patient, family, carers or staff.

5.2. A clear distinction is made between the activity, aims and outputs from reviews and those from PSIIs.

5.3. Different investigation techniques can be adopted, depending on the intended aim and required outcome. The Trust will use the following investigation techniques:

Technique	Method	Objective
Immediate safety actions	Incident recovery	To take urgent measures to address serious and imminent: a. discomfort, injury, or threat to life b. damage to equipment or the environment.
'Being open' conversations	Open disclosure	To provide the opportunity for a verbal discussion with the affected patient, family or carer about the incident (what happened) and to respond to any concerns.
Case record/note review	Clinical documentation review	To determine whether there were any problems with the care provided to a patient by a particular service. (To routinely identify the prevalence of issues; or when bereaved families/carers or staff raise concerns about care.)
Structured Judgment Review for delays	Clinical documentation review	This approach will be used to assess delays in both thematic reviews and individual cases. It is based upon the principle that trained clinicians use explicit statements to comment on the quality of healthcare in a way that allows a judgement to be made that is reproducible.
Debrief	Debriefing	To conduct a post-incident review as a team by discussing and answering a series of questions.
Safety huddle	Briefing	A short multidisciplinary briefing, held at a set time and place and informed by visual feedback of data, to: • improve situational awareness of safety concerns • focus on the patients most at risk • share understanding of the day's focus and priorities • agree actions • enhance teamwork through communication and collaborative problem-solving • celebrate success in reducing harm.
Incident timeline	Incident review	To provide a detailed documentary account of an incident (what happened) in the style of a 'chronology'.
After-action review	Team review	A structured, facilitated discussion on an incident or event to identify a group's strengths, weaknesses and areas for improvement by

Technique	Method	Objective
		understanding the expectations and perspectives of all those involved and capturing learning to share more widely.

5.4. Where incidents result in a death, a Learning from Deaths (LfD) review will be undertaken to assess where any care and service delivery problems occurred. There may be the requirement to undertaken a further specialist review of these and below are the review techniques that could be used:

Technique	Method	Objective
LeDeR (Learning Disabilities Mortality Review)	Specialist Review	To review the care of a person with a learning disability (recommended alongside a case note review).
Perinatal mortality review tool	Specialist review	Systematic, multidisciplinary, high quality audit and review to determine the circumstances and care leading up to and surrounding each stillbirth and neonatal death, and the deaths of babies in the post-neonatal period having received neonatal care.
Learning from Death review	Specialist Review	Review the care of a person who died under the care of the service.

5.5. In all incidents there maybe the need to undertake active monitoring and ensure that actions taken to address incident are effective. All incidents are monitored via the Trust Safety Investigation Assurance and Learning Group and the following techniques that could be used:

Technique	Method	Objective
Process audit	Audit	To determine whether the activities, resources and behaviours that lead to results are being managed efficiently and effectively, as expected/intended
Outcome audit	Audit	To systematically determine the outcome of an intervention and whether this was as expected/intended
Clinical audit	Outcome audit	A quality improvement cycle involving measurement of the effectiveness of healthcare against agreed and proven standards for high quality, with the aim of then acting to bring practice into line with these standards to improve the quality of care and health outcomes.
Risk assessment	Proactive hazard identification and analysis	To determine the likelihood of an identified risk and its potential severity (e.g. clinical, safety, business).

6. Roles and Responsibilities

6.1 This Trust 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.

6.2 **Chief Executive**

- The Chief Executive has overall responsibility for the effective management of all patient safety incidents, including contribution to cross-system/multi-agency reviewed and/or investigations where required.
- With the executive and non-executive team, models behaviours that support the development of patient safety reporting, learning and improvement system.
- Ensure that systems and processes are adequately resourced including; funding, management time, equipment and training.

6.3 The **Chief Paramedic & Quality Officer**, supported by the **Chief Medical Officer**, is the executive lead responsible for supporting and overseeing implementation of the Patient Safety Incident Response Framework (PSIRF) and includes;

- Ensuring processes are in place to support an appropriate response to patient safety incidents (including contribution to cross-system/multi-agency reviews and/or investigation where required).
- Oversee development and review of the Trust's PSIRP.
- Agrees sufficient resources to support the delivery of the PSIRP (including support for those affected, such as named contacts for staff, patients, families and carers where required.
- Ensures the Trust complies with the national patient safety investigation standards.
- Establishes procedures for agreeing patient safety investigation reports in line with the national patient safety investigation standards.
- Develops professional development plans to ensure that staff have the training, skills and experience relevant to their roles in patient safety incident management.

6.4 **The Quality Improvement and Learning Safety Team**

- Ensures that patient safety investigations are undertaken for all incidents that require this level of response (as directed by the Trust's PSIRP)

- Develops and maintains local risk management systems and relevant incident reporting systems to support the recording and sharing of patient safety incidents and monitoring of incident response processes.
- Ensures the Trust has procedures that support the management of patient safety incidents in line with the Trust's PSIRP (including convening review and investigation teams as required and appointing trained named contacts to support those affected).
- Established procedures to monitor/ review investigation progress and the delivery of improvements.
- Works with executive lead to address identified weaknesses/areas for improvement in the Trust's response to patient safety incidents including gaps in resource including skills and training.
- Supports and advises staff involved in the patient safety incident response

6.5 **Investigation Supervisors**

- Ensure that investigations are undertaken in line with the patient safety investigation standards.
- Ensure they are competent to undertake the investigation assigned to them and if not request it is reassigned.
- Undertake patient safety investigations and patient safety investigation related duties in line with latest national guidance and training.

6.6 **Lead Investigators**

- Under the direction of investigation supervisor undertake investigations in line with the patient safety investigation standards.
- Ensure they are competent to undertake the investigation assigned to them and if not request it is reassigned.
- Undertake patient safety investigations and patient safety investigation related duties in line with latest national guidance and training.

6.7 **Duty of Candour/Being Open**

- The LI and/or the supervisor will be the main point of contact for the patient families and carers to ensure they are fully supported and informed of the investigation and its progress
- Identify those patients, families and carers affected by patient safety incidents and provide them with timely and accessible information and advice
- Ensure they are provided with an opportunity to access relevant support services

- Act as liaison between patients, families and carers and investigation teams to help manage expectations.

All main contacts for patients, families and carers must have;

- Received appropriate training in communication of patient safety incidents including 'being open' and Duty of Candour.
- Sufficient time to undertake their role; that is they should be staff dedicated to the role or with dedicated time for this role.
- More information can be found in the Trust's Being Open (Duty of candour) Policy.

6.8 **Supporting Staff**

- Staff will be supported by their local management team, where required or requested can potentially arrange for LINC workers.
- The LI and/or the supervisor will be the main point of contact for staff involved in a patient safety incident investigation.
- Provide advice and support throughout the investigation process to staff affected by a patient safety incident.
- Facilitate their access to additional support services as required.
- Act as liaison between these staff and investigation team as required.

6.9 **Department Leads/managers**

- Encourage reporting of all patient safety incidents including near misses and ensure all staff in their area is competent in using the Datix reporting system and are provided sufficient time to record incidents and share information.
- Provide protected time for training in patient safety disciplines to support skill development across the wider staff group.
- Provide protected time for participation in investigations as required.
- Liaise 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 investigations that relate to their area of responsibility (including taking corrective action to achieve the desired outcome)

6.10 **All Staff**

- Understand their responsibilities in relation to the Trust's PSIRP.
- Know how to access help and support in relation to patient safety incident response process.

7. Patient Safety Incident reporting arrangements

7.1 The reporting of all incidents is essential so that, when things go wrong or could have gone wrong, we can learn and take action to reduce the risk of harm to patients and staff, and improve the quality of our services.

7.2 All members of staff must report (or ensure that a colleague has reported) all incidents in which they are involved or become aware of.

7.3 Incident Reporting Systems are considered to be a major tool in the way the Trust manage risks; their purpose:

- To ensure that all incidents/accidents (actual and near miss) are reported, recorded and managed
- To prevent the recurrence of preventable adverse clinical and non-clinical events
- To provide 'early warning' of complaints/claims/adverse publicity
- To ensure that sufficient information is obtained:
    a) to meet internal and external (e.g. NHS England, HSE) reporting requirements
    b) to respond to complaints and litigation should these ensue
    c) for trend analysis which in turn is intended to facilitate the identification and 'learning of lessons' from incidents/mistakes made

7.4 The process of complying with both internal and external notification requirements for the reporting of patient safety-related incidents can be found within the Trust's Incident Management Policy (TP117).

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

8.1 The Trust is open with patients and relatives when errors are made and ensures that the principles of Being Open and Duty of Candour (DoC) are applied, and adhered to.

8.2 This is integral to the response to incidents, complaints, legal and safeguarding processes. Being open is part of a 'just" culture required of all healthcare providers and is fundamental to being a learning organisation.

8.3 Local arrangements for supporting patients, families and carers are detailed within the Trust's Being Open (Duty of Candour) Policy and associated documents.

9. Procedures to support staff affected by PSIs

9.1 It is essential that with any PSI the staff involved are genuinely supported throughout the entirety of the process. It is well documented that staff that are involved in such incident are potentially a 'second victim' and clear procedures to ensure and escalate the appropriate support is pivotal to the developed PSIIRF.

9.2 In keeping with the ethos of 'just culture' staff should be informed as soon as possible that an incident they have been involved in is to be investigated as a PSI. Significantly a clear explanation of the 'how's and whys' the incident is to be investigated needs to be explained in a transparent way to ensure the staff are confident that the investigation is fair and appropriate.

9.3 The initial acknowledgement to staff is important and can 'set the tone' of the perceived investigation to follow in the eyes of the staff. Rather than being too prescriptive the initial contact should be based on 'best for staff' utilising local management knowledge of said individuals. A verbal and 'face to face' discussion with the staff should always be followed up with an 'individualised' written response to follow.

9.4 Key components that should be explained to staff at the onset and indeed reinforced in written follow up:

- Just culture
- Emphasis is on identifying organisational learning
- Staff to be provided with a copy of the national PSII standards to which the investigation will be completed
- Emphasis that their input / questions and contribution is pivotal to any investigation
- Shared understanding of the potential stress associated (staff should absolutely be provided with written evidence of support options available)
- Clear time frames explained (avoid the possible concern that periods of 'no news is bad news')
- Emphasis that there is no hidden agenda, transparency is key. (Access to FTSU given)
- Regular 'touch base' periods built in to any investigation.
- Draft reports to be shared with staff (see point 7) to encourage feedback and promote the ethos of transparency.
- Final report to be shared and debrief arranged as required.

10. Mechanisms to develop and support improvements following PSIIs

10.1 The Trust utilise the Quality, Service, Improvement and Redesign (QSIR) quality programme through their Royal Academy of Improvement. The Academy provides training, education and support for a wide variety of improvement projects.

10.2 There is a cohort of QSIR practitioners who have undergone training to support teams throughout the Trust with implementing improvements/solutions arising from patient safety incident investigations.

11. Evaluating and monitoring outcomes of PSIIs, Thematic Reviews and Incident reporting.

11.1 Robust findings from PSIIs and reviews provide key insights and learning opportunities, but they are not the end of the story.

11.2 Findings must be translated into effective improvement design and implementation. This work can often require a different set of skills from those required to gain effective insight or learning from patient safety reviews and PSIIs.

11.3 Improvement work should only be shared once it has been monitored and demonstrated that it can be successfully and sustainably adopted, and that the changes have measurably reduced risk of repeat incidents.

11.4 Reports to the board will be monthly and will include aggregated data on:

- patient safety incident reporting
- audit and review findings
- findings from PSIIs
- progress against the PSIRP
- results from monitoring of improvement plans from an implementation and an efficacy point of view
- results of surveys and/or feedback from patients/families/carers on their experiences of the Trust's response to patient safety incidents
- results of surveys and/or feedback from staff on their experiences of the Trust's response to patient safety incidents.

12. Complaints and appeals

12.1 Patient experience and feedback offer learning opportunities that allows us to understand whether our services are meeting the standards we set and addressing patients' expectations and concerns. With these objectives very much in mind, we take all patient and stakeholder feedback very seriously, clearly identifying any lessons and using these to improve our service.

12.2 We report trends and emerging themes through the Trust's governance processes and to widen the learning, we publish anonymised case examples on the Trust website. With the implementation of PSIRP we will continue to manage complaints in the usual way in accordance with Trust Policy and the NHS Complaint Regulations, with close liaison with the Quality Improvement and Learning Team in relation to any complaints about incidents that are also the subject of a thematic review.

12.3 Local arrangements for complaints and appeals relating to the Trust's response to patient safety incidents are detailed within the Trusts Complaints Policy.

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