East of England Ambulance Service NHS Trust

Serious Incident Policy

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Document Status:	Approved
Version:	V7.0

DOCUMENT CHANGE HISTORY		
Initiated by	**Date**	**Author (s)**
Serious Incident Panel	06/12/2013	Risk Manager
Version	**Date**	**Comments (i.e., viewed, or reviewed, amended approved by person or committee)**
Draft V0.1	April 2010	General Manager Patient Services
V1.0	September 2010	Approved by Executive Management Team
V1.1	February 2015	Amended post restructure and in line with the national SI framework

Version	Date	Comments (i.e., viewed, or reviewed, amended approved by person or committee)
V2	February 2015	Approved by Clinical Quality and Safety Group
V2.1	January 2016	Amendments in line with National Framework
V3.0	March 2016	Approved by Executive Leadership Board
V4.0	May 2017	
V4.1	October 2018	Minor amends to terminology, no process change.
V5.0	June 2019	Approved at MAG
V5.1	January 2020	Approved
V6.1	July 2020	Approved
V7.0	January 2022	Approved by CRG

Document Reference	NHS Patient Safety Strategy 2019Serious Incident Framework (2015), NHS England Health and Social Care Act 2008 (Regulated Activities) Regulations 2010; Regulation 19. Directorate: Clinical Quality and Improvement
Recommended at Date	Patient Safety and Experience Group 24 May 2022
Approved at Date	Compliance and Risk Group 20 June 2022
Valid Until Date	June 2025
Equality Analysis	Completed August 2020
Linked procedural documents	Management of Incidents Policy Duty of Candour (formerly Being Open) Policy Claims Policy Complaints Policy Whistle-blowing Policy Risk Management Strategy Learning from Deaths Policy
Dissemination requirements	All Managers and staff, via email and intranet
Part of Trust's publication scheme	Yes

The East of England Ambulance Service NHS Trust has made every effort to ensure this policy does not have the effect of unlawful discrimination on the grounds of the protected characteristics of: age, disability, gender reassignment, race, religion/belief, gender, sexual orientation, marriage/civil partnership, pregnancy/maternity. The Trust will not tolerate unfair

discrimination on the basis of spent criminal convictions, Trade Union membership or non-membership. In addition, the Trust will have due regard to advancing equality of opportunity between people from different groups and foster good relations between people from different groups. This policy applies to all individuals working at all levels and grades for the Trust, including senior managers, officers, directors, non-executive directors, employees (whether permanent, fixed-term or temporary), consultants, governors, contractors, trainees, seconded staff, homeworkers, casual workers and agency staff, volunteers, interns, agents, sponsors, or any other person associated with the Trust.

All Trust policies can be provided in alternative formats.

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1. Introduction

Serious incidents in healthcare are relatively uncommon but when they do occur, the Trust, as an NHS healthcare provider, has a responsibility to ensure that there are measures in place for safeguarding patients, staff, third parties and contractors, property, NHS resources and its reputation. This includes the responsibility to learn from these serious incidents in order to minimise the risk of them happening again.

The East of England Ambulance Service NHS Trust (EEAST) recognises the importance of developing the safety culture within the Trust and it appreciates the significance of effective serious incident management. Serious incident (SI) reporting and investigation is a fundamental tool of risk management, the aim of which is to collect vital information and evidence during an investigation, which will help to facilitate wider organisational learning. If SIs are not properly reported or managed, they may result in a loss of public confidence in the Trust and a loss of assets which could have an adverse effect on services to patients.

Serious incident investigation should be undertaken supportively and with a fair blame approach. Members of staff will not and must not be punished for genuine errors where it is identified that there were systematic issues leading to the incident occurring. Members of staff must be supported throughout the investigation, in order that the most open and transparent conversations can take place to achieve the richest of learning from the investigation.

2. Purpose

This policy has been developed in line with NHS England's Serious Incident Framework (2015). It is recognised that during 2022, the NHS Patient Safety Incident Response Framework (PSIRF) will begin to be implemented nationally and this will supersede the SI process.

The purpose of this policy is to make clear the serious incident management process, from incident recognition through to completion of the actions and closure.

Successful implementation of this policy has the overarching aim of reducing patient harm, preventing reoccurrence of incidents, and improving safety.

3. Duties

3.1 Lead Commissioner

The lead commissioner is responsible for monitoring the Trust's SI reporting process, the quality of serious incident investigations completed, compliance with Duty of Candour, and completion of action plans, on behalf of all local commissioners the Trust provides services for. The lead commissioner will report compliance of the above measures quarterly.

3.2 Integrated Care System (ICS) Quality Leads

The ICS Quality lead 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, the local CCGs and the lead commissioner.

3.3 The Trust Board

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 the reports.

3.4 Quality Governance Committee

The Committee is directly accountable to the Board and seeks to provide assurance relating to systems and procedures relating to patient safety. The Committee will receive reports relating to the SI process and issues highlighted through investigations in order to provide assurance to the Board, or to raise concerns.

3.5 Patient Safety and Experience Group (PSEG)

The PSEG is directly accountable to the Compliance and Risk Group and has decision-making powers devolved from the Board. Its purpose is to promote the delivery of safe, effective patient care outcomes and ensure patient and carers' views are actively sought, considered and acted upon and to ensure that appropriate

mechanisms are in place to deliver high quality care. The PSEG will receive reports from the patient safety lead on behalf of the SI Panel on SIs including trends, themes, issues to note, and lessons learned where appropriate.

3.6 Serious Incident Panel

The Serious Incident Panel is directly responsible to oversee the Serious Incident process from inception to completion of recommendations as outlined in the action plan and to monitor and provide Board assurance in relation to the reporting and investigation of Serious Incidents involving the Trust. It is directly accountable to the Executive Leadership Board. The Serious Incident Panel will also:

- Provide strategic leadership and direction on all matters relating to the Serious Incident.
- 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.
- 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.
- Monitor the progress and timely completion of the action plan
- The Serious Incidents Panel will also seek to obtain assurance that recommendations which have been implemented following learning and feedback of findings are sustained.

3.7 Chief Executive Officer

The Chief Executive, as Accountable Officer, has overall responsibility on behalf of the Trust Board for risk management, including the management of serious incidents.

3.8 Medical Director

The Director is responsible for overseeing the arrangements for clinical governance. This will provide assurance of the quality of clinical care and patient safety.

The Director is a member of the SI Panel that are responsible for confirming an incident as a serious incident.

3.9 Patient Safety Lead

The patient safety lead is responsible for leading the patient safety team in the timely identification of potential serious incidents. When such incidents are identified, they shall be escalated to the safety and risk lead so that a decision can be made on whether the criteria, as per the NHSE SI Framework (2015), is met.

The patient safety lead will be responsible for the generation of comprehensive final SI investigation reports, prior to sending to the relevant STP lead and lead commissioner. This function will be support by other senior clinical managers when required.

The patient safety lead is also responsible for gathering data and preparing reports to provide to the relevant groups and committees within the organisational governance structure. The reports will aim to provide assurance on patient safety within the organisation and any actions being taken to improve the position.

The patient safety lead will use data on known trends and themes of serious incidents to identify organisational risk to patient safety and coordinate an appropriate response to mitigate such risks.

The patient safety lead will also be the main point of contact between the Trust and the lead commissioner for matters relating to the management of serious incidents and quarterly updates.

3.10 Safeguarding Lead

The Trust Safeguarding Lead has a responsibility to ensure that all safeguarding matters are dealt with appropriately and that the Local Safeguarding Adults Board and Local Safeguarding Children's Board (or safeguarding partnership in localities where two, or more, Boards have merged) are informed of any relevant matters arising from serious incidents. The safeguarding lead will be advised by the safety and risk lead where an incident relates to a safeguarding matter.

3.11 Patient Safety Team

The patient safety team is responsible for reporting serious incidents on the national database (STEIS) which is monitored by the

CCGs within the region. Once the incident is reported, the team will pass all details of the incident to the investigations team to continue the investigations process.

This team comprises of patient safety specialists, safety advisors and safety coordinators who are assigned serious incidents to investigate. Safety team members will ensure that appropriate people are invited to the roundtable review in order that there is a balanced holistic view of the events, identification of excellence and service or delivery issues that need to be addressed. Throughout the investigation, the IO will maintain regular contact and provide feedback to staff involved in the incident and to ensure appropriate support is made available where appropriate.

Patient safety specialists are responsible for the discharge of the organisational Duty of Candour, in line with Regulation 20 of the Health and Social Care Act.

Once the report is complete, it will be reviewed by the SI panel and submitted to the CCG if approved or returned to the patient safety team if further work is required to maximise the learning

The patient safety team is then responsible for ensuring that the final report is approved by the safety and risk lead prior to submitting to the lead commissioner and STP lead within the 60-day timeframe.

3.12 Trust Managers

Trust managers will ensure that all staff understand how to identify and report all incidents appropriately.

When an incident has taken place, the appointed Trust manager will ensure that staff, patients, carers and relatives will receive support following an incident.

All staff involved in a serious incident, shall be assigned a welfare officer as soon as is practical (if required), following the leading operations manager (LOM), assistant general manager (AGM), or general manager (GM) receiving notification that the incident has been reported as such.

Where an incident involves medicine or equipment, the appointed manager will ensure that they are quarantined, labelled, and stored as appropriate

3.13 Welfare Officers

The welfare officer is a point of contact for staff members involved in an SI to receive pastoral support and updates into the progress of the investigation and any developments within.

Any member of staff involved in a serious incident should be made aware who their welfare officer is as soon as possible after the SI is declared, as well as the IO leading the investigation, for information to be easily shared where appropriate.

The welfare officer should be well briefed as to the SI process so that they can inform staff members of what to expect. Whilst the welfare officer can provide pastoral support to members of staff directly, they should also have a repository of sources available to them, to signpost staff as required.

There is a package of information available to welfare officers and this can be accessed by contacting the patient safety team or via the patient safety section of the intranet.

It is expected that, prior to providing welfare support to staff involved in Sis, the welfare officer should have undertaken the familiarisation package available.

It should be noted that welfare officers can be any member of staff within the organisation and does not need to be a manager.

3.14 All Staff

All staff employed by EEAST share the responsibility of highlighting any incident that is a cause for concern and which may need to be considered as a potential serious incident. Staff or workers should report any such concerns to a line manager, via the incident reporting system, without delay. Supporting documentation should also be passed on without delay.

Staff involved in a serious incident are required to fully participate in an investigation openly and honestly, in order to assist with establishing the facts and the reasons for the incident, and to

identify ways in which these lessons can be learned to avoid recurrence. They will be fully supported by a welfare officer and their local management team during the investigation.

3.15 Consultation and Communications with Stakeholders

The Policy has been discussed and determined in conjunction with members of the SI Panel. Previous versions have been shared with Commissioners for comment. The process changes have been discussed with the lead commissioner who approved the changes.

4. Definitions

4.1 Serious Incident Criteria

A serious incident is defined as an incident that occurred in relation to an NHS funded service and care resulting in one or more of the following:

- Acts of omission or commission occurring as part of NHS funded healthcare that result in:
    - **Unexpected** or **avoidable** death of one or more people, where the death is directly caused by the incident that has occurred. This includes suicide/self-inflicted death
    - **Unexpected** or **avoidable injury** to one or more people that has resulted in **serious harm**
    - Unexpected or avoidable injury to one or more people that requires further treatment by a healthcare professional in order to prevent either:
        - The death of the service user; or
        - Serious harm
- A Never Event
- An incident or series of incidents that prevents, or threatens to prevent, the organization's ability to continue to deliver an acceptable quality of healthcare services. This includes:
- Serious data loss
- Serious property damage
- Serious security breach
- Major loss of confidence in the service, including prolonged adverse media coverage or public concern about the organisation

- Actual or alleged abuse; sexual, physical, psychological or acts of omission which constitute neglect, where;
- Healthcare providers failed to take appropriate action to safeguard the individual
- Inappropriate enforcement/care provision under the Mental Health Act (1983) and/or the Mental Capacity Act (1995)
- A 'near miss' can also be reported if there was a high potential for severe harm, and there appears to be a system or process issue that if left unresolved, could cause a further incident.

See Appendix A for a list of examples of incidents meeting the criteria for SI reporting.

4.2 Other serious events

There are events which occur of a serious nature which do not meet the serious incident criteria as set out above and in Appendix A. These incidents could include events such as (list not exhaustive):

- Serious harm to one or more staff member
- Medication incidents of significant concern
- Events which involve members of the public
- Events which include harm caused by driving incidents

Such incidents may be more appropriately managed via alternative methods, such as a police investigation or the Health and Safety Executive. The Trust does commit to reviewing such cases through the SI Panel and being flexible in its approach to serious incident investigation should it be felt that this route is the most appropriate, or signposting to the most appropriate Trust process, such as the Management of Incidents Policy or employee relations routes such as the Disciplinary Policy.

5. Serious Incident Process

5.1 Identification and declaration

Once identified, the serious incident shall be reported to the commissioners within two working days of the SI being identified by the SI Panel.

Every serious incident requires a three-working day (72 hour) report to be submitted to the commissioner outlining:

1. Immediate actions taken
2. More detailed description of events and the timeline
3. The level of investigation (if not already identified at the time of reporting)

Incident grading will be given as follows:

Incident Level 1
Concise internal investigation required. The current timescale for completion of the investigation is 60 working days from the date the incident is reported to the CCG.

Incident Level 2
Comprehensive internal investigation required. The current timescale for completion of the investigation is 60 working days from the date the incident is reported to the CCG.

For some Level 2 incidents it may be necessary to carry out an independent investigation. This is generally commissioned to an independent body and the timescale for completion is 60 working days from the date that the incident is reported as a serious incident.

At any stage in the investigation, if it is identified that the incident does not meet the threshold, the patient safety team can request that the serious incident be downgraded to the management of incidents process (following approval by the safety and risk lead and the commissioners).

5.2 Submission Extension

Timely completion of a serious incident investigation may not be possible in some cases, in accordance with the national Framework. Examples of such include:

- Awaiting outcomes of court proceedings
- Awaiting Coronal inquests
- Awaiting forensic post-mortem findings
- Awaiting toxicology results

- Awaiting completion of an external review
- In direct response to a police request under a Memorandum of Understanding

It is the decision of the ICE lead whether the SI meets the criteria for an extension. Swift liaison between the Trust and the ICS lead is therefore essential.

5.3 Multi-Organisational Serious Incidents

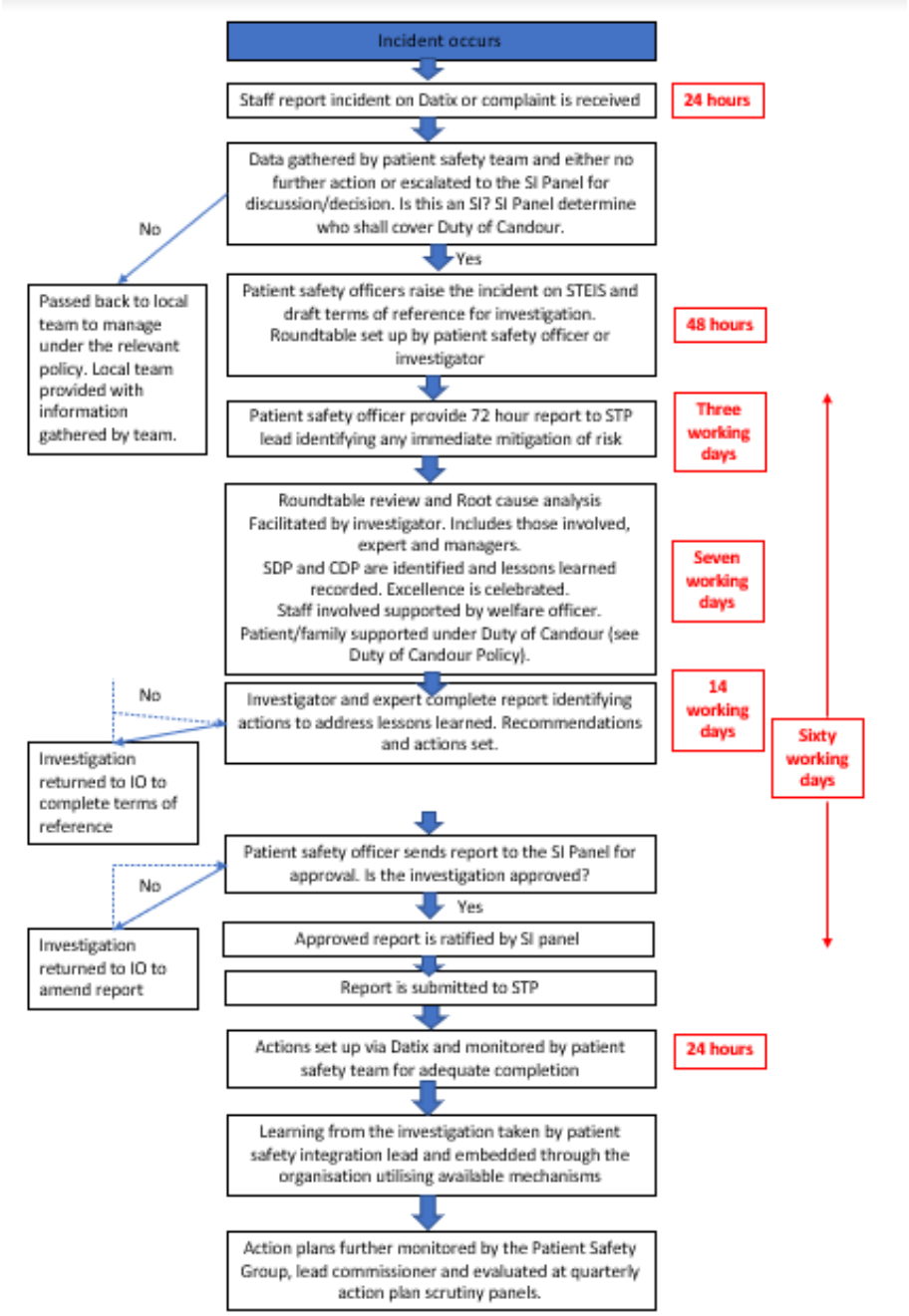
On some occasions, a serious incident may occur which directly involves more than one provider organisation and there is a need to investigate and review the whole care pathway. In these instances, close collaboration is required at each stage of the process.

The patient safety team will:

- Coordinate with the lead commissioner and provider organisations involved to determine the lead investigating organisation
- Ensure the Trust's IO is aware of the additional requirements and whether they are providing a Trust report for inclusion in a wider report, or whether they are tasked with co-ordinating the multi-organisation SI report (in instances where EEAST is the lead investigating organisation)
- Ensure that all organisations involved are satisfied with the final SI report final to approval

5.4 Serious Incident Process Flowchart

The following flow chart details the process to be followed from an adverse incident occurring, through to reporting as an SI, investigation and completion:



6. Learning

Lessons learnt and actions to take are essential to prevent recurrence of the incident.

Actions will be established during the investigation and roundtable process. The patient safety team will engage with the most appropriate specialists who will likely hold the actions. The specialist

shall review the draft report, advise on the actions, and advise a realistic and appropriate timeframe in which they can be completed.

Action owners are accountable for ensuring actions are completed within the timescale, or where this is not possible, keeping the patient safety team updated with a suitable rationale with regards to the delay. Issues with action completion will be escalated to the safety and risk lead and the director of clinical quality and improvement for review escalation.

The recommendations will be stated in the serious incident report and these will be considered and approved by the SI Panel. The resulting actions will be monitored by the patient safety team for completion and evidence will be required prior to formal closure and completion of the action.

General managers and equivalents are responsible for dissemination of general learning points from serious incidents as routine and the patient safety team will ensure that all approved SI reports are disseminated in a timely manner following completion.

The safety integration specialist is responsible for taking the learning identified during the investigation and, using mechanisms available within the organisation, ensure that this is embedded throughout the Trust.

7. Equality Impact Assessment

The East of England Ambulance Service NHS Trust has made every effort to ensure this policy does not have the effect of discriminating, directly or indirectly, against employees, patients, contractors, or visitors on the grounds of race, colour, age, nationality, ethnic (or national) origin, gender, sexual orientation, marital status, religious belief or disability. This policy will apply equally to full and part time employees. All East of England Ambulance Service NHS Trust policies can be provided in large print or Braille formats if requested, and language line interpreter services are available to individuals who require them.

8. Process for Monitoring Compliance and Effectiveness

The Executive Leadership Team has devolved responsibility for monitoring the serious incident process to the Patient Safety and Experience Group (PSEG). Regular reports identifying trends, remedial action and any organisational learning will be prepared by the patient safety team for submission to the PSEG. Assurance papers will also be provided by the safety and risk lead to the Quality Governance Committee for Board assurance purposes.

Compliance with the policy will be measured through set standards and key performance indicators (section 9 below) and will combine in an overarching monitoring table for the suite of clinical governance policies (see appendix B).

9. Standards/Key Performance Indicators

- Number of serious incidents reported each month
- Number of serious incidents occurring each month
- Number of serious incidents reported to the CCG within 48 hours of the incident being identified as a serious incident
- Serious incidents occurring by locality (and service line)
- Timeframes for investigation completion
- Actions completed within specified timescales

10. Associated Documents

Risk Management Strategy
Risk Management Procedure
Management of Incidents Policy
Duty of Candour Policy
Complaints Policy
Safeguarding Children, Young People and Vulnerable Adult Policy
Whistle Blowing Policy
Learning from Deaths Policy

Appendices

A Example SI Criteria

B Monitoring Table

C Equality Impact Assessment Summary

Appendix A – Example SI Criteria

SI Criteria	Specific Examples
Unexpected or **avoidable** death of one or more patients, staff, visitors or members of the public, where the death is directly caused by the incident that has occurred. This includes suicide/self-inflicted death	• Must be a clear causal link between the incident and the death • Consideration of Coroner's report and cause of death is essential and decision based on a sound evidence base
Unexpected or avoidable injury to a service user that has resulted in: • An impairment to the sensory, motor or intellectual functions of the service user which is not likely to be temporary • Changes to the structure of a service user's body • The service user experiencing prolonged pain, prolonged psychological harm or prolonged impairment to their normal working or personal life • The shortening of the life expectancy of the service user	• Medication errors resulting in significant harm • Injuries such as fracture during the course of care • Avoidable significant deterioration of a patient's condition due to delay in provision of service (could be telephone delay, initial response or back up) • RTC involving a Trust vehicle resulting in serious harm
Unexpected or avoidable injury to a service user that requires further treatment by a healthcare professional in order to prevent either: • The death of the service user; or • One or more of the outcomes mentioned above	• Fall of a patient from a stretcher or piece of manual handling equipment • Injury caused through a lack of appropriate manual handling procedures • Any of the above examples

SI Criteria	Specific Examples
An incident or series of incidents that prevents, or threatens to prevent, the organization's ability to continue to deliver an acceptable quality of healthcare services. This includes: • Serious data loss • Serious property damage • Serious security breach • Incidents and substantiated allegations of abuse	• Failure of the CAD or Pathways • Major incident impacting upon deliverability of core business • Serious data loss and breaches of confidentiality based on the ICOs SI criteria • Abuse, sexual abuse, or neglect with supporting evidence
Major loss of confidence in the service, including prolonged adverse media coverage or public concern about the organization	• National media attention • Sustained local media attention relating to that specific incident
Never Events	• During review of incidents, there may be incidents which arise that the SI Panel views as internal Never Events. These will be added to this Appendix if and when they are identified. • It should be noted that there are currently no contractual Never Events relating to NHS ambulance services.

Appendix B – Monitoring Table

What	Who	How	Frequency	Evidence	Reporting arrangements	Acting on recommendations	Change in practice and lessons to be shared
Number of serious incidents reported and occurring each month, by locality	Safety and Risk Lead	Datix monitors numbers, trends and themes.	Monthly	Safety section of the Quality Report	AMG for consideration and decision making. Quality Governance Committee for assurance. The Board for information.	SI Panel will determine actions as required. AMG will act upon recommendations made by the SI Panel.	Required changes to practice will be identified and actioned within a specific time frame. A lead member of the team will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders.
Timeframes for investigation completion	Safety and Risk Lead	Datix monitors numbers, trends and themes.	Monthly	Safety section of the Quality Report	AMG for consideration and decision making. Quality Governance Committee for assurance. The Board for information.	SI Panel will determine actions as required. AMG will act upon recommendations made by the SI Panel.	Required changes to practice will be identified and actioned within a specific time frame. A lead member of the team will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders.
Actions from SIs completed within specified timescales	Patient Safety Team	Datix monitors numbers, trends and themes	Monthly	Safety section of the Quality Report	AMG for consideration and decision making. Quality Governance Committee for assurance. The Board for information.	SI Panel will determine actions as required. AMG will act upon recommendations made by the SI Panel.	Required changes to practice will be identified and actioned within a specific time frame. A lead member of the team will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders.

Appendix C – Equality Impact Assessment Summary

<table>
<tr><th colspan="2">EIA Cover Sheet</th></tr>
<tr><td>Name of process/policy</td><td>Serious Incident Policy</td></tr>
<tr><td>Is the process new or existing? If existing, state policy reference number</td><td>Existing – POL014</td></tr>
<tr><td>Person responsible for process/policy</td><td>Safety and Risk Lead</td></tr>
<tr><td>Directorate and department/section</td><td>Medical Directorate</td></tr>
<tr><td>Name of assessment lead or EIA assessment team members</td><td>Anthony Brett, Safety and Risk Lead</td></tr>
<tr><td>Has consultation taken place?

Was consultation internal or external? (please state below):</td><td>Not required</td></tr>
<tr><td>The assessment is being made on:</td><td>
<table>
<tr><td>Written policy involving staff and patients</td><td>X</td></tr>
<tr><td>Strategy</td><td></td></tr>
<tr><td>Changes in practice</td><td>X</td></tr>
<tr><td>Department changes</td><td></td></tr>
<tr><td>Project plan</td><td></td></tr>
<tr><td>Action plan</td><td></td></tr>
<tr><td colspan="2">Other (please state)

Training programme.</td></tr>
</table>
</td></tr>
</table>

Equality Analysis		
What is the aim of the policy/procedure/practice/event? To document the process for the management of serious incidents.		
Who does the policy/procedure/practice/event impact on?		
Race	**Religion/belief**	**Marriage/Civil Partnership**
Gender	**Disability**	**Sexual orientation**
Age	**Gender re-assignment**	**Pregnancy/maternity**
Who is responsible for monitoring the policy/procedure/practice/event? Safety and Risk Lead		
What information is currently available on the impact of this policy/procedure/practice/event? Nil		
Do you need more guidance before you can make an assessment about this policy/procedure/ practice/event? No		
Do you have any examples that show that this policy/procedure/practice/event is having a positive impact on any of the following protected characteristics? Yes/No, If yes please provide evidence/examples:		
Race	**Religion/belief**	**Marriage/Civil Partnership**
Gender	**Disability**	**Sexual orientation**

Age	**Gender re-assignment**	**Pregnancy/maternity**

Please provide evidence:

Are there any concerns that this policy/procedure/practice/event could have a negative impact on any of the following characteristics? Yes/No, if so please provide evidence/examples:

Race	**Religion/belief**	**Marriage/Civil Partnership**
Gender	**Disability**	**Sexual orientation**
Age	**Gender re-assignment**	**Pregnancy/maternity**

Please provide evidence:

Action Plan/Plans - SMART

Nil

Evaluation Monitoring Plan/how will this be monitored?

N/A