# Management of Serious Incidents & Never Events Policy

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<th>ID Reference Number</th>
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**Purpose**

This policy outlines the process of reporting, investigating and managing Serious Incidents once declared in order to improve patient safety, share lessons learnt and to prevent the recurrence of similar incidents.

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<th>Patient Safety</th>
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<td>Date Approved by Controlled Document Review Group</td>
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<th>July 2021 Extension agreed by Director of Nursing</th>
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<td>Title of Originator/Author</td>
<td>Head of Governance Clinical Risk Manager</td>
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<td>Medical Director</td>
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<td>Impact / Equality Impact Assessed</td>
<td>Clinical Risk Manager</td>
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<td>Target Audience</td>
<td>All staff</td>
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1. Introduction

This Policy outlines George Eliot Hospital NHS Trust’s (the Trust) approach to the management of Serious Incidents including ‘Never Events’. This policy should be read in conjunction with the Incident Reporting Policy GOV042.

The Trust recognises that in the NHS, tens of thousands of patients are treated safely by dedicated healthcare professionals who provide high quality and safe clinical care. For the vast majority of patients, their treatment helps to alleviate or improve their symptoms and is a positive experience. However, when Serious Incidents occur, the NHS has a responsibility to ensure that there are systematic measures in place for safeguarding people, property, NHS resources and reputation. This includes responsibility to learn from these incidents to minimise the risk of them happening again (Serious Incident Framework - Supporting learning to prevent recurrence March 2015).

The process has been developed to support the Trust in its vision is to provide the best possible care to all our patients and the following the Trust’s Excel values.


The Revised Framework confirms that the fundamental purpose of patient safety investigations is to learn from incidents, and not apportion blame, while endorsing the application of the recognised system-based method for conducting investigations, commonly known as Root Cause Analysis, and its potential as a powerful mechanism for driving improvement.

- The NHS England Serious Incident Framework 2016
- NHS England Serious Incident Framework: Supporting Learning to prevent recurrence
  - NHS England Serious Incident Framework 2015/2016 – Frequently asked questions
- NHS England Revised Never Events Policy and Framework

2. Purpose

This Policy outlines the Trust’s approach to the management of Serious Incidents (including Never Events) a key component of the Trust’s Risk Management Strategy. It states the methods required to investigate comprehensively, develop relevant action plans, provide assurances and share the lessons learnt.

- The aim of the policy is to provide a robust approach to serious incident and Never Event management (not including pressure ulcers) that demonstrates compliance with external standards. All incidents will be managed and outlines the procedures and staff’s
responsibilities for reporting, investigating and learning lessons from serious incident’s and Never Event’s.

It provides:

- A standardised approach to incident management across the trust to:
  - Ensure that learning from incidents is an integral part of the trust’s culture
  - Support the analysis of trends which may identify the further need for intervention
  - Improve patient and staff safety by addressing systematic errors
  - Promote a culture of accountability without ‘blame’.

Consistent definitions of terms e.g. serious incident requiring investigation which is accepted both regionally and nationally:

- Clarification of roles and responsibilities
- Information on notification requirements and timescales
- A common investigation process,
- Monitoring of action plans and learning

This policy and associated procedures applies to all serious incidents and Never Events and incidents, patient safety and non-clinical. In order to provide a consistence approach to incident management and reporting this policy and procedures applies when:

- The person is working on official Trust business, either as a permanent employee, a temporary employee on short term contract, a placement student, an agency nurse/midwife or locum, or as a subcontractor or volunteer
- An incident occurs in a patient’s/client’s home, other healthcare premise whilst a member of directly employed Trust staff (including temporary nurses/midwives and healthcare professionals) are involved in providing care
- The patient/client is undergoing treatment
- The person is in a hospital, health centre or clinic for the purposes of health care or for the purpose of visiting another.

3. Definitions

<table>
<thead>
<tr>
<th>Clinical Commissioning Group (CCG)</th>
<th>CCGs are responsible for commissioning emergency and urgent care, including ambulance services and out-of-hours services, for anyone present in their geographic area.</th>
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<tbody>
<tr>
<td>Duty of Candour</td>
<td>Care Quality Commission (CQC) regulation to ensure that providers are open and transparent with people who use services and other ‘relevant persons’ (people acting lawfully on their behalf) in relation to care and treatment they have received. It sets out some specific requirements that providers must follow when things go wrong with care and treatment, including informing people about the incident, providing reasonable support, providing truthful information and an apology.</td>
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<tr>
<td>Human Tissue Authority (HTA)</td>
<td>The regulator for human tissue and organs.</td>
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| **Never Event** | Never Events are a particular type of Serious Incident that meet all the following criteria:  
1. They are wholly preventable, where guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers.  
However, serious harm or death is not required to have happened as a result of a specific incident occurrence, for that incident to be categorised as a Never Event. A list can be accessed at: [https://www.england.nhs.uk/wp-content/uploads/2015/03/never-](https://www.england.nhs.uk/wp-content/uploads/2015/03/never-). |
| **The Just Culture Guide** | The Just Culture Guide aims to help the NHS move away from attributing blame and instead find the cause when things go wrong. The goal is to promote fair and consistent staff treatment within and between healthcare organisations. |
| **Reporting of Injuries, Diseases & Dangerous Occurrences Regulations 2013 (RIDDOR)** | There is a requirement to report Work related accidents (WRA)  
- which cause death  
- Which cause certain serious injuries  
- When a certain industrial disease is diagnosed  
- Certain dangerous occurrences  
- When a WRA means an employee is away from work or unable to carry out their normal work duties for more than seven consecutive days  
- Certain patient incidences resulting in injuries  
For further guidance, please access the following link: [http://www.hse.gov.uk/riddor/](http://www.hse.gov.uk/riddor/) |
| **Screening programmes** | The systematic offering of a screening test to a population or a specified segment of a population, with the aim of identifying a disease at an early and more treatable stage. |
| **Serious Incident (SI)** | Is an event(s) 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. |
| **STEIS** | Strategic Executive Information System – electronic national reporting system for incidents that meet the SI criteria. |
| **Serious/Severe Harm/Death** | **Serious/Severe harm (patient safety incident that appears to have resulted in permanent harm to one or more persons receiving NHS-funded care);**  
|                           | **Chronic pain (continuous, long-term pain of more than 12 weeks or after the time that healing would have been thought to have occurred in pain after trauma or surgery ); or**  
|                           | **Psychological harm, impairment to sensory, motor or intellectual function or impairment to normal working or personal life which is not likely to be temporary (i.e. has lasted, or is likely to last for a continuous period of at least 28 days).**  
|                           | **Death as a direct result of the incident**  

| **Wet signature** | **An original signature written on a piece of paper.** |

### 4. Duties

The principal accountability of all providers of NHS-funded care is to patients and their families/carers. In their fulfilment of the Trust’s duty in this regard, the Trust Board accepts its responsibility to ensure that the Trust operates in the safest manner possible to protect users of its services and members of staff. Part of this responsibility is to ensure that an appropriate incident management system is in place for the reporting of incidents including serious incidents, never events, monitoring of incident trends and that lessons are learnt.

#### Chief Executive and the Trust Board

The Chief Executive is accountable and responsible to the Trust Board for ensuring that resources, policies and procedures are in place to ensure the effective reporting, recording, investigation and treatment of incidents. In practice the Chief Executive may delegate the day-to-day responsibility for this to another Executive Director. They are responsible for ensuring there is a policy in place and for overseeing the effective execution of a plan to achieve quality, safety improvement and harm reduction aims.

#### Medical Director

The Medical Director is responsible for providing assurance to the Quality Assurance Committee and the Trust Board that patient safety by:

- Ratifying an event as a SIRI, and ensures prompt communication both internal and external including the clinical commissioning groups and Local Area Team (NHS England).
- Appointing the investigation lead for incidents requiring an RCA following discussion with the Risk Manager, agreeing the terms of reference and scope of the investigation in association with the appointed Investigating lead.
- Agrees a communications strategy when appropriate with the Communications Team as soon as practicable.
- Specifically considers with the Communications Team, whether a ‘hotline’ should be established.
- Ensures that those principally involved are informed before any response is made to a media request.
Ensure the Duty of Candour Policy has been invoked appropriately.
- Chairs the Serious incident Group (SIG)
- Where appropriate, in the event of some Serious incidents, calls a major incident meeting

**Director of Governance**

The Director of Governance is the nominated Director responsible for ensuring that the Trust has appropriate arrangements in place for the management of incident reporting and associated investigation.

**Head of Governance**

Is responsible for ensuring that there are appropriate and robust systems in place for the investigation and management of Serious Incidents within the Trust, which are supported by evidence based policies. They are responsible for the development of policies, procedures and protocols for reporting, investigation and management of Serious Incidents, ensuring investigations are robust and sufficiently detailed to identify root causes or themes.

**Clinical Risk Manager**

The Risk Manager/ Risk Officer are responsible for ensuring the following processes are in place and operate effectively:

- Maintaining records of reported incidents using the Datix incident management system.
- Monitoring the appropriate reporting and grading of reported incidents, and seeking clarification from relevant managers should grading be inconsistent with trends.
- Ensuring appropriate notification of incidents to relevant internal and external stakeholders, agencies and regulatory bodies.
- Notifying the Chief Executive and Executive Directors and all other relevant stakeholders, of unexpected death or other serious incidents that may attract media attention.
- Providing appropriate advice and support to the Medical Director and Director of Nursing to enable the accurate identification, reporting and investigation of serious incidents.
- Obtaining appropriate management reports from the responsible manager in the event of a potential or actual serious incident.
- Instigating serious incident investigations and other internal investigations/reviews in line with this policy and published best practice guidance.
- 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 commissioning body.
- Ensuring an effective tracking system is in place so that progress against action plans arising from serious and other grades of incident can be monitored and reported on.
- Develop and deliver training packages for incident investigation and RCA training.
- Provision of support and advice on the investigation process to the investigation lead.
- Support for investigation lead in the facilitation of a Root Cause Analysis (RCA)
- Analysing incident data to produce performance, management and assurance reports.
- Alerting the appropriate director, manager, consultant, specific department or governance forum if any trend(s) is identified from reported incidents.
- Provide reports to internal groups and committees such as Quality Assurance Committee, Patient Safety Group, and via these committees to Trust Board.
- Ensure that the Complaints Manager and/or the Legal Services Manager are aware of any incident that may result in a complaint or claim.
- Manage the timescales for providing reports to internal & external organisations.
- Co-ordinate the Serious Incident Group, ensuring all RCA investigation reports are presented.
- Appropriate escalation of any delay in meeting deadlines.
- Responsible for supporting the development of policies and procedures related to Serious Incident management to ensure they comply with national standards.
- Support the panel members investigating the incident to be able to provide a comprehensive investigation, utilising appropriate tools to determine a root cause(s) and appropriate learning.
- Responsible for ensuring the Duty of Candour has been completed as per policy including liaising with patient and/or relevant persons as needed. Immediately alerting the Head of Governance, Director of Governance and the Medical Director of the occurrence of any incident that meets the Never Event criteria.
- Is responsible for reporting all Serious Incidents and Never Events ontoSTEIS.

Investigating Lead Manager

- To support the panel members investigating the incident to be able to provide a comprehensive investigation, utilising appropriate tools to determine a root cause(s) and appropriate learning.
- Ensure that patients and families are kept informed of the investigations into adverse incidents in line with the Trust’s Being Open policy and the Duty of Candour.
- Supporting the Consultants, Matrons, Ward Sisters and Managers in the completion of the contractual Duty of Candour requirements.

Head of Estates / EBME Manager

Has a responsibility to:

- Ensure the estates/ EBME team are supported and encouraged to report incidents
- Report appropriate incidents externally e.g. those related to medical equipment / devices to the MHRA and estates issue to NHS Estates.
- Participate or act as Investigation Lead in incidents related to estates or medical devices.
- Ensure investigation reports, lessons learned and action plans are included in departmental reports to Health & Safety Group and Patient Safety Group.

Local Security Management Specialist

The Security Manager will ensure that the relevant external agencies are informed of any incidents relating to security and violence and aggression (this may include the police). Provide support for investigations as required in relation to incident involving violence and aggression.

Communications Team

The communication team are responsible for handling media enquiries and liaising with the CCG and the Local Area Team (NHS England) communications team in the event a an incident with media interest.

Information Governance & FOI Manager

The Information Governance Manager, will be responsible for the classification, privacy impact assessment of IG incidents and assurance of compliance with NHS IG reporting requirement and action planning for the resolution of IG SIRI's.
**Health & Safety Manager**
Is responsible for ensuring any RIDDOR reportable incidents are reported to the Health & Safety Executive within the appropriate timeframe.
The Health and Safety Officer is responsible for ensuring reportable incidents (RIDDOR) are reported to the Health and Safety Executive within the acceptable timeframes.

They will:

- Review the appropriateness of incident grading on non-clinical incident reports, supporting managers in investigating RIDDOR reportable incidents and ensure that the appropriate action plans are put in place
- Analyse incident data for trends and update the Health & Safety Group of non-clinical incidents in the form of a bi-monthly report to the Health and Safety Group.

**Serious Incident Review Group (SIG)**
The Group is responsible for reviewing incidents to determine if they meet the Serious Incident criteria as outlined in the Serious Incident Framework. The Group monitors the action plans that have been completed as a result of a Serious Incident and supports the sharing of the lessons learnt across the Organisation.

**Datix System Lead**
Has a responsibility to:

- Inform the NHS England of all clinical/patient safety incidents via the NRLS as per standard operating procedures
- Provide reports from DATIX as requested
- Support training on the use of the DATIX system to include electronic incident reporting
- To maintain & update DATIX system
- Seek support & advice from Risk Management Team as required.

**Divisional Associate Directors**
Have a responsibility to:

- Promote a positive reporting culture by actively encourage all staff to report incidents and near misses.
- Ensure sufficient members of staff have received appropriate training in incident investigation to enable them to act as Lead Investigators.
- Ensure that the patient, carers and relatives are kept fully informed and the Duty of Candour procedure when appropriate has been applied.
- Ensure that, when appropriate, investigations into Serious Incidents Requiring Investigation (SIRI) are carried out by appropriately trained and resourced staff in accordance with NHS England Serious Incident Framework
- Ensure there are mechanisms/processes in place within their Division/Directorate to aid investigation leads to feedback on lessons learned as a result of incidents, complaints or claims within their own area of responsibility and across the trust in a timely manner.
Ensure recommended actions have been taken & that lessons learned from incidents are shared throughout the Division/Directorate via the governance meetings and across the trust and externally as appropriate.

Provide support to staff / patients / visitors who are involved in incidents or the investigation process.

Assist and support the lead investigators in removing barriers that may delay investigation

Contribute and monitor the implementation of action plans arising from RCAs

Act as investigation lead and coordinate the investigation team to carry out robust investigations as required facilitating root cause analysis, developing, implementing and monitoring action plans to address root causes identified in line with Trust Policy

Ensure that incidents trend investigation outcomes, lessons learnt and actions taken are discussed at Division/Directorate local governance meetings and that feedback is given.

Ensure investigation findings, lessons learned and action plans form part of the division/directorate quarterly report to the Patient Safety Group. Duty of Candour and progress against recommended actions should also be monitored through these meetings.

Ensure risks identified as a result of incident, complaints and claims investigations are recorded on the appropriate risk register or if appropriate escalated to the corporate risk register. This may be as a result of an isolated incident or identified trends.

Ensure that when members of staff are involved in traumatic or stressful incidents, complaints or claims they receive support to meet their needs. This may be internal or external to the organisation as appropriate.

To determine actions from the Serious Incident Report in line with the investigation findings and recommendations.

Reviewing all reports provided pertaining to their Division or Directorate and ensuring that the review of these are included in their Divisional/Directorate governance meetings and give Divisional sign off.

Supporting the Division and Directorates in ensuring that appropriate action is taken as a result of Serious Incident including the completion of actions plans to demonstrate learning from the incident.

Support all staff involved in a Serious Incident within their Division.

Consultants

Are responsible for ensuring that all junior doctors under their supervision are fully aware of this policy.

Complying with the Duty of Candour requirements.

To participate as part of a Serious Incident investigation when requested.

To share the learning identified from the investigations with their medical teams and support in the completion of identified actions (where applicable).

To support members of their team who are involved in investigations.

To support their patients, where appropriate, who have been involved in a Serious incident.

Associate Directors, Clinical Directors, Directorate Managers and Matrons

Have a responsibility to:

Promote a positive reporting culture by actively encourage all staff to report incidents and near misses.
Ensure sufficient members of staff have received appropriate training in incident investigation to enable them to act as Lead Investigators.

Ensure that the patient, carers and relatives are kept fully informed and the Duty of Candour procedure when appropriate has been applied.

Ensure that, when appropriate, investigations into Serious Incidents Requiring Investigation (SIRI) are carried out by appropriately trained and resourced staff in accordance with NHS England Serious Incident Framework.

Ensure there are mechanisms/processes in place within their Division/Directorate to aid investigation leads to feedback on lessons learned as a result of incidents, complaints or claims within their own area of responsibility and across the trust in a timely manner.

Ensure recommended actions have been taken & that lessons learned from incidents are shared throughout the Division/Directorate via the governance meetings and across the trust and externally as appropriate.

Provide support to staff / patients / visitors who are involved in incidents or the investigation process.

Assist and support the lead investigators in removing barriers that may delay investigation.

Contribute and monitor the implementation of action plans arising from RCAs.

Act as investigation lead and coordinate the investigation team to carry out robust investigations as required facilitating root cause analysis, developing, implementing and monitoring action plans to address root causes identified in line with Trust Policy.

Ensure that incidents trend investigation outcomes, lessons learnt and actions taken are discussed at Division/Directorate local governance meetings and that feedback is given.

Ensure investigation findings, lessons learned and action plans form part of the Division/Directorate quarterly report to the Patient Safety Group. Duty of Candour and progress against recommended actions should also be monitored through these meetings.

Ensure risks identified as a result of incident, complaints and claims investigations are recorded on the appropriate risk register or if appropriate escalated to the corporate risk register. This may be as a result of an isolated incident or identified trends.

Ensure that when members of staff are involved in traumatic or stressful incidents, complaints or claims they receive support to meet their needs. This may be internal or external to the organisation as appropriate.

- Are responsible for ensuring that systems are in place throughout the Directorates that support the Trust's Policy.

- Ensuring that the actions that arise as a result of a Serious Incident are completed and evidence is available as required.

- To participate as part of a Serious Incident investigation when requested.

- To share the learning identified from the investigations with their teams and support in the completion of identified actions (where applicable).

- To provide support where needed, to patients and staff involved in a Serious Incident.

**Departmental Mangers**

Have a responsibility:

- To promote a positive reporting culture.

- To investigate incidents as appropriate and for taking action to reduce the likelihood of an incident recurring and monitor any plans to mitigate risk.

- Disseminating lessons learned as a result of incident investigations within local forums.
For actively encouraging/supporting/promoting incident reporting system in their ward or Department including the onward communication and appropriate escalation of incidents according to the severity of the incident and type e.g. child protection team if there is a child protection issue, safeguarding if involves vulnerable adult

To support staff, patients and others involved in or affected by incidents as they may find the experience stressful or traumatic. Ward and Department Managers are usually the first senior person that a staff member will discuss an incident with and they must always offer support to anyone involved in an incident and ensure they can access the appropriate support.

Are responsible for ensuring they are aware of the Policy and ensuring that the staff they directly manage are aware of their responsibilities.

To participate as part of a Serious Incident investigation when requested.

To provide support where needed, to patients and staff involved in a Serious Incident.

To share the learning identified from the investigations with their teams and support in the completion of identified actions (where applicable).

All Trust Employees

Where requested, assist with any incident investigation including completing statements.

Ensure they are aware of lessons learnt as a result of a Serious Incident investigation and assist with the completion of any actions relevant to them.

To provide support to both patients and colleagues who have been involved in a Serious Incident.

Lead Investigating Officer/Incident Manager

The Lead investigator/ Incident Manager has the responsibility for conducting a comprehensive, unbiased investigation commensurate with the grade of the incident, identifying lessons learnt and actions to prevent/reduce the risk of reoccurrence. They also have the responsibility to:

To provide feedback to members of staff who have reported an adverse incident or near miss. This includes the creation of local action plans and dissemination for wider organisational learning.

If the incident require a full RCA the lead will:

- Identify an investigation team ensure the investigations includes key stakeholders (e.g. pharmacist must attend RCA’s involving medication)

Ensure that all staff involved in the review are supported and understand the process and for documenting the support in the RCA pro forma

Develop action plans with the team involved

Ensure all those with assigned tasks are aware of their responsibilities and timescales

Liaise with the patient, staff member or family member and keep them informed of progress and resulting action plans or nominate an appropriate staff member to do so. All communication with patients, carers (and staff if the incident is non-clinical) must be documented.

Individual Responsibilities

It is the responsibility of all Trust staff to report any incident, accident or near miss which has caused or has the potential to cause harm, loss or damage to any individual* involved, or loss
damage in respect of property or premises for which the Trust is responsible. This includes any incident that has the potential to result in litigation or adverse publicity.

Out of “Office Hours” Duties

These duties will only become effective in the case of SIRIs that are considered to be life threatening i.e. fire, chemical spill, for other SIRIs that meet the criteria for reporting to the CCG/Local Area Team NHS England, the person who first becomes aware of the incident must report it in the first instance to the onsite manager the onsite manager and Director on call who will inform the Manager on Call.

The Onsite Coordinator is responsible for:

- Immediate assessment of the situation and deciding, on the basis of the evidence available at the time, whether the event constitutes SIRI and immediate escalation to the Manager on Call.
- Ensuring that those affected by the incident patient/ carers / staff receive immediate support.
- Protecting & isolating any evidence/ equipment that may have been involved in the incident.
- Ensuring immediate action is taken to prevent any further patients/staff/visitors/areas are affected by the same issue.
- Ensuring that they have sufficient accurate information.
- Informing the Manager on Call.
- Informing Risk Management Team the next working day if not already informed (this can be via voice mail or email).
- Ensure an incident report on Datix has been completed.
- Request statements from those involved or who have witnessed the incident.
- Ensure that the incident is handed over to appropriate manager.
- Assess the impact of the incident for continuity of service delivery (if appropriate).
- Ensure if a patient is affected, that the patient & the family/ NOK are informed of the incident in line with the trusts Duty of Candour procedure. If they feel unable to do this they must escalate to the Manager on Call.

The Manager on Call is responsible for:

- Ensuring that the onsite manager is supported to include assessment of impact for continuity of service delivery (if appropriate).
- From the information provided by the Onsite Coordinator decide if the situation requires immediate escalation to the Director on Call and through them to the CCG/Local Area Team NHS England.
- Attend site if required to provide support.
- Informing the Director on Call.

Director on Call is responsible for:

- Providing advice and guidance to the Manager on Call.
- Confirming that, where appropriate, that Duty of Candour policy has been implemented.
- Inform the Chief Executive.
- Inform the CCG/Local Area Team NHS England.
• Receiving media enquiries and if necessary passing these to the on call Communications Lead
• Ensuring that sufficient resources & support are available to manage the incident.
• Attending the site if the situation warrants executive management support.
• Declaring a major incident if appropriate

The next working day the Director on Call must ensure that all necessary actions have been taken, and are handed over (if they are not in) to an appropriate senior manager

• Ensuring that the relevant Consultant (if appropriate & not already) is aware
• Ensuring that an Incident report has been completed
• Ensuring that statements/ verbal accounts are being obtained from all relevant nursing, medical and other staff
• Ensuring that all necessary additional resources, e.g. staff, have been brought in to handle the incident.
• Ensuring that evidence has been preserved / protected making an environmental examination of the area and a photographic record has been made if appropriate.
• Ensuring that staff involved in the incident, or affected by it have received appropriate & timely support
• Call a major incident meeting if appropriate

The Consultant on Call/In Charge of the patient in the case of a clinical incident is responsible for ensuring that:

• All appropriate medical care has been given to the patient or patients involved and that this is fully documented in the Health Records;
• The patient and or relatives or next of kin are informed that the event had occurred, its implications and actions that have been taken, and investigations that will take place, in accordance with the Trusts “Duty of Candour Policy”
• Ensuring that medical staff involved, or affected by the incident receive appropriate immediate support.
• Informing the Coroner if necessary.
• Decisions are made with the Director on Call to ensure patients and staff are protected, consideration should be given to use of the Just Culture Guide to ascertain the most appropriate course of action, for staff directly involved in the incident

Quality Assurance Committee (QAC)

The Quality Assurance Committee has an overarching assurance role to monitor that sufficient assurance is in place to demonstrate that risks are being managed. This role includes monitoring risks resulting from incidents.

• Ensure that the incident is handed over
• Ensure that where appropriate the Duty of Candour procedure has been applied.
• Ensure that sufficient & timely support is in place.
Serious Incident Group (SIG)

The SIG is an operational group who will ensure that all serious incidents are investigated comprehensively and lessons learnt. They provide assurance to the Board via the Quality Assurance Committee.

Patient Safety Group (PSG)

The Patient Safety Group is a multidisciplinary group chaired by the Medical Director, it is responsible for ensuring patient safety is operational and embedded throughout the organisation and patient experience and quality of care are improved.

5. Policy Details

The Trust is committed to a fair and just culture and encouraging a willingness to admit mistakes without fear of punitive measures. The Trust Board appreciates that completion of an incident report form may cause fear of disciplinary action, and that this may deter staff from reporting incidents. Completion of an incident report form is not considered an admission of liability. A clinical or non-clinical error, accident or incident, however serious, is rarely caused wilfully, errors are often caused by a number of factors including, process problems, human error, individual behaviour and a lack of knowledge or skills. Research carried out in the NHS has shown that systems failures are often the root cause of safety incidents, however, the most common response to a serious patient safety incident is to suspend and then discipline the staff involved. This can be unfair to employees and divert management from identifying contributory systems failures, suspending key employees can also diminish the quality of patient care provided. 

Learning from such incidents can only take place when they are reported and investigated in a positive, open and structured way. All members of staff are actively encouraged to openly report incidents where a mistake has occurred and will be fully supported through this process. Disciplinary action will not be taken as a result of incident reporting, except in cases of misconduct and gross misconduct, e.g. Fraud, physical assault, corruption, recklessness, criminal behaviour or where the incident is repeated on many occasions.

Where incident raises concerns in relation to an individual’s capability or competence, the staff member must be treated with care and consideration and supported within the principles of a ‘just culture’.

The Just Culture Guide is a national tool, designed is to help move away from attributing blame and instead focus on finding the cause when things go wrong, promoting fair and consistent staff treatment between healthcare providers. It is a helpful tool for managers and senior clinicians to:

- Decide whether it is necessary to suspend staff from duty following a patient safety incident;
- Explore alternatives to suspension, such as temporary relocation or modification of duties;
- Consider other possible measures to be taken as the investigation progresses.

Where appropriate the principal steps within the Just Culture Guide will be used to determine the most appropriate course of action to be taken in respect of non-clinical incidents. Wherever possible, preventative action such as retraining will be undertaken rather than disciplinary action. All decisions of potential professional involvement in the disciplinary process must involve the Medical Director or Director of Nursing and the identified professional lead.
Incident investigation is not part of the disciplinary process; however the investigation team has a responsibility to examine and comment on the discharge of professional duties (and accountability) by those involved in the incident, and to make recommendations. If disciplinary action is considered, a separate investigation lead needs to be identified and human resources have to be involved. Staff members who make a prompt and honest report will be treated fairly and be supported.

5.1 Reporting Staff Concerns

The Trust recognises that there may be occasions when members of staff are anxious about reporting particularly sensitive issues. In these circumstances members of staff can report their concerns anonymously on Datix. However this will mean that no follow-up feedback, help or support can be offered and any subsequent investigation will be limited, therefore this option should only be used as a last resort. Consideration should be given to discussing the situation with their line manager, a senior member of staff, Occupational Health, Trade Union Representative, a member of the Governance Team and/or HR as appropriate to ensure that staff gets the support they may need. Staff members are also able to raise concerns in line with the Trust’s Freedom to Speak Up policy.

If a member of staff has concerns regarding the welfare of an adult patient, staff should contact their Safeguarding Adults Lead and for concerns regarding the welfare of a child, staff should contact the named nurse for safeguarding children.

5.2 Staff Support

The Trust recognises that staff involved directly or indirectly in an incident may be upset and distressed. Most incidents will not cause undue anxiety, however for some incidents for example serious incidents, individuals regardless of grade or position, may feel anxious about their involvement and their future role in the incident investigation process and Root Cause Analysis (RCA). It is essential that these individuals are offered support at the time of the incident and whilst any incident investigation is ongoing. Staff must be assured that it is not the intention of the investigators to pursue an enquiry for the purpose of apportioning blame. They should be assured that the intention is to limit further damage both to patients and staff and to take steps to learn from the incident and prevent reoccurrence.

5.3 Duty of Candour, Communication and Support for Patients, Relatives and Carers.

The Duty of Candour arises whenever any unintended or unexpected incident occurs that in the reasonable opinion of a health professional could result in, or appears to have resulted in, the death of a patient (where this is directly related to the incident rather than the natural course of the patient’s condition) or severe harm, moderate harm or prolonged psychological harm to the patient. Moderate harm is defined as harm that is significant in that it requires a moderate increase in treatment and harm that is significant but not permanent. This includes any unplanned return to surgery or extra time in hospital either as an inpatient or outpatient, but the resultant harm must be significant.

Duty of Candour is more than a one-off event, it is a communication process with a number of stages. The duration of the process will depend on the incident, the needs of the patient, their family and carers, and how the investigation into the incident progresses. The Duty of Candour process begins with the recognition that a patient/service user has suffered a notifiable patient/service user safety incident. The incident must be reported on Datix and escalated to the admitting consultant/matron or appropriate departmental manager as appropriate.
The level of patient/family involvement clearly depends on the nature of the incident and the patient or family’s wish to be involved. Unless there are specific indications to the contrary or the patient/their family requests other arrangements, these issues should be covered in a series of open discussions between staff providing the patient’s care and the patient and/or their relatives or carers. All communications should be documented in the patient’s medical record regardless of the means of communications or a record/communication log must be kept if the medical records are not available.

Some incidents may result in media interest. In these circumstances, wherever possible, patients and their relatives and carers should be fully informed of any circumstances which involve them before any information is released to the media. The communication team must be kept fully briefed in these circumstances.

Note: Patients and families have the right to request information held by public authorities (Freedom of Information Act 2000). This includes access to medical records and any associated documentation (Public Sector Information Regulations 2005). This should be considered when writing incident investigation reports and actions.

5.4 Notifying External Agencies/Stakeholders.

The Trust has an obligation to report certain incidents to external agencies and or stakeholders to meet statutory requirements and best practice. It may be necessary to inform the CCG/ Local Area Team NHS England immediately depending on the nature of the incident, i.e. if it meets the criteria of a serious incident requiring investigation (SIRI). If a SIRI occurs out of hours details of the incident needs to be escalated to the On-site manager who will escalate to the manager on call. The Director on Call will make the decision whether to inform the CCG/ Local Area Team NHS England out of hours. Risk Management will need to be informed at the earliest opportunity, which can be by email to Datix.Mailbox@geh.nhs.uk. In all cases this should be followed by the completion of an incident report on Datix as soon as practicable following the incident but must be undertaken before the end of the working day/shift.
5.5 Internal Process for Incidents that are declared as a Serious Incident

**Incident Reported**
- Initial assessment form (72* brief) completed
- Staff statements gathered - the Just Culture Guide is considered
- 72* brief reviewed at Serious Incident Review Group (SIG)

**Serious Incident Review**
- Serious Incident/ Never Event discussed with Director, when confirmed, declared on STeIS (external agency reporting)
- Panel commissioned
- Consider Just Culture Guide
- Further evidence gathered e.g. theatre lists, duty rota, equipment reports

**First Investigation Panel Meeting**
- Review all evidence - including statements and the timeline
- Agree interviews
- RCA process commences using relevant tools
- First report with known facts WITHIN 1 WEEK

**Investigation Ongoing**
- Interviews
- Expert opinions sought as required (may be external to Trust)

**Second Investigation Panel Meeting**
- Root Cause agreed
- Just Culture Guide considered again if appropriate
- Contributory factors agreed
- Care/service delivery problems agreed
- Action plan agreed WITHIN 3 WEEKS

**Third Investigation Panel Meeting**
- Final draft report written WITHIN 6 WEEKS
- Presented to Executive team for signoff
- Division/Directorate representative in attendance to agree actions

**Final Report Generated**
- Circulated to SIG members for comment and appropriate amendments made
- Circulate completed report to the Division(s)/Directorate(s) for agreement and sign off

**SIG for Sign Off**
- Medical Director sign off at SIG

**CCG/NHS England Submission**
- Share with patient/family
- Share with staff
- Share with Division/Directorate
- Full RCA and Action plan onto Datix
5.6 Incident Reported

Once an incident is reported as causing moderate harm or above, or a cluster of incidents is identified further information is requested. This includes completion of a 72* brief, tabular timeline and the commencement of statement collection.

Any evidence relating to the incident should be preserved and any equipment involved be quarantined.

This information is then reviewed at the Serious Incident Review Group (SIG).

Please refer to the Incident Reporting Policy for detailed information.

5.7 Serious Incident Review Group (SIG) Decision

Once the Governance teams determine that an incident fulfils the reporting criteria as documented by NHS England in the Serious Incident Framework March 2015, the Clinical Incident/Governance Manager will report the incident onto STEIS. Whilst this process will alert the CCG that the Organisation has declared a Serious Incident a courtesy telephone call will also be made to discuss the incident.

The Just Culture Guide aims to move away from attributing blame and instead find the cause when things go wrong. The goal is to promote fair and consistent staff treatment within and between healthcare organisations. The IDT assists in deciding the most appropriate action to be taken with staff involved in incidents.

Serious Incidents will be investigated by a panel of individuals (with no conflict of interest) who are familiar with Root Cause Analysis techniques and have sufficient seniority in the organisation that they can probe and ask questions of individuals and processes to establish the root cause of an incident and make suggestions and recommendations for changes and actions which may be Trust wide.

The panel members will be informed of the request for them to participate with the investigation by email from the Clinical Risk Manager via Datix.

An investigation panel will consist of the following (as a minimum) depending on the incident:

- A Clinician
- A Registered Nurse/Midwife
- A Manager (where appropriate)
- A member of the Governance Team

Other members will be co-opted onto the panel depending on the nature of the incident e.g. Falls Prevention coordinator, Health and Safety Manager, Tissue Viability Nurse and if appropriate, an external independent expert.

In conjunction with the above, further evidence/information will be gathered by the investigation lead to assist the panel in their investigation.

The patient/relevant other involved in the Serious Incident will be offered the opportunity to contribute to the investigation within the Duty of Candour process.
5.8 Process for Reporting to External Agencies

Once a decision has been made that an incident fulfils the Serious Incident criteria this will be uploaded onto STEIS by the Clinical Incident Manager or deputy, within two working days. The Serious Incident report must not contain any patient or staff names and the description should be clear and concise.

5.9 First Investigation Panel Meeting

At the first investigation panel meeting the scope of the investigation and the terms of reference are agreed, expectations and tools to be used for the investigation will be explained by the Governance Team member on the panel. A review of the information gathered to date will be conducted and the team will determine which staff they need to interview. The interviews will then be arranged by the investigation lead – staff are reminded that they are obliged to support any investigation and therefore attend meetings/ interviews when requested. This meeting must take place no later than 5 working days after the incident has been reported on Datix.

5.10 Interviews

Staff will be invited to an interview by letter/email sent out by the Lead Investigator. The panel will determined which members will be involved in the interviews. The whole panel will not be present for the interviews due to the number however the interviews should have a minimum of two panel members in the interview.

Staff will be informed that they are able to have a colleague/union representative in the interview with them for support, but only they can answer the questions posed to them.

At this point a further review of the IDT will be conducted.

5.11 Second Investigation Panel Meeting

At this stage of the investigation, the panel will have sufficient factual information to agree the root cause of the incident. The contributory factors and care/service delivery problems will be agreed. Consideration should be given to reviewing the IDT to review the original decisions made once additional information is available. This meeting must take place no later than 15 working days after the incident has been reported on Datix.

5.12 Third Investigation Panel Meeting

Any final factual information will be added to the report and a final draft report written. The IDT will be reconsidered if appropriate. Divisional/Directorate representation will be invited to these so actions that address the root cause and recommendations can be agreed. This meeting must take place no later than 30 working days after the incident has been reported on Datix.

5.13 Final Report Generated

The final report will be reviewed by the SIG and any queries sent back to the investigation panel. Once the queries have been answered the report will be sent to the Division for Divisional sign off. This sign off will consist of either a “wet” signature or an electronic signature. This meeting must take place no later than 40 working days after the incident has been reported on Datix.
5.14 Executive review for Sign Off
The final report will be signed off with a “wet” signature by the Chair, Deputy Chair of SIG.

5.15 CCG Submission
The report, tabular timeline and action plan will be submitted to the CCG, NHSI and or NHS England as per the agreed timescales.

As part of the Duty of Candour process the report will be shared with the patient or relevant person at this stage and a further apology given. A meeting between the patient and/or relevant person, will be offered to go through the report with members of the investigation panel. This gives the patients/ relevant person e.g. next of kin / carer a chance to discuss the report and ask any questions they may have.

5.16 Shared Serious Incidents across involving other Providers
The Trust will work with and contribute to investigations that have occurred in other Organisations but involve the care given to a patient by the George Eliot Hospital NHS Trust.

If a Serious Incident occurs within this Organisation, but involves care given by other providers they will be asked to identify an impartial representative from that Organisation to be on the investigation panel. Likewise, the Trust will support investigations led by other Providers as required. This will be facilitated through the Governance Department.

The Trust will work with other care providers as per the guidance from the CCG relating to joint Serious Incident Investigations.

5.17 Root Cause Analysis Tools
A comprehensive root cause analysis investigation will ensure that the root cause of the incident is identified. This will allow for lessons to be learned and appropriate SMART (Specific, Measurable, Achievable, Realistic, Timely) actions to be developed to assist the Trust in delivering the Best Possible Care to our patients.

The list below outlines the most common tools that will assist the investigation however the list is not exhaustive:

- Tabular timeline
- Time/person grid
- Just Culture Guide
- Change analysis tool
- Contributory Factors Classification Framework
- Fishbone diagram
- Barrier analysis

The tools listed by the investigation panel will be documented within the investigation report.

5.18 Never Events
A Never Event will be reported as a Serious Incident and will follow the investigation process
A Director will be on the investigation panel
- The report will be signed off by a Director prior to submission to the CCG
- The CQC will be informed that an incident which meets the Never Event criteria has occurred

5.19 Duty of Candour

Duty of Candour must be undertaken in line with the Trust Duty of Candour Policy and Duty of Candour Procedures.

5.20 CCG Communication

The CCG are informed by the Governance Team, that the Organisation has declared and reported onto STEIS a Serious Incident.

An initial report is submitted to the CCG within 72 hours of the incident being uploaded to STEIS.

If the investigation/report is not completed within the 60 working day timescale due to issues beyond the Trust's control a formal request will be made to the CCG by the Governance Team for a clock stop.

The report is submitted to the CCG once completed with the tabular timeline and the action plan.

The CCG will send any queries they have from the report back to the Governance Team. These will be sent to the investigation panel to answer and the response sent back to the CCG in the required timescale by email.

5.21 Learning from Serious Incidents and Never Events

The systematic investigation of Serious Incidents and Never Events results in important lessons being learned and improvements identified and implemented. These improvements support the embedding of an effective safety culture thus allowing the delivery of high quality, safe patient care.

The lessons learned and actions from Serious Incidents are shared with staff across the Trust where lessons apply more widely through the publication of and discussion at team meetings.
The learning identified should be shared with staff through various forums such as:

- Team/Ward/Departmental Meetings
- Newsletters
- Governance Meetings (Directorate & Divisional)
- Safety alerts, bulletins
- Quarterly Governance newsletter, ‘Risky Business’
- Shared Governance Meetings
- Regional Patient Safety Learning Forum, hosted by the CCG

5.22 Assurance Process for Action Plan Completion

The Directorates/Divisions are responsible for ensuring the actions from Serious Incidents are implemented and completed. This will be uploaded onto Datix and compliance will be monitored through an exception report to SIG and will be included in a monthly report to Accountability Framework Directorate Report within the SI Report and a quarterly Divisional Report.

Overdue actions will be escalated to the Associate Director of Nursing/Midwifery, Associate Medical Directors and Associate Directors of Operations for the Division by the Clinical Risk Manager.

5.23 Dealing with the Media in relation to Serious Incidents and Never Events

All media enquiries relating to Serious Incidents or Never Events should be dealt with by the Trust’s Communications Team. Any queries received directly from the press, should be forwarded to the Communications Team. Out of normal office hours these should be referred to the Executive Director on Call.
The Communications Team are responsible for liaising with the Medical Director to prepare a response relating to a specific media enquiry or drafting a statement regarding the Trust’s position, in relation to an incident in advance of any media interest.

Under no circumstances should any member of staff discuss an incident with the media, without receiving express permission from the Director on Call.

If a member of staff considers that an incident may result in media or public attention or a media request for information is received, the Trust’s Communications Team must be informed. Information should only be released to the media through the Trust’s Communications Team.

The Medical Director will liaise with the investigating team who will provide the relevant information required, for any media response/statement. The investigating panel will also ensure that the local area is aware of the draft response/statement and its content.

Once approved by the Medical Director, the media response to a specific enquiry will be issued. Media statements prepared in advance of any enquiry will be held pending any media interest, when a decision will be made regarding their release, depending on the nature of the incident.

5.24 Risk Register

If an incident investigation highlights a significant risk for the Trust than it is important this is escalated and placed on the appropriate Risk register. The lead investigator, supported by the Risk Management Team, will be responsible for undertaking a risk assessment.

6. Dissemination

Appropriate education will be provided to all staff as part of corporate induction to ensure that they are aware of the process for incident reporting. Additional training/education on Root Cause Analysis (RCA) and Incident Investigation facilitated by the Risk Team are available for General Managers, Heads of Department/Incident Managers and can be booked via Learning & Development on line booking. Any additional training required, as identified via the appraisal process or Learning Needs Analysis (LNA), will be provided and supported by the Risk Team.

7. Implementation

Each member of staff is responsible for maintaining up-to-date awareness of existing policies, and for adhering to those policies in the course of their daily work. All new staff joining the Trust should be made aware through their line management of all current trust wide documents and directorate documents relevant to them.

Training will be provided and monitored centrally by the Governance Team via the following mechanisms:

- Corporate induction programme
- Corporate training programme
- Tailored training for Directorates
- Included as part of the RCA/ Incident investigation trainingsessions
8. Document Control / Archiving

The document will be managed as per the process described within the Trust’s Policy for the Development and Management of Controlled Documents.

This policy will be reviewed at the date specified or earlier if circumstances dictate. This document will be included on the Trust intranet site (SharePoint) under the Master Policy Library”.

9. Monitoring Table

<table>
<thead>
<tr>
<th>Aspect of compliance or effectiveness being monitored</th>
<th>Monitoring method</th>
<th>Individual or department responsible for the monitoring</th>
<th>Frequency of the monitoring activity</th>
<th>Group/committee/forum which will receive the findings/monitoring report</th>
<th>Committee/individual responsible for ensuring that the actions are completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Division/Directorate has sufficient and appropriate staff members trained.</td>
<td>Training records</td>
<td>Division/Directorate Management Team</td>
<td>On going</td>
<td>Division/Directorate Governance Meeting</td>
<td>Division/Directorate Management Team</td>
</tr>
<tr>
<td>Serious incidents are identified, and reported in a timely manner and reported within the correct timescale</td>
<td>SIRIs are identified and reported in a timely manner and reported within the correct timescale</td>
<td>Risk Management</td>
<td>Monthly</td>
<td>QAC through SIG</td>
<td>SIG</td>
</tr>
<tr>
<td>Incidents are reviewed and/or investigated in a timely manner</td>
<td>Extract from DATIX number of incident reports open after deadline.</td>
<td>Risk Management</td>
<td>Weekly</td>
<td>Division/Directorate Management Team</td>
<td>Division/Directorate Governance Meeting</td>
</tr>
<tr>
<td>Follow up of action plans</td>
<td>Review action plans Minutes of meetings</td>
<td>Division/Directorate Management Team Division/Directorate Management Team</td>
<td>Monthly Quarterly</td>
<td>Divisional Governance Meeting Patient Safety Group</td>
<td>Division/Directorate Management Team Division/Directorate Management Team</td>
</tr>
<tr>
<td>Lessons learned are shared at all levels within the Trust</td>
<td>Sample of team meeting agendas and minutes Demonstrate discussion</td>
<td></td>
<td></td>
<td>Patient Safety Group</td>
<td>Division/Directorate Management Team</td>
</tr>
</tbody>
</table>
10. References and Bibliography


Department of Health (2007) *Building a Safer NHS for Patients*. Available from:

Department of Health (2000) *An Organisation with a Memory*. Available at:


*Health and Safety at Work etc. Act 1974*, c.37. Available at:

Human Tissue Authority (no date) *Reporting an incident or concern*. Available at: https://www.hta.gov.uk/reporting-incident-or-concern (Accessed 30/8/2017).


11. GEH Associated Records
   - Incident Reporting Policy
   - Freedom to Speak Up Policy
   - Duty of Candour Policy
   - Duty of Candour Procedures

12. Staff Compliance Statement

   All staff must comply with the Trust-wide controlled document and failure to do so may be considered a disciplinary matter leading to action being taken under the Trust’s Disciplinary Procedure. Actions which constitute breach of confidence, fraud, misuse of NHS resources or illegal activity will be treated as serious misconduct and may result in dismissal from employment and may in addition lead to other legal action against individual concerned.

13. Equality and Diversity Statement

   The Trust aims to design and implement services, policies and measures that meet the diverse needs of the needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others.
Appendix 1 – Never Events List

Surgical

1. Wrong site surgery

An invasive procedure performed on the wrong patient or at the wrong site (e.g., wrong knee, eye, limb, tooth). The incident is detected at any time after the start of the procedure.

1. The start of an invasive procedure is when a patient’s anatomy begins to be permanently altered. For example, this is when the first incision is made that will scar the patient and take time to heal and recover from.

Includes: Interventions that are considered to be surgical but may be done outside a surgical environment – for example, wrong site block (including blocks for pain relief), biopsy, interventional radiology procedure, cardiology procedure, drain insertion and line insertion (e.g., peripherally inserted central catheter (PICC)/Hickman lines). This also includes teeth extracted in error that are immediately reimplanted.

Excludes:

• removal of wrong primary (milk) teeth unless done under a general anaesthetic
• interventions where the wrong site is selected because the patient has unknown/unexpected anatomical abnormalities; these should be documented in the patient’s notes
• wrong level spinal surgery*
• wrong site surgery due to incorrect laboratory reports/results or incorrect referral letters
• contraceptive hormone implant in the wrong arm.

*Excluded from the current list while NHS Improvement works with the relevant professional organisations to ensure development of robust national barriers to prevent this incident.

Setting: All settings providing NHS-funded care.

National safety requirement:

• Safer Practice Notice – Wristbands for hospital inpatients improves safety (2005). The key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.
• Safer Practice Notice – Standardising wristbands improves patient safety (2007). The key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.
• Patient Safety Alert – WHO surgical safety checklist (2009). The key points in the alert are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.
• Safe Anaesthesia Liaison Group – Stop before you block (2011).
• The Royal College of Radiologists – Standards for providing a 24 hour interventional radiology service (2008).
• Faculty of Pain Medicine – Safety checklist for interventional pain procedures under local anaesthesia or sedation (2017).
• Royal College of Surgeons (Faculty of General Dental Practice) – Toolkit for the prevention of wrong tooth extraction (2017).
• National safety standards for invasive procedures (NatSSIPs) (2015).
2. **Wrong implant/prosthesis**

Placement of an implant/prosthesis different from that specified in the procedural plan, either before or during the procedure. The incident is detected any time after the implant/prosthesis is placed in the patient.

**Excludes:**

- placed implant/prosthesis is intentionally different from that specified in the surgical plan, based on clinical judgement at the time of the procedure
- specified implant/prosthesis is placed as planned but later found to be suboptimal
- implant/prosthesis is different from the one specified due to incorrect preprocedural measurements or incorrect interpretation of the preprocedural data – for example, wrong intraocular lens placed due to wrong biometry or using wrong dataset from correct biometry.

**Includes:**

- **implantation** of an intrauterine contraceptive device different from the one in the procedural plan.

**Setting:** All settings providing NHS-funded care.

**National safety requirement:**

- Safer Practice Notice – *Wristbands for hospital inpatients improves safety* (2005). Key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.
- Safer Practice Notice – *Standardising wristbands improves patient safety* (2007). Key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.
- Patient Safety Alert – WHO surgical safety checklist (2009). Key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.

3. **Retained foreign object post procedure**

Retention of a foreign object in a patient after a surgical/invasive procedure.

**Surgical/invasive procedure** includes interventional radiology, cardiology, interventions related to vaginal birth and interventions performed outside the surgical environment – for example, central line placement in ward areas.

**Foreign object** includes any items subject to a formal counting/checking process at the start of the procedure and before its completion (such as for swabs, needles, instruments and guidewires) **except** where items:

- not subject to the formal counting/checking process are inserted any time before the procedure, with the intention of removing them during the procedure but they are not removed
- subject to the counting/checking process are inserted during the procedure and then intentionally retained after its completion, with removal planned for a later time or date as clearly recorded in the patient’s notes
- are known to be missing before completion of the procedure and may be inside the patient (eg screw fragments, drill bits) but action to locate and/or retrieve them is impossible or more damaging than retention.
Setting: All settings providing NHS-funded care.

National safety requirement:

• Patient Safety Alert – *WHO surgical safety checklist* (2009). Key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.
• Safer Practice Notice – *Reducing the risk of retained throat packs after surgery* (2009). Key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.
• Patient Safety Alert – *Reducing the risk of retained swabs after vaginal birth and perineal suturing* (2010). Key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.
• *National safety standards for invasive procedures* (NatSSIPs) (2015).

Medication

4. Mis-selection of a strong potassium solution

Mis-selection refers to:

• when a patient is intravenously given a strong2 potassium solution rather than the intended medication.

2 ≥10% potassium w/v (eg ≥0.1 g/mL potassium chloride, 1.3 mmol/mL potassium chloride).

Setting: All settings providing NHS-funded care.

National safety requirement:

• Patient Safety Alert – *Potassium chloride concentrate solutions* (2002; updated 2003). Key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.

5. Administration of medication by the wrong route

The patient is given one of the following:

• intravenous chemotherapy by the intrathecal route
• oral/enteral medication or feed/flush by any parenteral route
• intravenous administration of an epidural medication that was not intended to be administered by the intravenous route*

* During the transition period for the introduction of NRFit™ devices, the ‘intravenous administration of a medicine intended to be administered by the epidural route’ cannot be considered a Never Event. An update will be provided when this period ends.

Setting: All settings providing NHS-funded care.

National safety requirement:

• Patient Safety Alert – *Promoting safer measurement and administration of liquid medicines via oral and other enteral routes* (2007). Key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.
Patient Safety Alert – Safer practice with epidural injections and infusions (2007). Key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.

6. Overdose of insulin due to abbreviations or incorrect device

Overdose refers to when:

- a patient is given a 10-fold or greater overdose of insulin because the words ‘unit’ or ‘international units’ are abbreviated; such an overdose was given in a care setting with an electronic prescribing system.
- a healthcare professional fails to use a specific insulin administration device – that is, an insulin syringe or pen is not used to measure the insulin.
- a healthcare professional withdraws insulin from an insulin pen or pen refill and then administers this using a syringe and needle.

3 Electronic prescribing, dispensing and administration systems are an evidence-based method to reduce patient harm from medicines. All NHS organisations should introduce them as soon as possible. When the definitions for the insulin and methotrexate overdose Never Events were revised in 2015, it was agreed that those for insulin given in overdose because of the use of abbreviations for ‘unit’ and for all methotrexate overdose incidents would only apply to care settings with electronic prescribing systems as indicated. The systemic protective barriers for these two types of Never Event were found not to be strong enough in care settings where electronic barriers do not exist. For example, even though most acute hospitals do use a preprinted insulin prescription to try and prevent prescribers using the abbreviations ‘iu’ or ‘u’, this is not the case in all care settings. Also, preprinted prescriptions on their own are not a reliably strong enough barrier to prevent a potential 10-fold dosing error as prescribers can still prescribe insulin on general prescriptions.

Setting: All settings providing NHS-funded care.

National safety requirement:

- Rapid Response Report – Safer administration of insulin (2010). Key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.
- Patient Safety Alert – Risk of severe harm and death due to withdrawing insulin from pen devices (2016).

7. Mis-selection of high strength midazolam during conscious sedation

Mis-selection refers to when:

- a patient is given an overdose of midazolam due to the selection of a high strength preparation (5 mg/mL or 2 mg/mL) instead of the 1 mg/mL preparation, in a clinical area performing conscious sedation.
• excludes clinical areas where the use of high strength midazolam is appropriate; these are generally only those performing general anaesthesia, intensive care, palliative care, or areas where its use has been formally risk-assessed in the organisation.

**Setting:** All settings providing NHS-funded care.

**National safety requirement:**


**Mental health**

8. **Failure to install functional collapsible shower or curtain rails**

Involves either:

• failure of collapsible curtain or shower rails to collapse when an inpatient attempts or completes a suicide
• failure to install collapsible rails and an inpatient attempts or completes a suicide using non-collapsible rails.

**Setting:** All settings providing NHS-funded mental health inpatient care.

**National safety requirement:**

Health building notes:
- Health building note 03-01 – *Adult acute mental health units* (2013).

Estates and facilities alerts:
- Department of Health 08 – *Cubicle curtain track rail* (2007).

**General**

9. **Falls from poorly restricted windows**

A patient falling from a poorly restricted window. This applies to:

This includes windows where the provider has not put a restrictor in place in accordance with guidance.
- windows ‘within reach’ of patients; this means windows (including the window sills) that are within reach of someone standing at floor level and that can be exited/fallen from without needing to move furniture or use tools to climb out of the window
- windows located in facilities/areas where healthcare is provided and that patients can and do access
• where patients deliberately or accidentally fall from a window where a fitted restrictor is damaged or
  disabled, but not where a patient deliberately disables a restrictor or breaks the window immediately before
  they fall
• where patients can deliberately overcome a window restrictor using their hands or commonly available flat-
  bladed instruments as well as the ‘key’ provided.

Setting: All settings providing NHS-funded care.

National safety requirement:
• Health Building Note 00-10 Part D – *Windows and associated hardware.*
• Department of Health Estates and Facilities Alert – *Window restrictors of cable and socket design (2014).*
• Health and Safety Executive *Risk of falling from windows* (2016).

11. Chest or neck entrapment in bed rails

Entrapment of a patient’s chest or neck between bedrails or in the bedframe or mattress, where the bedrail
dimensions or the combined bedrail, bedframe and mattress dimensions do not comply with Medicines and
Healthcare products Regulatory Agency (MHRA) guidance.

Setting: All settings providing NHS-funded care including care homes, and patients’ own homes where
equipment for their use has been provided by the NHS. 2018

National safety requirement:

12. Transfusion or transplantation of ABO-incompatible blood components or organs

Unintentional transfusion of ABO-incompatible blood components.

Excludes:
• where ABO-incompatible blood components are deliberately transfused with appropriate management.

Unintentional ABO-mismatched solid organ transplantation.

Excludes:
• situations in which clinically appropriate ABO-incompatible solid organs are deliberately transplanted.

In this context, ‘incompatible’ antibodies must be clinically significant. If the recipient has donor-specific anti-
ABO antibodies and is therefore likely to have an immune reaction to a specific ABO-compatible organ, the
inadvertent transplantation of that organ without appropriate management is a Never Event.

Setting: All settings providing NHS-funded care.

National safety requirement:
• British Society for Histocompatibility and Immunogenetics and British Transplantation Society – *Guidelines
  for the detection and characterisation of clinically relevant antibodies in allotransplantation* (2014).
• Safer Practice Notice – *Wristbands for hospital inpatients improves safety* (2005). Key points are
  summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the
  Never Events list.
36

• Safer Practice Notice – *Standardising wristbands improves patient safety* (2007). Key points are summarised in Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list.

13. **Misplaced naso- or oro-gastric tubes**

Misplacement of a naso- or oro-gastric tube in the pleura or respiratory tract that is not detected before starting a feed, flush or medication administration.

**Setting:** All settings providing NHS-funded care.

**National safety requirement:**


14. **Scalding of patients**

Patient scalded by water used for washing/bathing.

**Excludes:**

• scalds from water being used for purposes other than washing/bathing (eg from kettles).

**Setting:** All settings providing NHS-funded care.

**National safety requirement:**

• Health Building Note 00-10 Part C – *Sanitary assemblies* (2013).
• Health and Safety Executive – *Managing the risks from hot water and surfaces in health and social care* (2012).
• Health and Safety Executive – *Scalding and burning* (2012).

15. **Unintentional connection of a patient requiring oxygen to an air flowmeter**

This applies when a patient who requires oxygen is connected to an air flowmeter when the intention was to connect them to an oxygen flowmeter.

**Excludes:**

• unintentional connection to an air cylinder instead of an oxygen cylinder as robust barriers to prevent this have not yet been identified.

**Setting:** All settings providing NHS-funded care.

**National safety requirement:**

• Patient Safety Alert – *Reducing the risk of oxygen tubing being connected to air flowmeters* (2016).

16. **Undetected oesophageal intubation**

This Never Event has been temporarily suspended pending further clarification.
Appendix 2 – RIDDOR Reporting

RIDDOR reporting

The Trust will ensure that it complies with Health and Safety Executive (HSE) statutory requirements in relation to Reporting of Injuries Diseases and Dangerous Occurrence Regulations. (RIDDOR)

RIDDOR requires certain types of work related injuries/illnesses and dangerous occurrences to be reported to the (HSE).

What is reportable?

RIDDOR (Reporting of Injuries, Diseases and Dangerous Occurrence Regulations)

Reportable deaths and specified injuries including amendments to previous RIDDOR notifications (must be reported within 10 days of the incident):

Incidents which affect a patient, employee (Trust or contractor), or visitor on the premises including:

- Death
- Fracture other than to fingers, thumbs or toes
- Amputation of an arm, hand, finger, thumb, leg, foot or toe
- Dislocation of the shoulder, hip, knee or spine
- Permanent loss of sight or reduction in sight in one or both eyes
- Serious burn injury (including scalding) which covers more than 10% of the whole body’s total surface area or causes significant damage to the eyes, respiratory system or other vital organs
- Any crush injury to the head or torso, causing damage to the brain or internal organs
- Any degree of scalping requiring hospital treatment
- Any loss of consciousness caused by head injury or asphyxia
- Any other injury arising from working in an enclosed space which leads to hypothermia or heat-induced illness or requires resuscitation or admittance to hospital for more than 24 hours

Patient falls may also require reporting under RIDDOR when it has arisen out of or in connection with a work activity. This includes where equipment or the work environment (including how or where work is carried out, organised or supervised) are involved.

Reportable over seven day injuries (must be reported within 15 days of the incident):

Must be reported where they result in an employee (permanent or temporary) being away from work, or unable to perform their normal work duties for more than seven consecutive days as a result of their injury. This seven day period does not include the day of the accident, but does include weekends and rest days. The report must be made within 15 days of the accident.

Reportable Occupational diseases (reported as soon as responsible person/employer receives diagnosis):

Employers must report diagnosis of certain occupational diseases, where these are likely to have been caused or made worse by their work. Includes:
• Carpal tunnel syndrome
• Severe cramp of the hand or forearm
• Occupational dermatitis
• Hand-arm vibration syndrome
• Occupational asthma
• Tendonitis or tenosynovitis of the hand or forearm
• Any occupational cancer
• Any disease attributed to an occupational exposure to a biological agent

Reportable dangerous occurrences are:

• These are certain, specified near-miss events. There are 27 categories of dangerous occurrences relevant within the general workplace (highlighted in bold those most relevant to GEH):

Lifting equipment - Collapse, overturning or failure of any load-bearing part of any lifting equipment, other than an accessory for lifting.

• Pressure systems
• Overhead electric lines

Electrical incidents causing explosion or fire

• Explosives

Biological agents – any accident or incident which results or could have resulted in the release or escape of a biological agent likely to cause human infection or illness

• Radiation generators and radiography
• Breathing apparatus
• Diving operations
• Collapse of scaffolding
• Train collisions
• Wells
• Pipelines or pipeline works
• Structural collapse

Explosion or fire – any unintentional explosion or fire in any plant or premises which results in the stoppage of that plant, or the suspension of normal work in those premises, for more than 24 hours

• Release of flammable liquids and gases

Hazardous escapes of substances – the unintentional release or escape of any substance which could cause personal injury to any person other than through the combustion of flammable liquids or gases
## Appendix 3 – Duty of Candour

### Duty of Candour

<table>
<thead>
<tr>
<th>Contractual service condition</th>
<th>Yes</th>
<th>No</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Initial Notification</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Yes</td>
<td>No</td>
<td>Details</td>
</tr>
<tr>
<td><strong>As soon as reasonably practicable after becoming aware of the incident, was the relevant person informed of the incident?</strong></td>
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<tr>
<td>2</td>
<td>Yes</td>
<td>No</td>
<td>Details</td>
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<tr>
<td><strong>As soon as reasonably practicable, was support provided to the relevant person in relation to the incident?</strong></td>
<td></td>
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<tr>
<td>3</td>
<td>Yes</td>
<td>No</td>
<td>Details</td>
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<tr>
<td><strong>Was this notification given in person?</strong></td>
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<tr>
<td>4</td>
<td>Yes</td>
<td>No</td>
<td>Details</td>
</tr>
<tr>
<td><strong>Did the notification provide an account, which to the best of the Provider’s knowledge is true, of all the facts the Provider knew about the incident as at the date of the notification?</strong></td>
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<tr>
<td>5</td>
<td>Yes</td>
<td>No</td>
<td>Details</td>
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<tr>
<td><strong>Was the relevant person informed at notification of the further enquiries and investigations into the incident the Provider believed to be appropriate?</strong></td>
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<tr>
<td>6</td>
<td>Yes</td>
<td>No</td>
<td>Details</td>
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<tr>
<td><strong>Did the initial notification include an apology?</strong></td>
<td></td>
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<tr>
<td>7</td>
<td>Yes</td>
<td>No</td>
<td>Details</td>
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<tr>
<td><strong>Was a written record kept of the notification and held securely by the provider?</strong></td>
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</table>

### Follow up written notification

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
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<td><strong>Was the notification followed by one or more written notifications given or sent to the relevant person containing:</strong></td>
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<td><strong>An account of all the facts the Provider knew about the incident</strong></td>
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<tr>
<td>10</td>
<td>Details of any enquiries and investigations to be undertaken</td>
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<tr>
<td>11</td>
<td>Details of any enquiries and investigations that have been carried out into the incident, and any causes of that incident, or other findings, that have been identified as a result of those enquiries investigations;</td>
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<td>12</td>
<td>Any steps that have been taken to prevent the recurrence of such an incident</td>
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<tr>
<td>13</td>
<td>An apology</td>
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</tbody>
</table>

**Unable to contact or declined by relevant person**

| 14 | If the Relevant Person cannot be contacted or declines to speak to the representative of the Provider was a written record of attempts to contact or speak to the Relevant Person kept? |   |

**Record keeping**

| 15 | Have copies of all correspondence and full written records of any meeting or other contact with the relevant person in relation to the incident been kept by the provider? |   |
## Appendix 4 – Action Plan Template

### Action Plan Template

<table>
<thead>
<tr>
<th>Agreed Action</th>
<th>By When</th>
<th>By Whom</th>
<th>Evidence compliance</th>
<th>Date completed</th>
<th>RAG</th>
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### Acknowledgement of Responsibility

<table>
<thead>
<tr>
<th>Action Lead - Name</th>
<th>Action Lead Job title/Role</th>
<th>Relevant actions</th>
<th>Signature</th>
<th>Date</th>
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<tbody>
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## Appendix 5 - Root Cause Analysis Tabular Timeline

STEIS No. & Datix Ref : Prepared by:
Version & Date:

<table>
<thead>
<tr>
<th>Date and Time</th>
<th>Event</th>
<th>Supplementary Information</th>
<th>Source</th>
<th>Data Gaps</th>
<th>Care/Service Delivery Problems</th>
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</table>
Appendix 6 - Time Person Grid

Root Cause Analysis Investigation tools

<table>
<thead>
<tr>
<th>Time and Staff Member</th>
<th>Activity</th>
<th>Activity</th>
<th>Activity</th>
<th>Activity</th>
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<tbody>
<tr>
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</table>

Appendix 7 - Change Analysis

<table>
<thead>
<tr>
<th>Normal / Accepted Procedure</th>
<th>Actual Procedure at time of Incident</th>
<th>Was there a change (Y/N)</th>
<th>If yes, what was the CDP/SDP that contributed to the incident</th>
</tr>
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<tbody>
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</table>

Appendix 8 - Contributory Factors Classification Framework

Root Cause Analysis Investigation tools

<table>
<thead>
<tr>
<th>Patient Factors</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical condition</td>
<td>- Pre-existing co-morbidity</td>
</tr>
<tr>
<td></td>
<td>- Complexity of condition</td>
</tr>
<tr>
<td></td>
<td>- Seriousness of condition</td>
</tr>
<tr>
<td></td>
<td>- Limited options available to treat condition</td>
</tr>
<tr>
<td></td>
<td>- Disability</td>
</tr>
<tr>
<td>Physical Factors</td>
<td>- Poor general physical state</td>
</tr>
<tr>
<td></td>
<td>- Malnourished</td>
</tr>
<tr>
<td></td>
<td>- Dehydrated</td>
</tr>
<tr>
<td></td>
<td>- Age related issues</td>
</tr>
<tr>
<td></td>
<td>- Obese</td>
</tr>
<tr>
<td></td>
<td>- Poor sleep pattern</td>
</tr>
</tbody>
</table>
| **Social Factors** | Cultural / religious beliefs  
|                  | Language  
|                  | Lifestyle (smoking/ drinking/drugs/diet)  
|                  | Sub-standard living accommodation (e.g. dilapidated)  
|                  | Life events  
|                  | Lack of support networks / (social protective factors - Mental Health Services)  
| **Mental/ Psychological Factors** | Motivation issue  
|                  | Stress / Trauma  
|                  | Existing mental health disorder  
|                  | Lack of intent (Mental Health Services)  
|                  | Lack of mental capacity  
|                  | Learning Disability  
| **Interpersonal relationships** | Staff to patient and patient to staff  
|                  | Patient engagement with services  
|                  | Staff to family and family to staff  
|                  | Patient to patient  
|                  | Family to patient or patient to family  
|                  | Family to family (Siblings, parents, children)  
| **Staff Factors** | Components  
| **Physical issues** | Poor general health (e.g. nutrition, hydration, diet, exercise, fitness)  
|                  | Disability (e.g. eyesight problems, dyslexia)  
|                  | Fatigue  
|                  | Infected Healthcare worker  
| **Psychological Issues** | Stress (e.g. distraction / preoccupation)  
|                  | Specific mental illness (e.g. depression)  
|                  | Mental impairment (e.g. illness, drugs, alcohol, pain)  
|                  | Lack of motivation (e.g. boredom, complacency, low job satisfaction)  
| **Social Domestic** | Domestic problems (e.g. family related issues)  
|                  | Lifestyle problems (e.g. financial/housing issues)  
|                  | Cultural beliefs  
|                  | Language  
| **Personality Issues** | Low self confidence / over confidence (e.g. Gregarious, reclusive, interactive)  
|                  | Risk averse / risk taker  
| **Cognitive factors** | Preoccupation / narrowed focus (Situational awareness problems)  
|                  | Perception/viewpoint affected by info. or mindset (Expectation/Confirmation bias)  
|                  | Inadequate decision/action caused by Group influence  
|                  | Distraction / Attention deficit  
|                  | Overload  
|                  | Boredom  
| **Task Factors** | Components  
| **Guidelines, Policies and Procedures** | Not up-to-date  
|                  | Unavailable at appropriate location (e.g. Lost/missing/non-existent/not accessible when needed)  
|                  | Unclear/not useable (Ambiguous; complex; irrelevant, incorrect)  
|                  | Not adhered to / not followed  
|                  | Not monitored/reviewed  
|                  | Inappropriately targeted/focused (i.e. not aimed at right audience)  
|                  | Inadequate task disaster plans and drills  
| **Decision making aids** | Aids not available (e.g. CTG machine; checklist; risk assessment tool; fax machine to enable remote assessment of results)  
|                  | Aids not working (e.g. CTG machine, risk assessment tool, fax machine)  
|                  | Difficulties in accessing senior / specialist advice  
|                  | Lack of easy access to technical information, flow charts and diagrams  
|                  | Lack of prioritisation of guidelines  


| Procedural or Task Design | Poorly designed (i.e. Too complex; too much info.; difficult to conceive or remember)  
| Guidelines do not enable one to carry out the task in a timely manner  
| Too many tasks to perform at the same time  
| Contradicting tasks  
| Staff do not agree with the ‘task/procedure design’  
| Stages of the task not designed so that each step can realistically be carried out  
| Lack of direct or understandable feedback from the task  
| Misrepresentation of information  
| Inappropriate transfer of processes from other situations  
| Inadequate Audit, Quality control, Quality Assurance built into the task design |
| Communication Components |  |
| **Verbal communication** | Inappropriate tone of voice and style of delivery for situation  
| Ambiguous verbal commands / directions  
| Incorrect use of language  
| Made to inappropriate person(s)  
| Incorrect communication channels used |
| **Written communication** | Inadequate patient identification  
| Records difficult to read  
| All relevant records not stored together and accessible when required  
| Records incomplete or not contemporaneous (e.g. unavailability of patient management plans, patient risk assessments, etc)  
| Written information not circulated to all team members  
| Communication not received  
| Communications directed to the wrong people  
| Lack of information to patients  
| Lack of effective communication to staff of risks (Alerts systems etc) |
| **Non verbal communication** | Body Language issues (closed, open, body movement, gestures, facial expression) |
| Communication Management | Communication strategy and policy not defined / documented  
| Ineffective involvement of patient/carer in treatment and decisions  
| Lack of effective communication to patients/relatives/carers of risks |
| **Equipment** | Components |
| **Displays** | Incorrect information / feedback available  
| Inconsistent or unclear information  
| Illegible information  
| Interference/unclear equipment display |
| **Integrity** | Poor working order  
| Inappropriate size  
| Unreliable  
| Ineffective safety features / not designed to failsafe  
| Poor maintenance programme  
| Failure of general services (power supply, water, piped gases etc) |
| **Positioning** | Correct equipment not available  
| Insufficient equipment / emergency back up equipment  
| Incorrectly placed for use  
| Incorrectly stored |
### Usability
- Unclear controls
- Not intuitive in design
- Confusing use of colour or symbols
- Lack of or poor quality user manual
- Not designed to make detection of problems obvious
- Use of items which have similar names or packaging
- Problems of compatibility

### Work Environment

#### Components

<table>
<thead>
<tr>
<th>Administrative factors</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unreliable or ineffective general administrative systems (Please specify, e.g.: Bookings, Patient identification, ordering, requests, referrals, appointments)</td>
<td></td>
</tr>
<tr>
<td>Unreliable or ineffective admin infrastructure (e.g. Phones, bleep systems)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Design of physical environment</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poor or inappropriate office design (computer chairs, height of tables, anti-glare screens, security screens, panic buttons, placing of filing cabinets, storage facilities, etc.)</td>
<td></td>
</tr>
<tr>
<td>Poor or inappropriate area design (length, shape, visibility, provision of space)</td>
<td></td>
</tr>
<tr>
<td>Inadequate security provision</td>
<td></td>
</tr>
<tr>
<td>Lack of secure outside space</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Environment</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facility not available (failure or lack of capacity)</td>
<td></td>
</tr>
<tr>
<td>Fixture or fitting not available (failure or lack of capacity)</td>
<td></td>
</tr>
<tr>
<td>Single sex accommodation limitation/breach</td>
<td></td>
</tr>
<tr>
<td>Ligature/anchor points</td>
<td></td>
</tr>
<tr>
<td>Housekeeping issues – lack of cleanliness</td>
<td></td>
</tr>
<tr>
<td>Temperature too high/low</td>
<td></td>
</tr>
<tr>
<td>Lighting too dim or bright, or lack of</td>
<td></td>
</tr>
<tr>
<td>Noise levels too high or low</td>
<td></td>
</tr>
<tr>
<td>Distractions</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Staffing</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inappropriate skill mix (e.g. Lack of senior staff; Trained staff; Approp. trained staff)</td>
<td></td>
</tr>
<tr>
<td>Low staff to patient ratio</td>
<td></td>
</tr>
<tr>
<td>No / inaccurate workload / dependency assessment</td>
<td></td>
</tr>
<tr>
<td>Use of temporary staff</td>
<td></td>
</tr>
<tr>
<td>High staff turnover</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Work load and hours of work</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shift related fatigue</td>
<td></td>
</tr>
<tr>
<td>Excessive working hours</td>
<td></td>
</tr>
<tr>
<td>Lack of breaks during work hours</td>
<td></td>
</tr>
<tr>
<td>Excessive of extraneous tasks</td>
<td></td>
</tr>
<tr>
<td>Lack of social relaxation, rest and recuperation</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delays caused by system failure or design</td>
<td></td>
</tr>
<tr>
<td>Time pressure</td>
<td></td>
</tr>
</tbody>
</table>

### Organisational

#### Components

<table>
<thead>
<tr>
<th>Organisational structure</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hierarchical structure/Governance structure not conducive to discussion, problem sharing, etc.</td>
<td></td>
</tr>
<tr>
<td>Tight boundaries for accountability and responsibility</td>
<td></td>
</tr>
<tr>
<td>Professional isolation</td>
<td></td>
</tr>
<tr>
<td>Clinical versus the managerial model</td>
<td></td>
</tr>
<tr>
<td>Inadequate maintenance</td>
<td></td>
</tr>
<tr>
<td>Lack of robust Service level agreements/contractual arrangements</td>
<td></td>
</tr>
<tr>
<td>Inadequate safety terms and conditions of contracts</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Priorities</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not safety driven</td>
<td></td>
</tr>
<tr>
<td>External assessment driven e.g. Annual Healthchecks</td>
<td></td>
</tr>
<tr>
<td>Financial balance focused</td>
<td></td>
</tr>
<tr>
<td>Externally imported risks</td>
<td></td>
</tr>
<tr>
<td>------------------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Unexpected adverse impact of national policy/guidance (from Department of Health / Health authorities /Professional colleges)</td>
<td></td>
</tr>
<tr>
<td>Locum / Agency policy and usage</td>
<td></td>
</tr>
<tr>
<td>Contractors related problem</td>
<td></td>
</tr>
<tr>
<td>Equipment loan related problem</td>
<td></td>
</tr>
<tr>
<td>Lack of service provision</td>
<td></td>
</tr>
<tr>
<td>Bed Occupancy levels (Unplanned bed opening/closures)</td>
<td></td>
</tr>
<tr>
<td>PFI related problems (Private Finance Initiative)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Safety culture</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Inappropriate safety / efficiency balance</td>
<td></td>
</tr>
<tr>
<td>Poor rule compliance</td>
<td></td>
</tr>
<tr>
<td>Lack of risk management plans</td>
<td></td>
</tr>
<tr>
<td>Inadequate leadership example (e.g. visible evidence of commitment to safety)</td>
<td></td>
</tr>
<tr>
<td>Inadequately open culture to allow appropriate communication</td>
<td></td>
</tr>
<tr>
<td>Inadequate learning from past incidents</td>
<td></td>
</tr>
<tr>
<td>Incentives for ‘at risk’/risk taking behaviors</td>
<td></td>
</tr>
<tr>
<td>Acceptance/toleration of inadequate adherence to current practice</td>
<td></td>
</tr>
<tr>
<td>Ignorance/poor awareness of inadequate adherence to current practice</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Education and Training</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Competence</td>
<td></td>
</tr>
<tr>
<td>Lack of knowledge</td>
<td></td>
</tr>
<tr>
<td>Lack of skills</td>
<td></td>
</tr>
<tr>
<td>Inexperience</td>
<td></td>
</tr>
<tr>
<td>Inappropriate experience or lack of quality experience</td>
<td></td>
</tr>
<tr>
<td>Unfamiliar task</td>
<td></td>
</tr>
<tr>
<td>Lack of testing and assessment</td>
<td></td>
</tr>
<tr>
<td>Supervision</td>
<td></td>
</tr>
<tr>
<td>Inadequate supervision</td>
<td></td>
</tr>
<tr>
<td>Lack of / inadequate mentorship</td>
<td></td>
</tr>
<tr>
<td>Training results not monitored/acted upon</td>
<td></td>
</tr>
<tr>
<td>Availability / accessibility</td>
<td></td>
</tr>
<tr>
<td>Training needs analysis not conducted/acted upon</td>
<td></td>
</tr>
<tr>
<td>On the job training unavailable or inaccessible</td>
<td></td>
</tr>
<tr>
<td>Emergency Training unavailable or inaccessible</td>
<td></td>
</tr>
<tr>
<td>Team training unavailable or inaccessible</td>
<td></td>
</tr>
<tr>
<td>Core skills training unavailable or inaccessible</td>
<td></td>
</tr>
<tr>
<td>Refresher courses unavailable or inaccessible</td>
<td></td>
</tr>
<tr>
<td>Appropriateness</td>
<td></td>
</tr>
<tr>
<td>Inappropriate content</td>
<td></td>
</tr>
<tr>
<td>Inappropriate target audience</td>
<td></td>
</tr>
<tr>
<td>Inappropriate style of delivery</td>
<td></td>
</tr>
<tr>
<td>Time of day provided in inappropriate</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Team Factors</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Role Congruence</td>
<td></td>
</tr>
<tr>
<td>Lack of shared understanding</td>
<td></td>
</tr>
<tr>
<td>Role + responsibility definitions misunderstood/not clearly defined</td>
<td></td>
</tr>
<tr>
<td>Leadership</td>
<td></td>
</tr>
<tr>
<td>Ineffective leadership – clinically</td>
<td></td>
</tr>
<tr>
<td>Ineffective leadership – managerially</td>
<td></td>
</tr>
<tr>
<td>Lack of decision making</td>
<td></td>
</tr>
<tr>
<td>Inappropriate decision making</td>
<td></td>
</tr>
<tr>
<td>Untimely decision making (delayed)</td>
<td></td>
</tr>
<tr>
<td>Leader poorly respected</td>
<td></td>
</tr>
</tbody>
</table>
Support and cultural factors:
- Lack of support networks for staff
- Inappropriate level of assertiveness
- Negative team reaction(s) to adverse events
- Negative team reaction to conflict
- Negative team reaction to newcomers
- Routine violation of rules/regulations
- Lack of team openness/communication with colleagues
- Inadequate inter-professional challenge
- Failure to seek support
- Failure to address/manage issues of competence (whistleblowing)

Appendix 9 - Fishbone Diagram
Appendix 10 - Barrier Analysis

Root Cause Analysis Investigation tools

<table>
<thead>
<tr>
<th>Hazard(s)</th>
<th>Barriers/controls defenses already in place</th>
<th>Failsafe attributes</th>
<th>Improve barriers by:</th>
<th>Additional Barriers Required</th>
<th>Cost implications</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Individual</td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Manager</td>
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<tr>
<td></td>
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<td></td>
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<td></td>
<td></td>
<td>Trust</td>
</tr>
</tbody>
</table>
A just culture guide

Supporting consistent, constructive and fair evaluation of the actions of staff involved in patient safety incidents

This guide supports a conversation between managers about whether a staff member involved in a patient safety incident requires specific individual support or intervention to work safely. Action singling out an individual is rarely appropriate - most patient safety issues have deeper causes and require wider action.

The actions of staff involved in an incident should not automatically be examined using this just culture guide, but it can be useful if the investigation of an incident begins to suggest a concern about an individual action. The guide highlights important principles that need to be considered before formal management action is directed at an individual staff member.

An important part of a just culture is being able to explain the approach that will be taken if an incident occurs. A just culture guide can be used by all parties to explain how they will respond to incidents, as a reference point for organisational HR and incident reporting policies, and as a communication tool to help staff, patients and families understand how the appropriate response to a member of staff involved in an incident can and should differ according to the circumstances in which an error was made. As well as protecting staff from unfair targeting, using the guide helps protect patients by removing the tendency to treat wider patient safety issues as individual issues.

Please note:
- A just culture guide is not a replacement for an investigation of a patient safety incident. Only a full investigation can identify the underlying causes that need to be acted on to reduce the risk of future incidents.
- A just culture guide can be used at any point of an investigation, but the guide may need to be revisited as more information becomes available.
- A just culture guide does not replace HR advice and should be used in conjunction with organisational policy.
- The guide can only be used to take one action (or failure to act) through the guide at a time. If multiple actions are involved in an incident they must be considered separately.

### Start here - Q1. deliberate harm test

1a. Was there any intention to cause harm?  
**Yes**  
Recommendation: Follow organisational guidance for appropriate management action. This could involve: contact relevant regulatory bodies, suspension of staff, and referral to police and disciplinary processes. Wider investigation is still needed to understand how and why patients were not protected from the actions of the individual.

**END**

### No go to next question - Q2. health test

2a. Are there indications of substance abuse?  
**Yes**  
Recommendation: Follow organisational substance abuse at work guidance. Wider investigation is still needed to understand if substance abuse could have been recognised and addressed earlier.

**END**

2b. Are there indications of physical ill health?  
**Yes**  
Recommendation: Follow organisational guidance for health issues affecting work, which is likely to include occupational health referral. Wider investigation is still needed to understand if health issues could have been recognised and addressed earlier.

**END**

2c. Are there indications of mental ill health?  
**Yes**  
Recommendation: Action singling out the individual is unlikely to be appropriate; the patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. These actions may include, but not be limited to, the individual.

**END**

### if No to all go to next question - Q3. foresight test

3a. Are there agreed protocols/accepted practice in place that apply to the action/omission in question?  
**Yes**  
Recommendation: Action singling out the individual is unlikely to be appropriate; the patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. These actions may include, but not be limited to, the individual.

**END**

3b. Were the protocols/accepted practice workable and in routine use?  
**Yes**  
Recommendation: Action singling out the individual is unlikely to be appropriate; the patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. These actions may include, but not be limited to, the individual.

**END**

3c. Did the individual knowingly depart from these protocols?  
**Yes**  
Recommendation: Action directed at the individual may not be appropriate; follow organisational guidance, which is likely to include senior HR advice on what degree of mitigation applies. The patient safety incident investigation should indicate the wider actions needed to improve safety for future patients.

**END**

### if Yes to all go to next question - Q4. substitution test

4a. Are there indications that other individuals from the same peer group, with comparable experience and qualifications, would behave in the same way in similar circumstances?  
**Yes**  
Recommendation: Action singling out the individual is unlikely to be appropriate; the patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. These actions may include, but not be limited to, the individual.

**END**

4b. Was the individual missed out when relevant training was provided to their peer group?  
**Yes**  
Recommendation: Action directed at the individual may not be appropriate; follow organisational guidance, which is likely to include senior HR advice on what degree of mitigation applies. The patient safety incident investigation should indicate the wider actions needed to improve safety for future patients.

**END**

4c. Did more senior members of the team fail to provide supervision that normally should be provided?  
**Yes**  
Recommendation: Action directed at the individual may not be appropriate; follow organisational guidance, which is likely to include senior HR advice on what degree of mitigation applies. The patient safety incident investigation should indicate the wider actions needed to improve safety for future patients.

**END**

### if No to all go to next question - Q5. mitigating circumstances

5a. Were there any significant mitigating circumstances?  
**Yes**  
Recommendation: Action directed at the individual may not be appropriate; follow organisational guidance, which is likely to include senior HR advice on what degree of mitigation applies. The patient safety incident investigation should indicate the wider actions needed to improve safety for future patients.

**END**

### if No
## Appendix 12 – Where to Report

<table>
<thead>
<tr>
<th>Incident type (as defined by the relevant agency)</th>
<th>Agency</th>
<th>Reporter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incidents that meet the criteria for external reportable SIRIs. Verbal report to the Lead Patient Safety CCG/CSU Details of incident to be entered on SORD &amp; STEIS</td>
<td>CCG/ Local Area Team NHS England</td>
<td>Risk Manager /Risk Officer or nominated deputy Director on call if out of hours</td>
</tr>
<tr>
<td>Ionising Radiation (Medical Exposure) Regulations 2000 (IRMER)</td>
<td>Care Quality Commission</td>
<td>Radiation Protection</td>
</tr>
<tr>
<td><strong>Incident type (as defined by the relevant agency)</strong></td>
<td>Agency</td>
<td>Reporter</td>
</tr>
<tr>
<td>Actual or suspected fraud</td>
<td>Counter-fraud Agency</td>
<td>Counter Fraud Security Service</td>
</tr>
<tr>
<td>Security Incidents relating to:</td>
<td>SIRS Main Office NHS Protect (previously NHS Security Management)</td>
<td>Local Security Management Specialist</td>
</tr>
<tr>
<td>• Security incident involving physical assault of NHS staff</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Non-physical assault of NHS staff (including verbal abuse, attempted assaults and harassment)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Theft of or criminal damage (including burglary, arson, and vandalism) to NHS property or equipment (including equipment issued to staff)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Major contamination of the environment</td>
<td>Environment Health Agency</td>
<td>Head of Estates</td>
</tr>
<tr>
<td>Incidents involving food poisoning originating in, or being transferred through the Trust</td>
<td>Environmental Health Agency</td>
<td>Hotel Services Manager</td>
</tr>
</tbody>
</table>
The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR), place a legal duty on employers to report work related death, major injuries or over seven day injuries, work related diseases and dangerous occurrences (See Appendix 2 for full details)

| Health and Safety Executive | Health and Safety Officer |
When the Trust withdraws permission for an individual to engage in a regulated or controlled activity, or would have done so had that individual not resigned, retired, been made redundant or been transferred to a position which is not a regulated or controlled activity
- Because they think that the individual has:
  - engaged in relevant conduct
  - satisfied the Harm Test; or
  - received a caution or conviction for a relevant offence

<table>
<thead>
<tr>
<th>Incident type (as defined by the relevant agency)</th>
<th>Agency</th>
<th>Reporter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suspected safety problems with medicines and medical devices,</td>
<td>Medicines and Healthcare Products Regulatory Agency (MHRA) via <a href="https://yellowcard.mhra.gov.uk">https://yellowcard.mhra.gov.uk</a></td>
<td>Medical Device Liaison Officer Risk Officer Blood Transfusion Practitioner Pharmacy</td>
</tr>
<tr>
<td>Patient safety incidents data</td>
<td>National Reporting &amp; Learning System (NRLS)</td>
<td>Risk management</td>
</tr>
<tr>
<td>Death or injury where it is considered there are unusual or suspicious circumstances Theft of / malicious damage to, Trust property Violent or aggressive incidents where it is considered police involvement is required. Arson</td>
<td>Police</td>
<td>Medical Director / Director of Nursing /Director</td>
</tr>
</tbody>
</table>

Information governance: Major breaches of confidentiality such as the loss or theft of personal identifiable records or information (including missing notes). An incident involving the actual or potential loss of personal information that could lead to identity fraud or have other significant impact on individuals should be considered as serious.

<table>
<thead>
<tr>
<th>Information governance:</th>
<th>Information Governance Commissioner</th>
<th>Information Governance Manager</th>
</tr>
</thead>
</table>

Information governance:
- Major breaches of confidentiality such as the loss or theft of personal identifiable records or information (including missing notes).
- An incident involving the actual or potential loss of personal information that could lead to identity fraud or have other significant impact on individuals should be considered as serious.

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<table>
<thead>
<tr>
<th>Incident type (as defined by the relevant agency)</th>
<th>Agency</th>
<th>Reporter</th>
</tr>
</thead>
<tbody>
<tr>
<td>B. Incidental transfusion events and near misses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Incorrect Blood Component Transfused - where a patient was transfused with a blood component or plasma product which did not meet the appropriate requirements or which was intended for another patient.</td>
<td></td>
<td>Transfusion Practitioner</td>
</tr>
<tr>
<td>- Any transfusion reaction sufficiently severe to require the transfusion to be stopped and the patient to have immediate treatment, or which results in or prolongs hospitalisation or morbidity.</td>
<td></td>
<td>Transfusion Practitioner</td>
</tr>
<tr>
<td>- Acute and delayed transfusion reactions</td>
<td></td>
<td>Transfusion Practitioner</td>
</tr>
<tr>
<td>- Transfusion transmitted infection</td>
<td></td>
<td>Transfusion Practitioner</td>
</tr>
<tr>
<td>- Transfusion related acute lung injury</td>
<td></td>
<td>Transfusion Practitioner</td>
</tr>
<tr>
<td>- Transfusion associated graft versus host disease</td>
<td></td>
<td>Transfusion Practitioner</td>
</tr>
<tr>
<td>- Post-transfusion purpura</td>
<td></td>
<td>Transfusion Practitioner</td>
</tr>
<tr>
<td>- Circulatory overload</td>
<td></td>
<td>Transfusion Practitioner</td>
</tr>
<tr>
<td>- Near miss - any error, which if undetected, could result in the</td>
<td></td>
<td>Transfusion Practitioner</td>
</tr>
</tbody>
</table>

Where there are concerns about the practice of a healthcare professional.

Professional Regulatory Bodies.

Medical Director / Director of Nursing / specific professional lead, depending on healthcare professional involved.

All clinical incidents related to national screening programmes should be reported to NHS England as detailed in “Managing Serious Incidents in the English NHS National Screening Programmes – updated interim guidance.”

Regional Quality Assurance Director for the relevant programme

Lead for the relevant screening programme

Adverse transfusion events and near misses

- Incorrect Blood Component Transfused - where a patient was transfused with a blood component or plasma product which did not meet the appropriate requirements or which was intended for another patient.
- Any transfusion reaction sufficiently severe to require the transfusion to be stopped and the patient to have immediate treatment, or which results in or prolongs hospitalisation or morbidity.
- Acute and delayed transfusion reactions
- Transfusion transmitted infection
- Transfusion related acute lung injury
- Transfusion associated graft versus host disease
- Post-transfusion purpura
- Circulatory overload
- Near miss - any error, which if undetected, could result in the
### Human Tissue incidents related to:
- Post mortems, the HTA guidance is at: [http://www.hta.gov.uk/_db/_documents/Guidance_for_reporting_HTARIs.pdf](http://www.hta.gov.uk/_db/_documents/Guidance_for_reporting_HTARIs.pdf)
- Research; and
- Transplant licences

### Safeguarding incident – children and adults
- Referred to local authority (as appropriate as per safeguarding reporting thresholds)

### Sudden or unexpected death
- HM Coroner

---

### Appendix 13 – Severe and Death levels of Harm Definition

#### 4. Severe- Any unexpected or unintended incident that caused permanent or long-term harm to one or more persons.

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute</td>
<td>Perforation of the bowel during surgery, requiring a temporary colostomy and subsequent major operations. Problems with blood transfusion (e.g. transportation) resulting in the blood not arriving in time, patient suffers brain damage following haemorrhage. Wrong blood given to a young woman, who then develops anti-D antibodies which will affect any future pregnancy. Removal of wrong organ or wrong limb due to mis-identification. A patient is given someone else’s medication. They have an allergic reaction to it, have a cardiac arrest and suffer brain damage as a result of receiving the medication.</td>
</tr>
<tr>
<td>Primary care</td>
<td>Continuing treatment with warfarin without monitoring clotting levels which results in a brain haemorrhage and brain damage. A new born baby with an inborn error of metabolism fails to be screened for phenylketonuria resulting in irreversible brain damage. A patient incurs an extravasation injury (soft tissue burn) from an intravenous line at home, causing irreversible scarring and bone damage. Failure to diagnose meningitis by GP or A&amp;E department, child is discharged home, then collapses which leads to permanent brain damage.</td>
</tr>
</tbody>
</table>

#### 5. Death - Any patient safety incident that directly resulted in the death of one or more persons receiving NHS-funded care.

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute</td>
<td>Death as a direct consequence of perforation of the bowel during surgery. Pacemaker battery change is undertaken by a person with no expertise – causing the patient to have a cardiac arrest and then die. Wrong blood is given resulting in multi-organ failure and death. Death as a direct result of a hospital-acquired infection. A patient is given someone else’s medication. They have an allergic reaction to it, have a cardiac arrest and die as a result of receiving the medication.</td>
</tr>
<tr>
<td>Primary care</td>
<td>Continuing treatment with warfarin without monitoring clotting levels which results in a brain haemorrhage and death. A patient suffering from chest pains is asked to wait for a free slot; he goes for a walk, collapses and dies in the GP car park.</td>
</tr>
</tbody>
</table>
Serious Incident Details and Summary – complete those applicable

<table>
<thead>
<tr>
<th>STEIS Number:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Datix Number</td>
<td></td>
</tr>
<tr>
<td>Incident Type:</td>
<td>(as per STEIS entry)</td>
</tr>
<tr>
<td>Reason for Reporting:</td>
<td>(as per STEIS entry)</td>
</tr>
<tr>
<td>Actual Effect/Harm to Patient:</td>
<td></td>
</tr>
<tr>
<td>Incident Date:</td>
<td></td>
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<tr>
<td>Organisation/s involved:</td>
<td></td>
</tr>
<tr>
<td>Ward/Service:</td>
<td></td>
</tr>
<tr>
<td>Investigation Lead (Organisation):</td>
<td></td>
</tr>
<tr>
<td>Patient Date of Birth:</td>
<td></td>
</tr>
<tr>
<td>Author(s): (Name, Job title)</td>
<td></td>
</tr>
<tr>
<td>Report Date:</td>
<td></td>
</tr>
<tr>
<td>Signed Off By Name: (Name, Job title)</td>
<td></td>
</tr>
<tr>
<td>Serious Incident Group Sign Off:</td>
<td></td>
</tr>
<tr>
<td>Document Version:</td>
<td></td>
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</tbody>
</table>
INVESTIGATION REPORT
Final Report re: Incident Report
Datix Reference:
STEIS Reference Number:

Divisional sign off by:

Dr
Divisional Director

Executive sign of by:

Date:

Review of Harm Group

CCG sign off: Date:
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Executive summary

Brief incident description

Findings/Conclusion

Recommendations

Patient Details

<table>
<thead>
<tr>
<th>Age</th>
<th>Diagnosis and other comorbidities</th>
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<tr>
<th>Gender</th>
<th>Disability</th>
<th>Ye</th>
<th>No</th>
<th>N/A</th>
<th>Details:</th>
</tr>
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<thead>
<tr>
<th>Marital/civil partnership status</th>
<th>Ethnic origin</th>
<th>Religion/belief</th>
<th>Sexual orientation</th>
<th>Level of harm</th>
<th>GP location</th>
<th>Service/speciality involved</th>
<th>Directorate/Division/Clinical Business Unit</th>
<th>Safeguarding incident</th>
<th>Current admission date</th>
<th>Current ward / location / nursing team / care home</th>
<th>Other clinical services/organisations involved</th>
<th>Commissioner funding care</th>
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<tbody>
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<td></td>
<td>No</td>
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Terms of Reference

Purpose

Involvement of patient/relatives

Objectives
Key Issues and Scope

Key Deliverables

List of Data Sources

Investigation Team

<table>
<thead>
<tr>
<th>Name</th>
<th>Job Title</th>
<th>Organisation</th>
<th>Role/responsibility</th>
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Background

Description of Patient

Description of Service/s Involved

Other Services Provided to Patient

Relevant National and Local Policy/Guidance (at time of incident)

Support

Description of Support for Patient and/or Family/Carers/Guardians

Description of Support for Staff

Description Of Events

Tools Used

Good Practice

Care Management and Service Delivery

Problems Contributory Factors

Safeguarding Concerns

A Just Culture Guide

Deliberate Harm Test

Incapacity Health Test
Foresight Test

Substitution Test

Root Causes

Lessons Learned

Actions Taken To Prevent Future Incident

Recommendations for Further Action

Conclusion

Statement from the Serious Incident Review Group (SIG)

Arrangements for Shared Learning

Distribution List

References

Appendix A – Glossary: A Description of Acronyms And Technical/Clinical Terms

Appendix 15 – Declaration List

DECLARATION LIST
  (Policy for the Development and Management of Controlled Documents)
Use the appendix to record that staff in your service area have read the controlled document.

CONTROLLED DOCUMENT TITLE

Staff are only permitted to carry out this Policy, Procedure, Protocol or Guideline when they have signed this declaration list to verify that they have read, understood and agreed to abide by the provisions of the controlled document.

<table>
<thead>
<tr>
<th>Name (printed)</th>
<th>Signature</th>
<th>Position</th>
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<tbody>
<tr>
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</table>
### Appendix 16 – Equality and Diversity Assessment

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>Yes/No</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Does the document/guidance affect one group less or more favourably than another on the basis of:</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Race</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>- Ethnic origins (including gypsies and travellers)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Nationality</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>- Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Culture</td>
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<tr>
<td></td>
<td>- Religion or belief</td>
<td></td>
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<td></td>
<td>- Sexual orientation including lesbian, gay and bisexual people</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>- Age</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>- Disability - learning disabilities, physical disability, sensory impairment and mental health problems</td>
<td></td>
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</tr>
<tr>
<td>2.</td>
<td>Is there any evidence that some groups are affected differently?</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>If you have identified potential discrimination, are there any exceptions valid, legal and/or justifiable?</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>Is the impact of the document/guidance likely to be negative?</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>If so, can the impact be avoided?</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>What alternative is there to achieving the document/guidance without the impact?</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>Can we reduce the impact by taking different action?</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>