South East Coast Ambulance Service NHS
NHS Foundation Trust

Serious Incident Policy

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Name of originator/ author:	
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1 Statement of Aims and Objectives

1.1. Serious Incidents in healthcare are relatively rare but when they do occur the Trust has a responsibility to ensure that there are measures in place for safeguarding patients, protecting staff and contractors, managing NHS resources and the minimizing impact on organisation's reputation. This includes the responsibility to learn from Serious Incidents and to reduce the risk of them reoccurring.

1.2. The Trust is committed to complying with the legislation and standards that organisations are required to uphold and have a procedure in place for the reporting, investigation and management of Serious Incidents allowing the organisation to learn, share valuable lessons and continually improve systems and processes. This will assist the Trust to deliver high quality, safe, accountable healthcare, minimising risks to patients, clients, staff and maximising available resources.

1.3. The objectives of this policy are as follows;

- Identify the responsibilities of individual postholders and groups in response to Serious Incidents.
- Define what constitutes a Serious Incident.
- Ensure the Trust prioritises the management and governance of Serious Incidents.
- Maintain consistency in approach across the Trust.
- Ensure the Trust acts in a transparent manner.
- Involve and fully inform service users, stakeholders and staff and act in a manner consistent with Duty of Candour.
- Ensure there is an emphasis on learning and action is taken to minimise reoccurrence.
- Share learning across the Trust and when appropriate the Ambulance Service and wider NHS.

2 Definitions

2.1. **Serious Incidents**: events 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. Serious Incidents include an act or omission that results 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, "Never Events", incidents that prevent (or threaten to prevent) an organisation's ability to continue to deliver an acceptable quality of healthcare services and incidents that cause widespread public concern resulting in a loss of confidence in healthcare services (NHS England, 2015). There is no definitive list of events/incidents that constitute a Serious Incident.

2.2. **Incident:** Any event or circumstance that did or could lead to unintended or unexpected harm, loss or damage to Trust services, patients, carers, visitors, staff, other members of the public, premises, property, other assets, information, or any other aspect of the organisation. They may involve any number of different factors, e.g. injury, damage, loss, fire, theft, violence, abuse, accidents, ill health, disruption to services etc.

2.3. **Appendix A** identifies the types of incidents (with a working definition) that could be sufficiently serious to lead to a Serious Incident.

2.4. **Hazard:** Something with the potential to cause injury, ill health, harm, damage or loss and may include substances, equipment, or a work practice.

2.5. **Accident:** An unplanned and uncontrolled event that has led to harm to people, property or process. Examples include incidents that have caused injury, ill health, loss or damage to equipment.

2.6. **Near Miss:** Any event, circumstance or situation that could have resulted in an incident but did not, due to either chance or well-timed intervention.

3 Responsibilities

3.1. **The Lead Commissioner**: is responsible for monitoring the Trust's Serious Incident reporting process and the quality of Serious Incident Investigations completed and submitted to them, on behalf of all local commissioners the Trust provides services for. They are responsible for closing Serious Incidents, and for monitoring swift completion of action plans.

3.2. **The Local Commissioner**: will monitor all Serious Incident information provided to them by the Trust and the Lead Commissioner for their locality. They are responsible for raising any concerns within a timely manner to the Trust and the Lead Commissioner.

3.3. **The Trust Board**: will receive information on Serious Incidents in order to seek assurance in relation to the Serious Incident process. It will also consider the overall safety of the organisation based upon the trends and themes within reports.

3.4. **The Quality & Patient Safety Committee**: is directly accountable to the Board and seeks to provide assurance on systems and procedures relating to patient safety. The Committee will receive reports relating to the Serious Incident process and issues highlighted through investigations in order to provide assurance to the Board, or to raise concerns.

3.5. **The Serious Incident Group:** is directly responsible for overseeing the Serious Incident process from inception to completion and for identifying recommendations and to monitor and provide Board assurance in relation to the reporting and investigation of Serious Incidents involving the Trust.

3.6. The Serious Incident Group will also:

- Provide strategic leadership and direction on all matters relating to the Serious Incident and have responsibility for the management and co-ordination of Serious Incidents.
- Ensure robust systems are in place and operating effectively for the identification, assessment and investigation of all potential Serious Incidents, both within the organisation and for independent contractor services.
- Be responsible for the decision to report an incident as a Serious Incident and agree any downgrade requests.
- Receive and approve the final investigation report and associated action plan and to be assured that the root cause of the incident has been established and learning has been realised.
- Sign off final reports and action plans.
- Monitor the progress and timely completion of the action plan
- The Serious Incident Group will also seek to obtain assurance that recommendations which have been implemented following learning and feedback of findings are sustained.

3.7. **The Deep Dive Mortality & Morbidity Group** will review SI themes on a quarterly basis. The SI Lead will provide data and investigation reports on emerging themes to allow a deep-dive into root causes and learning from incidents.

3.8. **The Chief Executive Officer**: as Accountable Officer, has overall responsibility on behalf of the Trust Board for risk management, including the management of Serious Incidents. The Chief Executive delegates specific roles and responsibilities to the appointed executive director/senior managers to ensure incident management is co-ordinated and implemented equitably to meet the Trust's objectives.

3.9. **The Executive Director of Nursing & Quality**: has executive responsibility for Serious Incidents, Duty of Candour and Freedom to Speak Up and will ensure there is an open and transparent culture throughout the incident process.

3.10. **Executive Directors**: have unitary responsibility for the safety of services. Each Executive Director is also responsible for the safety of the services within their remit and as such will take the lead in the decision to declare a Serious Incident and approving the final report and recommendations.

3.11. **The Head of Patient Safety**: is responsible for ensuring this policy is in line with government legislation, Department of Health and regulatory policy and frameworks. They are also responsible for ensuring the Serious Incident process is not isolated and has integration with incident reporting processes and evaluation of patient experience and clinical outcomes.

3.12. **The Serious Incident Lead**: is responsible for monitoring compliance with timescales for investigation and submission of Reports and Action Plans to the Lead Commissioner. They are also responsible for monitoring the quality of investigation reports and action plans, monitoring the completion of the action plans and for identifying themes and trends of reported SIs.

3.13. **The Serious Incidents Managers:** are responsible for co-ordinating and overseeing the investigation process, supporting investigators to use root cause analysis (RCA) methodologies, ensuring the Duty of Candour requirements are met and that learning from incidents is identified.

3.14. **Safeguarding**: a representative from the Safeguarding team is a member of the Serious Incident Group. All declared SIs are notified to the Safeguarding Lead once entered onto StEIS (Strategic Executive Information Service).

3.15. **Investigating Managers:** responsible for completing a Root Cause Analysis investigation and agreeing an action plan with relevant staff or groups using the methodology they are trained in. SI reports should be submitted to the internal groups for Trust sign off to allow submission for closure within timeframes defined in the National SI Framework.

3.16. **All staff:** have a responsibility for identifying, reporting and managing incidents and implementing learning from them. This includes improving the delivery/quality of services through the implementation of corrective/mitigating actions and preventative action plans through lessons identified. If necessary support to report an incident is available from the Trust's Freedom to Speak Up (FTSU) Guardian.

4 Principles and Process

Approach

4.1. The Trust promotes a culture that fosters learning and improvement whilst encouraging accountability by committing to an open and fair culture and promoting a non-punitive approach to the investigation of incidents reported. The Trust can learn many important lessons through an open approach, which would not otherwise be learned where blame is apportioned or staff feel under threat through incident reporting.

4.2. The Trust recognises that a root cause analysis approach to investigating incidents focusses on the systems, processes, and failures that allow errors to occur. The priority is to identify root causes so that improvements can be made to eliminate/reduce the chance of reoccurrence. This policy is not primarily concerned with the performance and disciplining of staff

4.3. Staff will not be subject to disciplinary action or suffer any material loss or disadvantage, if they have made an honest mistake. See Appendix B

4.4. If during a Root Cause Analysis (RCA) Investigation it becomes clear that an individual has acted contrary to the Guiding Principles of Human Error (Appendix B) a disciplinary investigation may be required. The individual involved must be removed from the SI investigation process and proceed down the disciplinary route. The timeline within the RCA will still contain enough data in relation to the individual's actions so that the patient journey can still be described accurately. There should be no association between the RCA and the disciplinary and information relating to the disciplinary should be kept separate.

4.5. An SI investigator **must never be** assigned to also be the investigator of any linked disciplinary investigation.

Process

4.6. The Trust operates an electronic incident reporting system for all incidents, including Serious Incidents. On submission of the report form an automatic notification is provided to key individuals, such as the line manager, or responsible lead to ensure that prompt and appropriate support is provided. All Trust staff must be able to access this system.

4.7. Where an incident relates to concerns raised by non-Trust staff (members of the public or clinical staff from external organisations) this must be raised on the electronic incident reporting system on their behalf by the member of staff receiving notification of the incident.

4.8. It is the responsibility of all staff to report any adverse incidents, potential incidents (i.e. near miss) and all identified hazards and risks. In all cases, reports must be made without delay on the electronic reporting system. All incidents must be recorded electronically within 24 hours of the incident.

4.9. Sub-contractors and external consultants working on behalf of the Trust are equally required to report all adverse incidents. If staff are unable to access the electronic system, they will need to seek assistance from a Trust employee. Inability to access the electronic system is not an explanation for failing to report incidents. If necessary, support to report an incident is available from the Trust's FTSU Guardian.

4.10. It is essential that potential incidents (near misses) are also reported using the electronic system in order to maintain the Trust's proactive approach to both clinical and non-clinical risk management.

4.11. If, at the time of identifying the incident, the member of staff thinks the incident reaches the threshold of a serious incident then it must be reported to the responsible director (or their nominated deputy) within one working day. The responsible director/deputy will make the decision at this stage whether to identify the incident as a Serious Incident and implement any necessary remedial action to prevent further risk or reoccurrence. The director/deputy is then responsible for alerting other Board colleagues if this is considered necessary.

4.12. On receipt of the electronic incident report the Risk Department will review the risk rating and actions to ensure they are proportionate to the level of risk. The Risk Department will also forward any additional paperwork that may be required for additional reporting.

4.13. The Risk Department will review all possible Serious Incidents and will also act as a second check for those that may have been declined by Executive Directors. If the reviewer considers the incident was sufficiently serious at the time to have been reported as a Serious Incident, they will inform and seek advice from a clinical Director (or their nominated deputy) and refer the incident to the Serious Incident Group.

4.14. Once incidents have been identified as a Serious Incident they can only be de-escalated with the involvement of the Lead Commissioner, Responsible Executive and the Chair of the Serious Incident Group. The Lead Commissioner has the final decision to de-escalate.

Incident Grading

4.15. As part of the electronic recording all incidents must be scored to establish a base line risk rating. In line with NHS England guidance on grading, the Trust uses the same scoring matrix for risks, incidents and Serious Incidents. This is illustrated in the following matrix:

Table 1: Incident Grade = Consequence x Likelihood of recurrence

		Likelihood				
Impact		**Rare**	**Unlikely**	**Possible**	**Likely**	**Almost certain**
Negligible	1	2	3	4	5
Minor	2	4	6	8	10
Moderate	3	6	9	12	15
Major	4	8	12	16	20
Catastrophic	5	10	15	20	25

The level of investigation will be dependent upon the risk rating and the type of incident/risk.

4.16. Whilst there is no automatic score within the risk matrix to trigger an incident being declared as a Serious Incident consideration should be given for all risks, arising out of an incident, viewed as serious enough to be placed on the corporate risk register.

Serious Incident Investigation Level

4.17. Any incident that is regarded as sufficiently serious to be declared as a Serious Incident will be investigated using a comprehensive report

template. There may be occasion when a concise template may be appropriate, by agreement with the SI Lead. The concise template will be used for Internal RCA reports that do not meet the SI criteria and will be managed under the same process.

4.18. In rare instances, timely completion of a Serious Incident investigation may not be possible. In accordance with the National Framework, examples of such include:

- Awaiting outcomes of court proceedings
- Awaiting Coroner Inquests
- Awaiting forensic post-mortem findings
- Awaiting toxicology results
- Awaiting completion of an external review
- In direct response to a Police request under Memorandum of Understanding

Serious Incident Reporting

4.19. The SI Procedure supports this policy by identifying the expectations for the reporting and investigating of Serious Incidents.

4.20. It is the responsibility of the Serious Incident Lead to ensure any legislative, national guidance or commissioning changes are reviewed and, if appropriate, incorporated into the SI Procedure.

Reporting to External Agencies

4.21. All Serious Incidents must be declared to the Lead Commissioner. It is the responsibility of the Serious Incident Lead to ensure that this is undertaken.

4.22. Where a member of Trust staff is involved in, witnesses or subsequently discovers an incident caused by or occurring in another NHS Trust or healthcare organisation it is the responsibility of the Head of Patient Safety or SI Lead to ensure the external organisation is informed of incidents occurring on their premises, involving their staff or in relation to their care. The Trust will cooperate with or lead investigations involving other agencies as multi-agency SIs.

4.23. The Trust is required to regularly report all patient safety incidents to NHS Improvement Patient Safety Division. This is undertaken by scheduled upload from the electronic system to the National Reporting and Learning System.

4.24. Where required, through local or national protocol, when other organisations need to be informed the Trust's SI Lead or Head of Patient Safety will advise and ensure the external agencies and organisations are informed.

Never Events

4.25. Never Events are serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented. The national list of Never Events is published by NHS England and is updated and reviewed as necessary and staff will need to ensure they are familiar with the up to date list before deciding an incident does not qualify as a Never Event. The Serious Incident Group will report all Never Events to the executive board.

Duty of Candour & Confidentiality

4.26. Duty of Candour must be enacted where actual harm has occurred to a patient that has been measured as moderate, severe or death. It is the responsibility of the investigating manager to ensure this is actioned and that the family/relatives are kept informed at relevant stages of the process.

4.27. Staff involved in the incident must also be open and honest with their colleagues, managers and relevant organisations and take part in reviews and investigations (when requested) and also be open and honest with their regulators.

4.28. All media enquiries should go through the Trust Communications Team. Any enquiries from the media will be answered as openly as possible but without compromising the confidentiality of those involved.

4.29. Rarely there may be an incident that is sufficiently serious but, due to the confidentiality of the individuals involved, it cannot be managed through the normal Serious Incident process. This could include incidents involving allegations against Trust Board members, or other sensitive issues. These should be exceptional and rare. The decision to manage the incident outside of the process must take place with the involvement of the Chief Executive Officer. The rationale for the decision should be recorded and discussed with the Chair.

5 Competence

5.1. All members of staff appointed as the Investigating Officer will have received appropriate training.

5.2. Where the investigating officer does not feel adequately experienced then support or assistance should be sought. This is particularly important for Duty of Candour responsibilities.

6 Monitoring

6.1. The Serious Incident Group has devolved responsibility for ensuring adherence to this policy and will oversee a set of metrics to monitor the operational management of Serious Incidents and quality of RCA reports (via the Closure Checklist). These are identified in Appendix D.

6.2. The SI Group will identify themes and trends in incidents and SIs and learning from them. The Deep Dive Group will undertake an analysis of trends on a quarterly basis and any identified trends will be escalated to the Quality & Patient Safety Committee and the Executive Management Board through a report.

6.3. An annual report will be produced by the Chair of the Serious Incident Group which will report on overall compliance and themes.

7 Audit and Review

7.1. The Serious Incident process will be audited at least every three years by internal audit to ensure systems and processes are as effective as possible.

7.2. All policies have their effectiveness audited by the responsible Management Group at regular intervals, and initially six months after a new policy is approved and disseminated.

7.3. Effectiveness will be reviewed using the tools set out in the Trust's Policy and Procedure for the Development and Management of Trust Policies and Procedures (also known as the Policy on Policies).

7.4. All changes made to this policy will go through the governance route for development and approval as set out in the Policy on Policies.

7.5. This policy will be reviewed after 12 months or sooner if new legislation, codes of practice or national standards are introduced.

8 Equality Analysis

8.1. The Trust believes in fairness and equality, and values diversity in its role as both a provider of services and as an employer. The Trust aims to provide accessible services that respect the needs of each individual and exclude no-one. It is committed to comply with the Human Rights Act and to meeting the Equality Act 2010, which identifies the following nine protected characteristics: Age, Disability, Race, Religion and Belief, Gender Reassignment, Sexual Orientation, Sex, Marriage and Civil Partnership and Pregnancy and Maternity.

8.2. Compliance with the Public Sector Equality Duty: If a contractor carries out functions of a public nature then for the duration of the contract, the contractor or supplier would itself be considered a public authority and have the duty to comply with the equalities duties when carrying out those functions.

9 Associated Documentation

9.1. The following documents are related to this Serious Incident Policy.

- Risk Management Strategy
- Serious Incident Procedure
- Complaints Policy
- Being Open and Duty of Candour Policy
- Risk Register and Associated Risk Assessments and Action Plans
- Board Assurance Framework
- Freedom to speak up: Raising Concerns (whistleblowing) Policy
- Capability Policy
- Disciplinary Policy
- Driving Standards Policy
- Security Policy
- Counter Fraud Policy
- Safeguarding Policy
- Policy for the Identification and Sharing of Learning

10 References

NHSE Serious Incident Framework 2015

National Reporting and Learning System Website
http://www.npsa.nhs.uk/nrls/reporting/what-is-a-patient-safety-incident/

NHSE Never Events
https://www.england.nhs.uk/patientsafety/never-events/

Reporting injuries, diseases and dangerous occurrences in health and social care: Guidance for employers
http://www.hse.gov.uk/pubns/hsis1.pdf

2017/1818 NHS Standard Contract
https://www.england.nhs.uk/nhs-standard-contract/17-18/

CQC Regulation 20 Duty of Candour

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

Serious Incident Framework- frequently asked question (March 2016)
https://improvement.nhs.uk/uploads/documents/serious-incdnt-framwrk-faqs-mar16.pdf

Appendix A: Types of Incidents (with working definition)

Patient Safety Incident: Any unintended or unexpected incident that could have or did lead to harm (e.g. injury, suffering, disability or death – physical, psychological or social) for one or more persons (adult and child) receiving NHS-funded healthcare, e.g. an occurrence, procedure or intervention which has or could have given rise to actual injury, or to an unexpected or unwanted effect.

Medication Incidents: Any incident involving a medicine. The Trust Medicines Management & Quality Team provides advice and support for managing and reporting medication incidents. In the event of the Trust being notified of a controlled drugs (CD) incident, this will be escalated to the Controlled Drugs (CDs) Accountable Officer.

Sudden Unexpected Death: Unexpected deaths are where a death has not been considered as the outcome. There are a number of circumstances where a death is reportable to the coroner and cases that meet the coroner threshold must be part of the incident process. These are;

- cause of death is unknown
- death was violent or unnatural
- death was sudden and unexplained
- person who died was not visited by a medical practitioner during their final illness
- medical certificate isn't available
- person who died wasn't seen by the doctor who signed the medical certificate within 14 days before death or after they died
- death occurred during an operation or before the person came out of anesthetic
- medical certificate suggests the death may have been caused by an industrial disease or industrial poisoning

Maternal Deaths: A maternal death is defined internationally as a death of a woman, during or up to six weeks (42 days) after the end of pregnancy (whether the pregnancy ended by termination, miscarriage or a birth, or was an ectopic pregnancy) through causes associated with, or exacerbated by, pregnancy (World Health Organisation 2010). A late maternal death is one which occurs more than six weeks but less than one year after the end of pregnancy.

Health & Safety Incident: An unplanned and uncontrolled event that has led to or could have caused injury, ill health, harm to persons, damage to equipment or loss. Some accidents at work constitute an injury or a dangerous occurrence reportable under RIDDOR.

Buildings Incident: Where an incident occurs due to defects and failures in Trust Estates and Facilities:

COSHH (Control of Substances Hazardous to Health): COSH is the legal framework applied to most substances that are hazardous to health.

Medical Devices: An incident involving the use of medical equipment. The Head of Risk Management will advise the Medicines and Healthcare Products Regulatory Agency (MHRA) and ensure that any devices involved are isolated for inspection. The manufacturer/supplier and will notify other Ambulance Trusts as necessary. Following the failure of a medical device the item of equipment must be immediately withdrawn from service and held securely for inspection.

Violence/Abuse/Discrimination: All incidents of discrimination are reportable, including social, racial, religious, sexual, ethnic or age-related discrimination.

Fire Incident: Any incident involving a fire or any incident where the fire alarm sounds requiring evacuation (unplanned).

Security Incident (including Information Governance breaches): Any incident where a breach or a lapse of security is the dominating factor, e.g. theft or vandalism, premises window left open overnight, or data security incidents, e.g. missing health records, theft of a PC or unauthorised disclosure of patient identifiable information.

Information Technology (IT) incidents: In line with Health and Social Care Information Centre (HSCIC) Information Standards Board (ISB) guidelines and standards, IT systems implemented in healthcare settings must be delivered, deployed and operated in an acceptably safe manner for patients. Information technology incidents/failures, which has or has the potential to put patients at risk will be reported as a Serious Incident, this may include:

- Failure or loss of clinical systems
- Loss of clinical data with no access to back up
- Data corruption, such as incorrect merging of clinical records
- Inappropriate access to clinical records;
- Misuse of access rights, such as using smartcard to inappropriately view clinical records

Infection Control Incident: MRSA Bacteraemia/Clostridium Difficile and outbreaks.

All patient safety incidents will be assessed to see if it meets the criteria for a Serious Incident. The assessment and reporting process is detailed in the supporting procedure.

Appendix B: Open Culture – Honest Mistake – Human Error

Staff will not be subject to disciplinary action or suffer any material loss or disadvantage when an incident is the result of human error.

Guiding Principles when assessing human error:

1. The intention of the staff member was to do their best for the patient.
2. The member of staff can offer an explanation/personal logic to their behaviour.
3. Another body of individuals possessing the same level of skill and experience in the same set of circumstances would be likely to behave in the same way.
4. The absence of criminal behaviour.
5. The absence of patient abuse.
6. The absence of gross negligence.
7. The absence of the intention to cause harm to the patient.
8. The absence of a drug or alcohol problem within the member of staff.

Where there is ambiguity in response to some of these questions, the decision is based on the following guiding principle:

The purpose of incident reporting is to identify areas for learning in order to increase safety for patients. Therefore, the guiding principle when there is ambiguity relating the possible responses by the organisation to an incident should be to consider which process offers the organisation the greater level of learning. This will invariably be a systems investigation looking at contributory factors and not focusing on the individuals that made the error.

Appendix C: Metrics

Reported SIs	Monthly Report
Submission to STEIS within 2 Days of identification	Monthly Report
72 hr report submission	Monthly Report
Submission of completed investigation to CCG Closure Group within SI Framework timescales	Monthly Report

Document Control

Committee to approve	JPPF	
Version No. V1.0111	Final	Date: 16/07/2019

Approval

Person/ Committee	Comments	Version	Date
SIG	1st Draft for subject experts	V0.01	15/8/2017
Head of Risk (Interim)	Review	V0.02	20/10/2017
Staffside	Review Prior to Staff Consultation Included additional clause relating SI investigators and linked disciplinary investigations	V0.02	1/11/2017
CCG	Review	V0.02	Nov 2017
JPF	Review. Amendments requested	V0.03	5/1/2018
SMT	For Approval. Amendments requested	V0.04	6/4/2018
SMT	For approval	V0.05	1/5/2018
SMT/JPF	For approval following comments	V0.06	6/6/2018
NHSI	Review for Freedom to Speak Up	V.0.07	25/6/18
SMT/JPF	For Approval	V0.07	25/7/2018
	Published	V1.0	25/7/2018
SI Lead	Review – circulated to SIG for comment	V1.01	10/06/2019
SIG	For approval	V1.02	19/06/2019

Circulation

Records Management Database	Date: 16/07/2019
Internal Stakeholders	
External Stakeholders	

Review Due

Manager		
Period	12 months or sooner if new legislation, codes of practice or national standards are introduced	Date: 16/07/2020

Record Information

Security Access/ Sensitivity	Public Domain
Publication Scheme	Yes / No
Where Held	Records Management database
Disposal Method and Date	

Supports Standard(s)/KLOE

	Care Quality Commission (CQC)	**IG Toolkit**	**Other**

Criteria/KLOE:	Name core service area and CREWS elements		