



London Ambulance Service **NHS**
NHS Trust

Serious Incident (SI) Policy and Procedure

DOCUMENT PROFILE and CONTROL.

Purpose of the document: To define the Trust's reporting process for the identification and management of SI's.

Sponsor Department: Governance and Assurance

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Links to Related documents or references providing additional information		
Ref. No.	Title	Version
TP/004	Complaints and Feedback Policy and Procedure	2.7
TP/005	Risk Management Policy	9.1
TP/009	Policy for Access to Health Records	4.1
TP/012	Data Protection Policy	3.7
TP/013	Claims Handling Policy and Procedure: clinical negligence, liabilities to third parties and property expenses scheme claims	5.3
TP/015	Procedure for responding to enquiries	5.3
TP/019	Safeguarding Adults in Need Policy	5.2
TP/034	Duty of Candour and Being Open Policy and Procedure	7.1
TP/062	Information Governance Policy	2.1
TP/097	Anti-Fraud, Bribery and Corruption Policy	2.3
HS/001	Health and Safety Organisation Policy Statement	2.0
HS/012	Violence Avoidance and Reduction Procedure	4.2
HR/003	Freedom to Speak Up: Raising Concerns (Whistleblowing Policy)	4.3
HR/021	Disciplinary Policy and Procedure	3.3
Appendix 1	Terms of Reference; SI's Group	1.1
Appendix 2	72 Hour Report	1.0
Appendix 3	Serious incident investigation SOP	
Appendix 4	Statement template	
LA 277	Notification of High Risk - Register	
LA 420	Crew safety assault report forms	

	<i>NHS England: Serious Incident Framework, March 2015</i> http://www.england.nhs.uk/wp-content/uploads/2015/04/serious-incident-framework-upd.pdf	
	<i>NHS England Serious Incident Framework – Frequently Asked Questions 2016</i> https://www.england.nhs.uk/patientsafety/wp-content/uploads/sites/32/2016/03/serious-incident-framework-faqs-mar16.pdf	
	<i>Local Authority Social Services & NHS Complaints (England) Regulations (2009)</i> http://www.opsi.gov.uk/si/si2009/uksi_20090309_en_1	-
	<i>Regulation 20: the Duty of Candour</i> <i>The Health and Social Care Act 2008 (Regulated Activities (Regulations 2014) will come fully into force on 1 April 2015.</i> http://www.cqc.org.uk/sites/default/files/20141120_doc_fppf_final_nhs_provider_guidance_v1-0.pdf	
	<i>CQC Fundamental Standards of Care</i> http://www.cqc.org.uk/content/regulations-service-providers-and-managers <i>With effect from 1 April 2015</i>	
	References to the resources provided by the National Patient Safety Agency have been removed as the NPSA ceased to exist on April 1 st 2012. When a link to the archived documents is published it will be included in the Policy.	

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1. Introduction

- 1.1 The London Ambulance Service NHS Trust (LAS) manages in excess of 1.7 million 999 calls and attends more than one million patients every year. The vast majority of patients receive very high standards of care. It is recognised that Serious Incidents (SI's) are rare, however when identified it is essential that all healthcare providers ensure they have systematic measures in place to respond to incidents.
- 1.2 SI's in health care are adverse events, where the consequences to patients, families and carers, staff or organisations are so significant or the potential for learning is so great, that a heightened level of response is justified.
- 1.3 SI's include acts or omissions in care that result in;
- Unexpected or avoidable death
 - Unexpected or avoidable injury resulting in serious harm - including those where the injury required treatment to prevent death or serious harm
 - Abuse including serious safeguarding concerns
 - Never Events
 - Incidents that prevent (or threaten to prevent) an organisation's ability to continue to deliver an acceptable quality of healthcare services
 - Incidents that cause widespread public concern resulting in a loss of confidence in the healthcare service.
- 1.4 Responding appropriately to identified SI's will ensure measures are in place in order to protect patients and guarantee that robust investigations are carried out to reduce the risk of an incident recurrence and implement learning.
- 1.5 Patient safety is the responsibility of all staff working for, or on behalf of, the Trust. The Executive Leadership Team (ELT), Senior Management Team (SMT)

and sector/department/directorate managers will model the behaviours expected by a fair and just culture and will set clear expectations around multi-disciplinary involvement within the SI process.

- 1.6 This policy provides guidance on how and when in-depth investigation processes should be undertaken following an incident. In order to learn from incidents it is necessary to obtain the facts and details of the incident. These must be recorded as soon after the incident as reasonably possible. Furthermore, detailed information will be gathered and collated as part of the investigation process.
- 1.7 The depth and level of investigation will be dictated by the severity of the incident. When the key facts of the incident have been identified, recommendations for change will be made and reviewed to prevent, or reduce the likelihood of similar circumstances reoccurring.
- 1.8 As part of the investigation process the requirements relating to the Health and Social Care Act (2008) Regulated Activities (2014): Regulation 20 will be followed as per the Trust policy TP/034 Duty of Candour and Being Open Policy and Procedure.
- 1.9 The Trust is registered with the Care Quality Commission (CQC) and is required to notify the CQC about notifiable incidents that occur.

2. Scope

- 2.1 The LAS is committed to promoting and improving the quality and safety of care and treatment all patients receive, as well as preserving the safety of its staff, visitors and others. In order to achieve this, it is important to support and embed a positive reporting culture throughout the organisation to enable learning when things go wrong.

2.2 Fear of blame may deter staff from reporting an incident or near miss event. The response to incidents must not be one of blame but one of organisational learning to encourage participation in the process and the support of staff.

2.3 This policy applies to all LAS staff, including those employed on a bank or agency staff contract. This document outlines how the Trust will report, manage, analyse and learn from SI's. Implementation, however, does not replace the personal responsibilities of staff with regard to issues of professional accountability.

3. Objectives

3.1 The objectives of this policy are:

3.1.1. To ensure a consistent approach to the management of SI's in a timely and open manner.

3.1.2. To ensure action is taken to protect patients and staff, where necessary.

3.1.3. To provide guidance on the identification and management of SI's.

3.1.4. To provide guidance on the use of root cause analysis methodology and investigatory procedures

3.1.5. To facilitate organisational learning.

3.1.6. To reduce the likelihood of the same incidents recurring or to reduce the impact should they occur.

3.1.7. To demonstrate a commitment to learning from each SI in a non-judgmental way.

3.1.8. To ensure any changes to systems and processes recommended during the root cause analysis are implemented.

3.1.9. To ensure there are clear lines of accountability for all elements of the investigation and dissemination of the learning.

3.1.10. To ensure appropriate levels of debrief and communication of lessons learned take place following incidents.

3.1.11. To ensure an 'open and just' culture is promoted to assure staff that no one will be unfairly blamed when things go wrong.

3.1.12. To set out the reporting arrangements for a SI's to the Trust Board, lead Clinical Commissioning Group (CCG), NHS England, NHS Improvement, the Care Quality Commission (CQC) and other external agencies, where necessary, to meet the requirements of external stakeholders

4. Responsibilities

4.1 All Staff

4.1.1 All staff have a responsibility to read and understand this policy.

4.1.2 All staff have a duty to report any incident, including SI's and to take immediate steps to protect individuals, information and/or the environment. All members of LAS staff – whether permanent, locum, agency or contractors are required to co-operate with all investigations as requested.

4.1.3 Staff are entitled to be accompanied by a member of a Trade Union or other staff side representative when giving statements or when being interviewed in the course of an SI investigation.

4.1.4 Arrangements for staff support following an SI will be provided by the individual's management team who may also make a referral to the Occupational Health Team as required.

4.2 Trust Board:

4.2.1. The Trust Board holds principal accountability and must ensure that an appropriate incident management system is in place for the reporting and investigation of incidents.

4.2.2. The Board will ensure there is robust monitoring of incident trends, including serious incidents, and the recording of all Never Events. The Trust Board are accountable for establishing effective organisational governance and learning following a serious incident. It is the duty of the

Board to ensure appropriate arrangements are in place throughout the Trust to meet this expectation.

4.3 Chief Executive Officer (CEO)

4.3.1. The CEO has overall responsibility for the systems of internal control and for protecting the health, safety and welfare of all who come into contact with the organisation.

4.3.2. The CEO is ultimately accountable for the implementation of an organisation-wide process associated with the investigation, analysis, learning and subsequent implementation of actions arising from incidents, complaints, contacts and claims.

4.3.3. The CEO will ensure that there is a nominated Executive Director with overall responsibility to ensure robust processes are in place in order to implement and monitor the requirements of this policy.

4.4 Chief Quality Officer (CQO)

4.4.1. The CQO is the nominated Executive Director responsible for ensuring the Trust has appropriate arrangements and resources in place for the management of incident reporting and associated investigations.

4.4.2. The CQO will ensure the Serious Incident Group (SIG) functions within the agreed terms of reference for the meeting (appendix 1).

4.5 Medical Director

4.5.1. The Medical Director is accountable to ensure that appropriate clinical representation is evident throughout all stages of the serious incident investigation and that patient safety is not compromised.

4.5.2. The Medical Director will lead on specific work streams related to the Trust's Clinical Strategy and ensure that areas of concerns are captured and shared across the Trust.

4.6 Deputy Director of Clinical Education and Standards

4.6.1. The Deputy Director of Clinical Education and Standards is responsible for ensuring that appropriate representation is made at each SIG meeting.

4.6.2. The Deputy Director of Clinical Education and Standards will lead on specific work streams related to the Trust's Training and Education Strategy and ensure that areas of concerns are captured and shared across the Trust.

4.7 Quality, Governance and Assurance Team

4.7.1. The Quality, Governance and Assurance Team is responsible for ensuring the systems for investigating SI's are in place and operate effectively by:

4.7.1.1 Maintaining records of reported incidents using the Datix incident management module.

4.7.1.2. Provide administration support to the SI process including preparing the required documents, agenda and minutes for the SIG meeting, circulating the meeting documents to the relevant attendees prior to the meeting, completing the meeting minutes and circulating them to the panel and ensuring actions from the meeting are documented and circulated to the relevant individuals.

4.7.1.3. Ensuring all SI's are logged on the Strategic Executive Information System (StEIS) within 48 hours of identification.

- 4.7.1.4. Notifying the ELT and all other relevant stakeholders, of unexpected deaths or other SI's that might attract media attention.
- 4.7.1.5. Liaising with the Trust's Communications Department on any incidents that might result in media interest.
- 4.7.1.6. Ensuring 72 hours reports are completed and submitted to the CCG once a SI is declared on StEIS.
- 4.7.1.7. Ensuring an effective quality assurance process is in place to monitor the quality of investigations, associated reports and action plans prior to submission to the Trust Board or designated assurance groups/committee, and the CCG.
- 4.7.1.8. Ensuring an effective tracking system is in place so that progress against action plans arising from SI's can be monitored and reported to the Trust Board.
- 4.7.1.9. Ensuring that evidence is collected and appropriately stored to validate the implementation of recommendations and actions arising from SI's.
- 4.7.1.10. Ensuring assurance evidence relating to implemented actions/recommendations can be retrieved in a timely way when required by the Trust Board or other internal or external stakeholders, as appropriate.
- 4.7.1.11. Supporting a culture of continuous quality improvement and safety across the organisation and ensuring that themes and trends of root causes are escalated.

4.7.1.12. Ensure that all supporting evidence relating to SI's is requested (Quality Assurance Reports, Clinical Opinions, Call Demand Data etc).

4.8. Lead Investigator (LI):

4.8.1. The LI will be appointed at the SIG to undertake a thorough and open investigation ensuring that all relevant operational, clinical and technical information/evidence is taken into account.

4.8.2. Where necessary the LI will be expected to interview the members of staff involved in order to gain a better understanding of the contributing factors leading to the SI.

4.8.3. The LI will be expected to chair the required 10 day multi-disciplinary team meeting.

4.8.4. All related information, reports, documentation and supporting evidence must be kept and managed in accordance with the Trust information governance procedures.

4.8.5. All LI's must have undertaken the formal investigation training provided by the Trust or by an external organisation prior to being assigned to conduct an investigation.

4.8.6. It is expected that the Trust holds a record of up to 50 appropriately trained investigators across all the directorate/sectors.

4.9. Quality and Risk Business Partners

4.9.1. The Quality and Risk Business Partners will support the LI's throughout the investigation. The Quality and Risk Business Partner will take responsibility for coordinating all aspects of the investigation, including:

- 4.9.1.1. Arranging and recording all meetings relating to the SI investigation.
 - 4.9.1.2. Collating evidence and facilitating the MDT event.
 - 4.9.1.3. Safe storage and labelling of equipment where necessary.
 - 4.9.1.4. Preparing chronological timelines.
 - 4.9.1.5. Supporting evidence analysis.
 - 4.9.1.6. The quality assurance of draft reports.
 - 4.9.1.7. Working with senior managers for the Trust to complete comprehensive action plan's that meets the recommendations from the report findings.
 - 4.9.1.8. Feeding report findings back to the sector/directorate and relevant governance forums to maximise the opportunities for learning.
 - 4.9.1.9. Ensuring the final reports are provided to the Executive Panel for approval.
 - 4.9.1.10. Ensuring the final reports (that have approval) are sent to the relevant CCG leads ten days before the designated deadline.
 - 4.9.1.11. Escalating any concerns that a report will not meet the required milestones in a timely manner.
- 4.9.2. The Quality, Governance and Assurance team will track completion of investigations throughout the process. The department will also track the relevant actions ensuring appropriate evidence of completion is received prior to the action being closed.
- 4.9.3. The Quality, Governance and Assurance team will provide administrative support to the governance forums referred to in this policy with responsibilities for SI's.

4.10. Clinical Advisor to Legal and Governance Services

- 4.10.1. The Clinical Advisor to Legal and Governance Services is responsible for liaising with member of the Medical Directorate to provide an initial clinical review of the incident.
- 4.10.2. Additional checks will include ensuring that the death of a patient has not been reported to the Trust as an Inquest. Where an Inquest has been opened in relation to a potential incident the Clinical Advisor to Legal and Governance must highlight the concerns to the relevant Claims and Inquests Manager. If required the Head of Legal Services will be asked to attend the relevant SIG meeting.
- 4.10.3. The Clinical Advisor is responsible for providing a formal clinical opinion within the first 10 days of an incident being declared. Where this is not possible the reasons for the delay must be communicated to the LI and Quality and Risk Business Partner with an estimated completion time being provided.
- 4.10.4. Where applicable the Clinical Advisor will review the incident, and the written opinion, with members of the Medical Directorate to ensure a reasonable and rounded opinion has been concluded.
- 4.10.5. It is expected that on occasions the Clinical Advisor will need to interview the members of staff involved in the SI. To ensure any operational downtime is kept to a minimum and the welfare of the members of staff is prioritised, the Clinical Advisor should liaise with the LI prior to arranging the interview and consideration be given to a joint interview.
- 4.10.6. Where the Clinical Advisor is unable to complete a formal clinical opinion, due to time constraints or a subject matter expert is required, the opinion will be allocated to a member of the Medical Directorate for completion.

4.11. Medical Directorate

- 4.11.1 Members of the Medical Directorate will be required to provide specialist clinical advice when required. The directorate hosts a number of subject matter experts who may be called upon to provide a formal clinical opinion, clinical review, be present during interviews, provide guidance to the LI or provide feedback to the staff involved.
- 4.11.2. It is expected that the Consultant Paramedics will provide a presence at the weekly SIG meeting on a rotational basis as per the terms of reference.
- 4.11.3. A subject matter expert may be requested to attend the SIG meeting to discuss specific incidents relating to their area of expertise. If it is not possible for the individual to attend, they will be required to provide an overview of the incident prior to the SIG meeting.
- 4.11.4. On occasions a subject matter expert will be required to attend the 10 day MDT meeting to present their clinical opinion. Where this is not possible the clinician will be required to submit their formal clinical opinion to the LI prior to the 10 day MDT meeting.

4.12. Directorate and Sector Managers and Quality, Governance and Assurance Managers (QGAM's)

- 4.12.1. Each Directorate/Sector will ensure that all permanent and temporary staff (including bank, agency and locum staff) receive information during induction on incident reporting (including their responsibilities under the Duty of Candour process) and the use of the Datix web system.
- 4.12.2. Directorate/Sector leads will support the investigation process by ensuring that there is sufficient time and resources to conduct the investigation and that staff are able to attend interviews as necessary.
- 4.12.3. Action plans arising from investigations are the responsibility of the Directorate Management and each department is responsible for implementing changes where appropriate. The Directorate/Sector

management teams are responsible for ensuring that all actions are implemented and assurance given to the Executive Panel (see point 6.2).

4.12.4. Directorate/Sector Leads are responsible for ensuring that there is a clear plan for sharing lessons learned from each SI, in collaboration with the Quality, Governance and Assurance team.

4.12.5. Directorate/Sector Leads are responsible for ensuring that any member of staff within department/sector that is involved in a Serious Incident is provided the appropriate level of support throughout the investigation.

4.13. Nominated Contact (Formally the Family Liaison Officer)

4.13.1. The Trust will appoint a single point of contact for the patient and/or their next of kin or representative to ensure they are fully supported and informed of the investigation and its progress.

4.13.2. The nominated contact will ensure that the Trust obligations under the Duty of Candour are met and arrange to formally meet with the patient and/or their representative following the completion of the investigation.

4.13.3. Each nominated contact will have undergone formal training to ensure they are equipped with the necessary skills to offer guidance and support to the patient and/or their representative. They will not be involved in the investigation at any stage.

5. Definitions

5.1 Serious Incident

A SI is an event in health care where the potential for learning is so great, or the consequences to patients, families and carers, staff or organisations are so significant, that they warrant using additional resources to mount a comprehensive response.

SI's can extend beyond incidents that affect patients directly and include incidents which may indirectly impact patient safety or an organisation's ability to deliver ongoing healthcare.

The occurrence of a SI demonstrates weaknesses in a system or process that need to be addressed to prevent future incidents leading to avoidable death or serious harm to patients or staff, future incidents of abuse to patients or staff, or future significant reputational damage to the organisations involved.

SI's require an investigation in order to identify the factors that contributed towards the incident occurring and the fundamental issues (or root causes) that underpinned these. SI's can be isolated, single events or multiple linked or unlinked events signaling systemic failures within a commissioning or health care system.

5.2 Incident

An incident is defined as any unexpected or unintended event or circumstance that leads to, or could have led to, harm, loss or damage to people, property or reputation. They may be clinical or non-clinical; e.g. suspected suicide, missing person, fire, theft, or violence.

5.3 Incident Decision Tool

The incident decision tool was developed as an aid to improve the consistency of the decision making by the SIG when reviewing potential SI's. It will be used by those who have the authority to declare an incident as an SI and instigate a formal investigation.

5.4 Investigation

The investigation is the process of examining all aspects of an incident. It allows the Trust to consider if any mitigating actions should be put in place to stop the incident reoccurring or to reduce the impact of the incident where the risk cannot be removed completely.

5.5 Patient Safety Incident

A patient safety incident is any unexpected or unintended event or circumstance that results in, or could result in, harm to a patient.

5.6 Non-patient Safety Incident

A non-patient safety incident is any unexpected or unintended event or circumstance that results in, or could result in, harm to a member of staff (including contractors), visitor or loss/damage to the Trust (including financial/reputational/assets).

5.7 Notifiable Safety Incident

A notifiable safety incident is defined by the CQC as any unintended or unexpected incident that occurs in response of a patient's care that, in the reasonable opinion of a healthcare professional, could result in, or appears to have resulted in:

5.7.1. The unexpected death of a patient

An unexpected death is the death of a patient following a harm-related incident that is not related to the natural course of their disease. Unexpected deaths must be verified and certified by a medical practitioner and reported to the Coroner.

5.7.2. Severe harm (patient or staff)

Severe harm is defined as a permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including removal of the wrong limb, or organ or brain damage, which is directly related to the incident and not to the natural course of the patient's illness or underlying condition.

5.7.3. Moderate harm (patient or staff)

Moderate harm is temporary, significant harm which is defined as the lessening of bodily, sensory, motor, physiologic or intellectual functions that is directly related to the incident and not to the natural course of the patient's illness or underlying condition and moderate increase in treatment, such as an unplanned return to surgery, an unplanned readmission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment or transfer to another treatment area (such as intensive care, HDU).

5.7.4. Prolonged psychological harm for a continuous period of at least 28 days

Prolonged psychological harm is defined as harm which a patient has experienced or is likely to experience, for a continuous period of at least 28 days.

5.7.5. Expected death

The death of a patient that is expected as a natural course of their disease or condition and where there is no active intervention to prolong life. As an example, cancer patients who are on an End of Life pathway who die would be included as an expected death. Expected deaths are not considered to be SI's.

The identification of a notifiable safety incident does not automatically imply error, negligence or poor quality care. It suggests that an unexpected and undesirable clinical outcome that resulted from some aspect of the patient's care, rather than their underlying condition, has occurred.

The LAS has a responsibility to investigate the incident in order to identify why it occurred and to take active steps to minimise the risk of recurrence. All notifiable safety incidents trigger the statutory Duty of Candour requirements.

5.8 Automatic SI's (Never Events)

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Whilst it is accepted that there is not currently a designated list of Never Events for NHS Ambulance Trusts, the Trust has composed a list of events or circumstances that are to be automatically declared as an SI. This list includes:

5.8.1. Maternal death

5.8.2. Serious morbidity associated with labour/delivery

5.8.3. Medication related incidents leading to the death of a patient where it is believed that the incorrect administration/management of the medication contributed to the patient's death

5.8.4. Unrecognised oesophageal intubation

5.8.5. Delayed defibrillation of a initial shockable cardiac arrest rhythm

5.8.6. Fall from an ambulance trolley bed

5.8.7. Fall from a moving vehicle

5.8.8. Conveyance of a clear ST elevated myocardial infarction (in the absence of a compromised airway) to a local ED rather than the nearest PCI centre

5.8.9. Conveyance of a clear FAST positive patient (in the absence of a compromised airway) to a local ED rather than the nearest HASU

5.9 SI reports

5.9.1. 72 hour reports

72 hour reports must be completed for every SI declared for investigation (appendix 2). The report must contain the known facts relating to the incident and be sent to the CCG within the 72 hours following the identification of the SI. The purpose of the 72 hour report is to recognise and mitigate immediate risks at an early stage of the investigation.

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5.9.2. Level 1 investigation

A level 1 investigation will be referred to by the Trust as a Root Cause Analysis (RCA) investigation. The report will be shared locally but there is no requirement to send the final report externally. The time frame associated with a RCA investigation is 45 working days. The process for the invitation of an RCA will mirror that of an SI investigation.

The identification of an RCA will be any incident that obtains the overall incident decision tool score between 16 and 20.

All level 1 investigations will be documented in the same reporting template as a level 2 investigation.

5.9.3. Level 2 investigation

A level 2 investigation is a comprehensive investigation produced when an incident has been declared as an SI. The report will be shared externally with the CCG and has a required time frame of 60 working days.

The identification of an SI will be any incident meeting the 'automatic SI' criteria detailed in point 5.8 or any incident that obtains an overall incident decision tool score of 21 or above.

5.9.4. Level 3 investigation

A level 3 investigation is required where the findings of the investigation are likely to be challenged or where it will be difficult for the Trust to conduct an objective investigation. A level 3 investigation must be completed by an external body/organisation within six months of the incident being declared.

5.9.5. Investigation template

The Trust has developed a designated investigation template to be used by all LI's to document the findings of their investigation. The template will be shared with all LI's by their supporting Quality and Risk Business Partner.

The template has been developed in accordance with the NHS SI Framework and the CCG's. Reports documented on any template other than the approved documentation will not be accepted by the Quality, Governance and Assurance Team and sent back to the LI for amendment.

5.10 Datix

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 SI's. Further information relating to the management of incidents can be found in the Incident Reporting and Investigation Workshop SOP.

Each declared SI 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 Quality and Risk Business Partners to ensure the records are accurate and up to date.

5.11 Identification of an SI

The Quality, Governance and Assurance Team will be notified of potential SI's through a variety of groups, audits, reports and departments.

Examples include:

- Datix reports marked as severe or death will automatically be referred to SIG

- Incidents graded as no harm, low harm, and moderate harm reported via Datix will be reviewed for accuracy in grading and referred to SIG where applicable
- Maternal death reviews
- Major Trauma auditing
- Patient (24hr) Re-contact auditing
- Cases reviewed by the Medical Directorate meeting the SI criteria.
- Safeguarding Team (including child death reviews)
- Mortality Review Group
- Patient Experiences Department
- Legal Services

5.12 Near miss/prevented incident

A near miss is any incident that had the potential to cause harm but was prevented, resulting in no harm. Not every near miss needs to be reported as a SI but the potential for severity of harm should be a prime consideration.

5.13 Strategic Executive Information System (StEIS)

StEIS is a Department of Health management information system used to collect information about NHS organisations, including SI's. It is a requirement that the Trust records all SI's on StEIS within 48 hours after the incident has been declared.

5.14 Clinical Opinions

Each RCA or SI investigation that is to be undertaken must be reviewed by the Clinical Advisor to Legal and Governance Service for advice on if a formal

clinical opinion is required. Incidents that have identified possible errors in the provision of optimum care must receive a formal clinical opinion.

The clinical opinion will include a summary of the actions taken by the attending clinicians (including the Clinical Hub) and an opinion on if these actions were appropriate and in accordance with Trust procedure.

Where missed opportunities or errors are identified the author of the clinical opinion will offer a summary of the optimum care that should have been provided supported with references to local and national guidance.

Where a case is identified that requires a subject matter expert, the Clinical Advisor will allocate the opinion to a member of the Medical Directorate for completion.

It should be noted that it is beyond the scope of a clinical opinion to comment on the following:

- 5.13.1. Cause of death (unless obtained by a post mortem report)
- 5.13.2. Causation
- 5.13.3. Negligence

5.15 10 day Multi-disciplinary Team (MDT) Meeting

As part of the SI investigation process a MDT meeting will be held 10 days after an incident has been identified as that requiring a formal investigation. Further details on the MDT meeting can be found in section 10 of this policy.

5.16 Action planning MDT Meeting

As part of the SI investigation process it is expected that the LI will provide a number of recommendations to reduce the risk of an incident reoccurring, reduce the impact of the incident should it reoccur, share learning across the Trust, provide individuals with additional support, learning or training etc.

It is appreciated that incidents that typically occur across several areas of the Trust rather than in isolation. As such it

5.17 De-escalation request

It is appreciated that on occasions the SIG will be expected to make a decision on whether an incident meets the criteria for a SI or RCA investigation on limited information.

As additional evidence or supporting information becomes available to the LI it may become apparent that the incident no longer meets the criteria requiring a formal investigation. In such instances a formal de-escalation form must be completed and submitted to the SIG for formal consideration.

Should the SIG approve the de-escalation request, it will be submitted to the CCG for consideration. It is essential that the investigation continues until formal approval from the CCG has been received by the Trust that the de-escalation request has been accepted.

Once formal approval has been received from the CCG the investigation can be stood down with immediate effect. It the responsibility of the SI Business Partner to ensure that this is communicated to the staff involved and the Nominated Contact to inform the patient and/or representative of the decision.

5.18 Open, fair and just culture

Incident reporting, investigation and learning will not be effective in an organisation that does not respond to incidents using the principles and practices of a Just Culture.

A Just Culture is such that it:

- 5.17.1. Recognises that individual practitioners should not be held accountable for system failings over which they have no control

- 5.17.2. Recognises that many errors represent predictable interactions between human operators and systems in which they work
- 5.17.3. Recognises that competent professionals make mistakes (human factors (1))
- 5.17.4. Acknowledges that even competent professionals will develop unhealthy norms (shortcuts and 'routine rule violations' at risk behaviour (2))
- 5.17.5. Has a zero tolerance for reckless behaviour (3)

- 1. Human factor: inadvertently doing something other than what should have been done; slip, lapse or mistake.
- 2. At-risk behaviour: behavioural choice that increases risk where risk is not recognised or is mistakenly believed to be justified.
- 3. Reckless behaviour: behavioural choice to consciously disregard a substantial and unjustifiable risk.

6. Committee and Oversight Responsibilities

6.1. SIG

The SIG panel will meet weekly as per the terms of reference to review all incidents reported over the previous week that have been graded as severe harm/death.

Additionally, incidents raised within Datix and graded as a low/moderate risk will be reviewed by the Quality, Governance and Assurance team, and referred to SIG as a potential SI should the incident warrant further discussion.

6.2. Executive Team Members

Executive Team Members will review and approve all final SI reports prior to the report being submitted to the CCG. It is expected that all final reports will be provided to the Executive Panel by day 40 of the 60 day investigation time line.

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Any feedback required from the Executive Panel will be communicated to the relevant SI Business Partner for review and amendment.

The three nominated Executive Leads are:

- 6.2.1. Chief Quality Officer
- 6.2.2. Medical Director
- 6.2.3. Deputy of Operations

The respective deputies for the above leads are:

- 6.2.4. Deputy Director of Nursing and Quality
- 6.2.5. Deputy Medical Director
- 6.2.6. Deputy Director of Operations (either Control Services or Operations)

7. Duty of Candour

- 7.1. The Trust recognises the importance of full, open and honest communication in feeding back to patients or their nominated representative. There is a legal duty to give a genuine apology and an explanation of the facts as they are known at the time of the first discussion.
- 7.2. A nominated individual will be appointed to act as the single point of contact for the patient or their representative throughout the SI investigation process.
- 7.3. The Duty of Candour and Being Open Policy provide full details on the legal requirements of Regulation 20 of the Health and Social Care Act 2008 (Regulation 14: Regulated Activity).
- 7.4. It is the responsibility of the Quality and Risk Business Partner to ensure that the Trust obligations in relation to the Duty of Candour are followed and recorded appropriately within the Datix record.

8. Confidentiality

It is essential that patient and staff confidentiality is maintained at all times throughout the investigation and any related records or documents are kept in accordance with the Trusts information governance procedures.

All supporting evidence must be redacted prior to including the relevant documents in the reports.

LAS staff must not be named in the report or supporting evidence such as the clinical opinion. Additional patient identifiable documentation such as GP records, hospital notes, patient report forms etc must be redacted if included in the report.

Further guidance is available in the LAS Confidentiality Code of Conduct.

9. SI investigation principles

A level 2 investigation (SI) process endorses the application of the following key principles in the investigation of SI's.

9.1 Open and transparent

It is essential that the needs of the individuals affected by the incident are the primary concerns of those involved in the investigation process. The principles of being open are detailed in Trust Policy TP/034 Being Open and Duty of Candour and must be applied in all investigations.

9.2 Preventative

SI investigations are undertaken to ensure that weaknesses in the operating systems within the Trust are highlighted and analysed to understand how and why they went wrong and what can be done to prevent similar incidents

occurring again.

9.3 Objective

Individuals appointed to undertake the SI investigation should not be directly involved in the management of the members of staff involved in the incident. Those who are directly involved in the management of staff involved and/or the development of the systems in place that are under investigation may fail to fully challenge the system/individual which is crucial for the identification of weaknesses and opportunity for learning.

9.4 Responsive

Incidents that have been identified as those which have caused serious harm or death must be reported on StEIS within the 48 hours following identification.

The final report must be submitted to the CCG no later than 60 working days after the identification of the SI. Appendix 3 details the expected timeline and relevant milestones to be followed when investigating a SI.

10. 10 Day MDT Meeting

The purpose of the MDT meeting is to collate all the relevant information gained in the first 10 days of the investigation process and identify any immediate risks, contributory factors, and root causes; providing mitigation where necessary. It will be an opportunity for the LI to raise any new concerns highlighted as part of the investigation and clarify, with subject matter experts, any information that is unclear.

It is expected that the following individuals attend the 10 MDT meeting:

5.14.1. Lead Investigator (Chair)

5.14.2. Quality and Risk Business Partner (vice chair)

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5.14.3. Nominated contact

5.14.4. EOC representative (where required)

5.14.5. Author of the clinical opinion (if required)

5.14.6. Staff involved in the incident (if appropriate)

5.14.7. Subject matter experts (as required)

5.14.8. Claims and Inquest Manager (where applicable)

The MDT should provide the LI with enough information to commence the production of a first draft report.

Where staff are to be invited to attend, the invitations must be sent to their direct line manager to arrange an appropriate time to speak with the member of staff prior to being informed of the meeting. LI's are expected to be mindful that this communication may be the first time a member of staff has been made aware that there has been an SI raised. If a statement is required it is expected that the staff are asked to complete the statement using the template provided by the Quality, Governance and Assurance Team (Appendix 4).

Where an incident is linked to an inquest (or actually/potential claim), the Claims and Inquests Managers is to be invited to the MDT meeting. This will ensure a collaborative approach to the case is maintained and reduce the risk of duplicating work.

Any cases where a de-escalation is being considered must be reviewed at the MDT prior to the submission of a de-escalation request at SIG.

It is expected that the MDT meeting will follow the following key principles.

10.1 Systems based

All SI investigations must be conducted using a recognised systems-based

methodology that identifies:

- 9.5.1. What the problem is
- 9.5.2. The contributory factors that led to the problem
- 9.5.3. The fundamental root cause of the problem that requires addressing

10.2 Proportionate

The scale and scope of the investigation should be proportionate to the incident to ensure that resources are used effectively.

The level of the investigation required will be have been determined by the SIG supported by the Incident Decision Tool.

10.3 Collaborative

On occasions it is appreciated that certain SI's involve several organisations. In such instances the LAS will work in partnership with the other organisations to ensure incidents are effectively managed.

For this to be effective it is essential that clear arrangements are in place relating to the roles and responsibilities of each Trust to avoid any duplication of work. Cases will be managed on a case by case basis in collaboration with the other Trusts involved.

11. Learning Lessons

11.1 SI investigation reports should identify specific recommendations for improvement and the prevention of recurrence. These recommendations must be supported by actions for completion by an identified lead within a defined timescale. The Directorate/Sector Management Teams are

responsible for following up and reporting on compliance with agreed actions and confirming that embedded learning has been achieved.

11.2 The Trust is committed to ensuring that robust investigations are conducted which result in the organisation learning from SI's to minimise the risk of the incident occurring in the future, or to reduce the potential harm, and, as such, expects any actions to result in "embedded learning".

11.3 Embedded learning is defined as a change of behaviour at individual, team or organisational level.

11.4 If appropriate, the SI investigation executive summary, or report, can be shared. The executive summary includes a précis of the incident and investigation and is fully anonymised to preserve the confidentiality of the people involved. This will enable the executive summary to be widely shared. Learning can be shared from individual investigations or as an aggregate of similarly themed incidents. Learning programmes can take a variety of forms and the information can be tailored to suit the audience.

11.5 A summary of all closed SI investigation during a specific month will be reported to the Executive Leadership Team on a monthly basis. The summary will include the executive summary of the reports, root cause and recommendations made.

11.6 The Quality, Governance and Assurance team will carry out regular sample analysis of open and completed actions to ensure that supporting evidential documentation is uploaded to Datix, and that open actions are on track for the estimated completion dates.

12. Training and Implementation

12.1 The Trust shall provide training and support to managers and their delegated representatives to enable them to fulfil their responsibilities in the investigation of incidents.

12.2 The Trust will train LI's in Root Cause Analysis investigation techniques. Those who have been trained will undertake the investigation of SI's as directed by the SIG panel.

12.3 Over time, a pool of individuals nominated to lead on investigations will be developed. The scope of this training will be:

11.3.1. Learning from incidents within the Trust

11.3.2. Overview of SI's

11.3.3. What is a SI?

11.3.4. Why SI's are investigated

11.3.5. Sources of evidence

11.3.6. Serious Investigation process

11.3.7. Documentation (72hr reports, five whys, SI template, MDT's, RCA)

11.3.8. Learning and recommendations

11.3.9. The role of the Nominated Contact

11.3.10. Timescales and milestones

11.3.11. Report approval process (Internal and external)

The root cause analysis toolkit is available for all staff from <http://www.npsa.nhs.uk/nrls/improvingpatientsafety/patient-safety-tools-and-guidance/rootcauseanalysis/rca-investigation-report-tools/>

13. Policy Review

The Policy will be reviewed by the Policy Monitoring and Approval Group.

IMPLEMENTATION PLAN

Intended Audience	All LAS Staff
Dissemination	Available to all staff on the Pulse and to the public on the LAS website.
Communications	Revised Policy and Procedure to be announced in the RIB and a link provided to the document.
Training	The Trust provides Root Cause Analysis training sessions. Where an investigation needs to use Root Cause Analysis an appropriately trained multi-disciplinary team will be appointed. Training for the Nominated Contact role is being developed and will be available to those staff nominated for the role.

Monitoring:

Aspect to be monitored	Frequency of monitoring AND Tool used	Individual/ team responsible for carrying out monitoring AND Committee/ group where results are reported	Committee/ group responsible for monitoring outcomes/ recommendations	How learning will take place
Policy review	First review in one year and then every three years	Head of Quality, Governance and Assurance Patient Safety Committee, Quality and Safety Committee	TBC	This policy will be reviewed in conjunction with any changes to relevant legislation, national frameworks or Trust objectives A revised Policy will be published via the Trust Intranet system for trust-wide access.

Numbers of SI's by Sector/Directorate by category	SI's will be reported monthly	Head of Quality, Governance and Assurance Trust Board (monthly), Patient Safety Committee (monthly) and the Quality and Safety Committee (bimonthly)		Any gaps/deficiencies and overdue actions will be reviewed and necessary action taken to resolve these. Agreement from Patient Safety Committee
Reviews of themes and trends	Quarterly thematic reports	Head of Quality, Governance and Assurance Trust Board, Patient Safety Committee		Any gaps/deficiencies highlighted will be reviewed and necessary action taken to resolve these. Agreement from Patient Safety Committee
Audit against the policy and associated standard operating procedures (SOPs).	Yearly	Head of Patient Safety Patient Safety Committee		Any gaps/deficiencies will be reviewed and necessary action taken to resolve these

Serious Incident Group (SIG)

1. Purpose

1.1. The purpose of the SIG is to provide clinical expertise and executive oversight of all reported patient safety incidents identified as a potential serious incident and/or incidents that have been deemed, by the Trust, to be 'never events'.

1.2. The group will be made aware of potential serious incidents via the following reporting mechanisms:

- a. Datix incident reports (Trust wide)
- b. Inquests
- c. Complaints
- d. Claims
- e. Safeguarding (including child death reviews)
- f. Medical Directorate
- g. Major Trauma compliance audit
- h. Patient (24hr) re-contact audit
- i. Maternal death reviews
- j. Mortality review

1.3. The group will review such incidents and will consider whether the incident meets the criteria for a serious incident (or never event). The panel, supported by the decision making tool, will determine whether the incident is to be declared as a:

- Externally reportable serious incident
- Incident requiring an internal Root Cause Analysis (RCA) investigation
- Reportable to the CQC as a notifiable incident
- Stand down the incident and refer for local investigation

- 1.4. The group will provide assurance to the wider executive team and the Board that all serious incidents (or never events) are appropriately declared and investigated, that commissioners are informed in a timely manner and lessons are learnt.
- 1.5. The panel will use the NHS England Serious Incident Framework (2015); NHS England Revised Never Event Policy and Framework; and the Trusts revised policies on Serious Incidents, Duty of Candour and Being Open, and any other relevant guidance in the execution of its duties.

2. Constitution

- 2.1 The SIG will be established on the authority of the Chief Quality Officer.

3. Accountability

- 3.1 The Group will report to the Quality Oversight Group, which in turn reports to the Executive Group, which reports to the Trust Board of Directors.
- 3.2 Any matters requiring Board approval under the Trust's Scheme of Delegation and Reservation will be submitted to the Board via the Executive Group.

4. Chairperson(s)

- 4.1. Chief Quality Officer
- 4.2. Medical Director
- 4.3. Head of Quality, Governance and Assurance will be the Vice Chair.

5. Membership

Core members:

- Chief Quality Officer and Medical Director
- Head of Quality Assurance or Deputy
- Deputy Director of Operations
- Deputy Director of Clinical Education and Standards
- Clinical Adviser to legal Services and Quality & Assurance
- Consultant paramedic representative
- Quality, Governance and Assurance Manager (QGAM) representative
- Head of Safeguarding/Deputy

Additional

Any additional individuals to be invited to the SIG meeting must be communicated and approved by the Chair prior to the meeting taking place.

- Senior subject specialists will be required to attend as appropriate
- Other operational leads/experts may be invited to attend relevant to the areas being considered
- Head of Health and Safety
- Trust Commissioners when a request to attend has been received
- Head of Legal Services

6. Attendance

6.1 There is a requirement for core members to attend all meetings and a minimum of 80% per annum. This will be monitored by the Governance Team and reported to the Chief Quality Officer quarterly.

6.2 If a deputy attends on behalf of a core member they must have sufficient authority to make decisions on the core member's behalf.

6.3 Other attendees from relevant directorates may be invited to attend as and when appropriate.

6.4 Any additional individuals required to attend must be communicated to the Chair prior to the meeting they wish to attend.

7. Quorum

7.1 The meeting will be considered quorate providing the Chair or Deputy Chair is in attendance alongside at least two core members of the panel.

7.2 In the event that only two core members are in attendance one must be from operations and the other from the medical directorate.

8. Frequency

8.1 The panel will meet on a weekly basis, reviewing the incidents from the date of the previous SIG meeting.

8.2 It is expected that the meeting will take place on the Wednesday of each week.

8.3 Where unforeseen circumstances arise and the SIG meeting is unable to meet on the assigned day it is expected that the meeting will be re-arranged before the end of that working week.

8.4 Should this not be possible the Head of Quality, Governance and Assurance and the Clinical Advisor for Legal and Governance will:

- Review the reported incidents for that week
- Grade them according to the National Patient Safety matrix
- Complete the decision support tool
- Complete a synopsis of the incident
- Present the report to the Chief Quality Officer and Medical Director for the overall decision.

This will ensure a timely decision is made without further delay.

9. Key responsibilities

- 9.1 Review any outstanding incidents from the previous week. These will typically be incidents that required additional supporting material (quality assurance reports, staff statements etc).
- 9.2 Review all de-escalation requests submitted by Lead Investigators for approval.
- 9.3 Review all the relevant information provided relating to new incidents in support of the reported incident and agree on the outcomes of the decision support tool.
- 9.4 Any incidents that require additional supporting information should be risk assessed in relation to delaying the initiation of an investigation and/or immediate remedial action prior to agreeing to bring the incident back to the following meeting.
- 9.5 Seek assurance that urgent remedial actions will be taken to address the immediate safety of the patient(s) and/or staff to reduce risk of recurrence.
- 9.6 Documented any immediate remedial actions in a 72 hour report.
- 9.7 Commission the appropriate level of investigation required (depending on the decision support tool outcome).
- 9.8 Confirm the nomination of, and approve the person(s) to conduct the investigation. Ensure that they have been trained in investigation techniques, and that there is appropriate independence.

- 9.9 Receive assurance that contractual requirements for Duty of Candour are being discharged or that Being Open guidance is being considered. The SI Business Partner will be responsible for providing assurance regarding the SI's they are leading.
- 9.10 Receive assurance that the correct external notifications for serious incidents have been considered and followed, including statutory notifications to the Care Quality Commission.
- 9.11 Be responsible for informing the executive team and sector leads of decisions taken and any immediate patient or staff safety risks.
- 9.12 Highlight to the executive team incidents that need urgent attention or which may attract media attention, potential litigation or which may adversely impact on the Trust's registration or compliance with the Care Quality Commission requirements.
- 9.13 Ensure that any complaint, inquests or claims have been identified to ensure a collective and joint response from the Trust. All relevant departments (Legal Services and the Patient Experience's Department) must be informed that an incident is to undergo a formal investigation and who the point of contact is to be (Lead Investigator).

10. Process for Monitoring compliance with Terms of Reference

- 10.1 Minutes of the meetings will be disseminated to the executive team which will include attendance of core members.

11. Links to other quality forums

- Medicine Management Group
- Safeguarding Assurance Group
- Infection Prevention and Control Committee
- Control Services Clinical Governance Group
- Patient Safety Meeting

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- Executive Leadership Team
- Mortality Review Group

12. Review Date

12.1 All Terms of Reference will be reviewed annually.

72 Hour Initial Incident Management Review

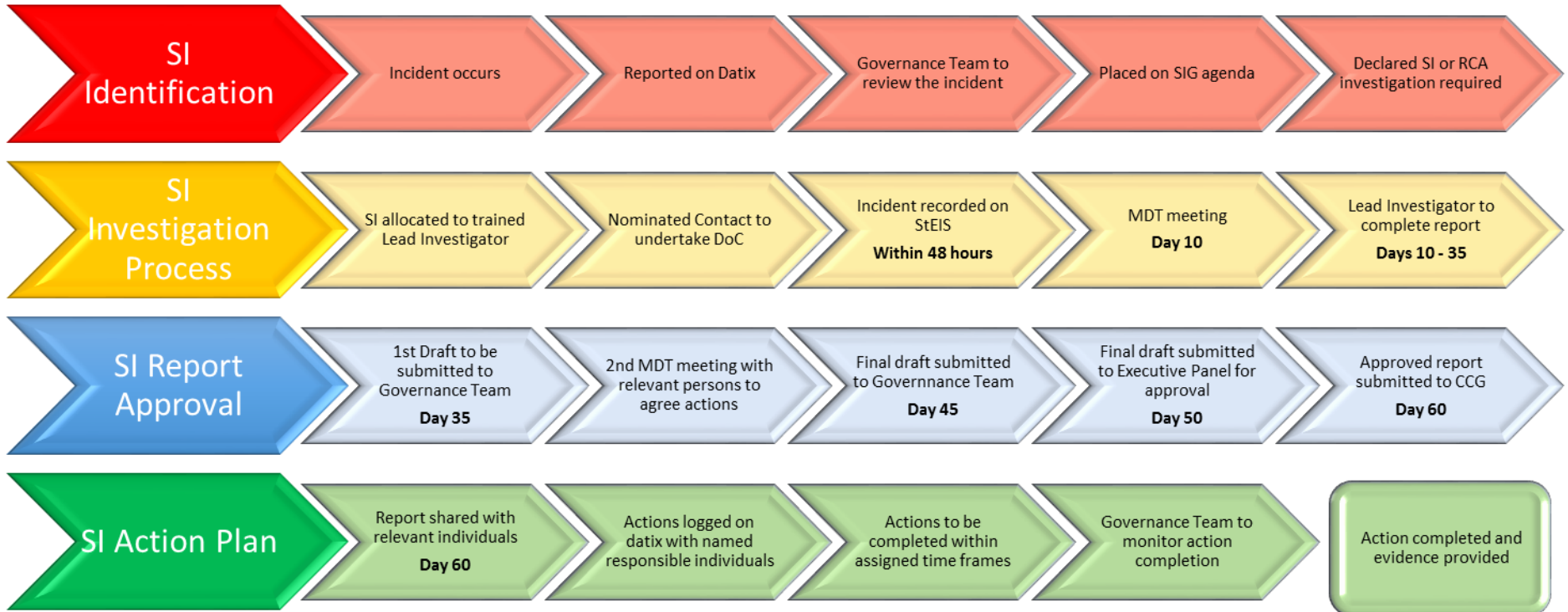
CONFIDENTIAL

SECTION 1 – THE INCIDENT	
Organisation	London Ambulance Service NHS Trust
Datix Incident reporting reference number	
StEIS Reference	
Date of Incident	
Time of Incident	
Type of incident	
Site and Location of incident	
Multi-agency involvement (Clearly state any other agencies involved or notified)	
<u>Brief Description of Incident</u> <i>Briefly describe what is known to have occurred</i>	
<u>Immediate action taken after the incident</u>	
SECTION 2 – The Patient	
Patients Borough of Residence or Post Code	

Patients GP Details	
Evidence of the Organisations compliance with the Duty of Candour and Being Open principles <i>(description of timely acknowledgement of the incident and of anticipated support to the patients involved, their relatives and staff)</i>	
SECTION 3 – OTHER INFORMATION	
Details of responsible Clinical Commissioning Group (e.g. Central London CCG)	
SECTION 4 – INITIAL INVESTIGATION FINDINGS	
This section outlines the findings of an investigation carried out within 72 hours of an incident. It may not reflect the later findings of a full and detailed investigation, but is intended to enable the need for urgent action to be taken where necessary and to inform and assist any further investigation that may be required	
1. Title and Designation of person(s) identified to liaise with patient or family regarding this SI	
2. Title and Designation of people involved with carrying out the initial investigation into this SI	
3. Did non-compliance with any key policies, procedures or practices play a part in this incident?	
4. Is there immediate evidence of any contributory factors in relation to	

<p>this SI?</p>	
<p>5 Is there immediate evidence of root causes in relation to this SI?</p>	
<p>6 Are there any issues which you have immediately identified which require further investigation?</p>	
<p>7 Are there any immediate actions that need to be taken either in relation to this SI or to avoid/minimise repetition?</p>	
<p>8 Recommendations (ensure these are clear, achievable and measurable)</p>	

Details of Person completing the form	
Name:	
Title/Designation:	
Contact Details:	



LONDON AMBULANCE SERVICE NHS TRUST

XXXXXXXXX DIRECTORATE

Serious Incident Statement

To [Insert Lead Investigator Here] **Date** [Date of completion]

From [Insert Your Name Here] **Reference** [Datix Ref]
[StEIS Number]

Location Station/Department/Directorate

Date

Event No: [CAD Number]

During the completion of your statement please answer the following questions: