Blackpool Teaching Hospitals
NHS Foundation Trust

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Blackpool Teaching Hospitals NHS Foundation Trust aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that they are not placed at a disadvantage over others. The Equality Impact Assessment Tool is designed to help you consider the needs and assess the impact of your policy in the final Appendix.

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1 PURPOSE

The Trust Board and the Chief Executive are committed to the establishment of a supportive, open and learning culture that encourages staff to report incidents and near misses through the appropriate channels. The aim is not to apportion blame but rather to learn from incidents and near misses and improve practice accordingly. The Trust will take a systems approach to investigating Incidents, as it believes that a focus solely on the failings of individual staff will miss important causes of incidents and hamper effective learning.

This document details the Trust's procedures for the reporting and investigation of all Untoward Incidents including Near Misses. This procedure should be read in conjunction with the Trust's Risk Management Policy.

2 TARGET AUDIENCE

The reporting and investigation of incidents is an integral part of all employees' duties. It applies to ALL staff and all untoward events and near misses. The Trust utilises the Safeguard Risk Management System as a database in which the Incident Reporting Module collates the Trust's incidents information.

3 PROCEDURE

3.1 Roles, Responsibilities and Duties

3.1.1 Chief Executive

- Ensures the Trust has adequate systems for the reporting of all incidents and near misses.

3.1.2 Medical Director

- Ensures organisational learning occurs following the investigation into reported incidents and near misses.
- Implementation of this procedure.
- Ensures the Trust Board are appraised of all Serious Incidents by presenting serious incident reports as necessary.
- Authorised named person who will be responsible for deciding if an incident triggers the Serious Incident process (SI).

3.1.3 Director of Nursing and Quality

- Has the Executive Lead for Risk Management.
- Ensures organisational learning occurs following the investigation into reported incidents and near misses.
- Implementation of this procedure.

- Authorised named person who will be responsible for deciding if an incident triggers the Serious Incident process (SI).

3.1.4 Senior Information Risk Owner (for information security and Information Technology (IT) incidents only)

- Provide the focus for the management of information risk at Board level.

3.1.5 All Managers

- Ensure that their staff are fully aware of Trust procedures for the reporting of all incidents and near misses.
- Ensure any potential Serious Incident or Never Event is escalated to their Divisional Management Team and the Risk Management Department.
- Develop mechanisms within their Departments / Divisions for sharing and learning of lessons from reported incidents and near misses.
- Present reports and action plans for all adverse events / SI's where Root Cause Analysis has been undertaken to the appropriate Divisional / Departmental Governance Meeting.
- Ensure that recommendations from incident review processes are implemented.
- Ensure support is instigated for staff when identified as appropriate following a stressful or traumatic incident.
- Where a patient or visitor to the Trust is injured as a result of an accident / incident and sustains a fracture, the Health and Safety, Security Team must be informed in order that an electronic Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) report form is completed through the Health and Safety Executive (HSE) website.
- Where a member of staff is injured, as a result of a work related accident / incident and is absent for more than seven working days, the Health and Safety, Security Team must be informed in order that an electronic Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) report form is completed through the Health and Safety Executive (HSE) website.
- Consider the utilisation of the Incident Decision Tree as a means of ensuring a fair and consistent approach when an incident has occurred (Appendix 1).
- Decommission or isolate any equipment that may have been involved. In the case of serious incidents, isolate any danger areas or areas that may need to be preserved.
- Quality-check and submit all Root Cause Analysis (RCA's) relevant to their specific area.
- Review or complete all relevant risk assessments.

3.1.6 All Staff

- Must ensure they report accurately and responsibly any incident or near misses they have been involved in or witnessed through the Safeguard Incident Reporting System. **(see section 3.4 for how to report incidents and near misses)**
- Escalate to their direct Manager any potential Serious Incident / Never Event.
- Seek support as necessary following a stressful or traumatic incident.

3.1.7 Risk Management Team

- To ensure all reported incidents and near misses are assigned a manager and action is taken according to severity.
- To review incidents and trends on an organisation wide basis.
- Ensure lessons learned are collated at the Learning from Incidents and Risk Committee (LIRC) and applied across the organisation by way of the Trust Lessons Learned Newsletter.
- Report to the Trust Board, via the Quality Committee, trends and outcomes from Serious Incidents.
- Maintain a contemporaneous record of all RCA's performed within the Trust.
- Report relevant incidents to monitoring organisations as required.
- Ensure that additional analysis of incidents can be provided as requested.
- Ensure all patient safety incidents are collated, anonymised and sent to the National Reporting and Learning System (NRLS) via the Safeguard Incident System Database on at least a monthly basis by the Authorised User.
- Review all reported incidents as they are submitted for any trends and to identify serious incidents.
- The Local Security Management Specialist will receive notification of incidents in the following categories: -
- Physical assault on staff.
- Non-physical assault on staff.
- Theft or criminal damage (including burglary, arson and vandalism) to NHS property or equipment (including equipment issued to staff).
- Theft or criminal damage to staff or patient personal property arising from these types of security incident.

3.1.8 Assigned Manager

Ensure that all incidents are reviewed and impact scored according to the actual harm which may include some or all the following actions:

- Gather information on the circumstances surrounding the incident [who, what, where, why, when].
- Ensure that a risk assessment is carried out within 48 hours of the incident (if appropriate).
- Maintain a contemporaneous record of management and ensure this is recorded within the web reporting database.
- Seek advice from specialist advisors, such as risk management, information governance, infection prevention, health and safety, estates etc.
- Refer to and act in accordance with other Trust policies as required such as in relation to medical equipment.
- Develop action plans as required and ensure these are recorded and updated on the web reporting database.
- Review the grading of the incident following the investigation and implementation of the action plan.
- The assigned manager must, following investigation, grade the actual impact of the incident as 'near miss' or on a score of 1-5 in accordance with the National Patient Safety Agency (NPSA) Incident Consequence and Likelihood Scoring Process (Appendix 3) – see section 3.5, which maps through to the correct NRLS PD09 Degree of harm code for NRLS uploading.
- Ensure timely investigation and closure of incident within the Trust timescales as outlined in this policy.

3.2 Why Should an Incident be Reported?

3.2.1 Incidents must be reported so the following objectives can be achieved:

- It is a legal requirement.
- To establish the facts of each incident.
- To establish controls to prevent recurrence.
- To identify trends and potential risks.

In order to develop and improve upon standards and in the interest of staff, others and patient safety, the Trust encourages fairness and constructive criticism.

3.2.2 How Staff Can Raise Concerns

E.g. whistle blowing / open disclosure.

The Untoward Incident Reporting Procedure should be used in conjunction with other policies and procedures. The process for staff to raise concerns, e.g. whistle blowing, is included in the Freedom to speak up: raising concerns (whistle blowing) policy (CORP/POL/214).

3.3 What Should Be Reported

This Trust welcomes knowledge of adverse events as an opportunity to learn for the benefit of our patients and staff. Unless there is clear evidence of flagrant malpractice, a complete disregard for the safety of others, malicious intent to harm, theft or fraud, disciplinary policies will not be used for investigatory purposes.

The Trust utilises the Safeguard Risk Management System in which the Incident Module is hosted to report all incident information, this is provided by Ulysses.

An incident can be described as an event or circumstance which could have resulted or did result in unnecessary harm, damage or loss to a patient, staff member, visitor or to the organisation.

A trigger factor is a prompt for staff to generate an untoward incident report. The following general criteria must always trigger a report under the Untoward Incident Reporting Procedure: -

- Where it is suspected that any person was put at risk, was injured, or died as a result of an action or lack of an action by a member of Trust staff including agency staff and contractors.
- A patient, staff member or visitor to the Trust was injured or died as a result of any procedure, or instructions, lack of proper procedures or a failure to follow current procedures or instructions.
- A patient, staff member or visitor to the Trust was put at risk, was injured or died due to faulty equipment, drugs or an unsafe environment.
- Where a member of staff at work, a patient or others at risk, harms him or herself or commits suicide whilst in the Trust's care or employment.
- A fire, flood, theft or other event, which endangers the safety of staff, patients, and the public, causes injury or death or causes substantial damage and or loss to the Trusts capital or other assets.
- Any incident resulting in financial or material loss for a staff member, a patient or the organisation.
- Any incident involving the actual or potential loss of personal information (electronic media or paper records) that could lead to identity fraud or have other significant impact on individuals or the organisation.
- An event that has or could result in the integrity of the system or its data being put at risk or the availability of the system or information being put at risk.
- An incident that had the potential to cause harm but was prevented through the barriers and control measures in place (near miss).

It is the responsibility of each Divisional Quality Manager / Governance Lead to ensure that their staff are aware of these trigger factors and are reporting relevant incidents.

The core patient safety trigger factors are: -

- Medication error.
- Patient accident (fall, sharps, cuts, collision, burn).
- Unexpected serious injury, e.g. in-patient fall, resulting in fractured neck of femur.
- Unexpected patient death (all deaths following elective surgery must be reported).
- Tissue viability incident i.e. a pressure ulcer developed whilst an inpatient or under Community care.
- Missed or incorrect diagnosis.
- Inappropriate treatment.
- Poor, unsafe or inappropriate discharge.
- Patient suicide or self-harm.
- Patient record and record keeping issues.
- Patient abuse.
- Safeguarding concerns
- Venous Thromboembolism.

Infection Prevention and Control and Outbreaks trigger factors are: -

- Any deliberate or unavoidable breach in Infection Prevention and Control Policies, e.g. Staphylococcus Aureus Care Pathway not followed.
- Incidence of Methicillin-Resistant Staphylococcus Aureus (MRSA) Bacteraemia.
- Any disruption to services / supplies, which may have an impact on Infection Prevention and Control e.g. linen, consumables i.e., pulp products, Chloraprep.
- Any delays in equipment repair which may have an impact on Infection Prevention and Control e.g. blocked sinks or macerators.
- Pest Control, infestation of flies, ants and silverfish.
- Outbreak i.e. diarrhoea and vomiting, scabies.

All of the above incidents are to be also reported directly to the Infection Control Team.

The core Health and Safety, Security trigger factors are:-

- Unexpected injury / death.
- Sharps incidents.
- Violence and aggression.
- Security incidents.
- Lost property.

- Equipment failure.
- Patient absconding.
- Manual handling injuries.
- Exposure to harmful substances.
- Other incidents resulting in any injury or ill health.
- Staff, patient or visitor accident.
- Damage to Trust property.
- Environmental hazards.

The Core Information Security trigger factors are:

- The disclosure of confidential or sensitive information to any unauthorised individual
- Theft or accidental loss of personal information (electronic or paper based)
- Unauthorised access to personal information
- Inappropriate disclosure of personal information or
- Failure to follow procedure when dealing with personal and or sensitive information
- IT Incidents trigger examples are:
- An adverse impact, for example:
- Embarrassment to the Organisation
- Threat to personal safety
- Threat to privacy
- Legal obligation or penalty
- Financial loss
- Disruption of activities

The majority of IT Incidents will be innocent and unintentional and will not normally result in any form of disciplinary action being taken. The most likely result will be the recognition for and implementation of improved security and increased awareness of the need for security review.

The definitions above for IT incidents may also have the potential to cause a breach of security and as such the Trust's Incident Management process has mechanisms in place to alert the Information Governance Team to such incidents.

3.3.1 Near Miss:-

A near miss is a situation in which an event or incident fails to develop further. It is an incident that had the potential to cause harm but was prevented through the barriers and control measures in place examples would be:-

- A prescribing error that is identified by a nurse before the drug is administered.
- A staff member preventing a patient fall by intervening.
- Identifying a used sharp that has been incorrectly disposed of before an injury occurs.

3.3.2 Undesired Circumstance:-

This is a set of conditions or circumstances that have potential to cause injury, ill health or damage to the Trust's reputation. These include:-

- A slippery floor or leads trailing across a floor.
- Slates hanging off guttering.
- No sharps bin available.
- Unencrypted piece of mobile media.
- Equipment being used outside of its maintenance requirements.

3.3.3 Never Events:-

A Never Event is a serious, largely preventable patient safety incident that should not occur if the available preventative measures have been implemented by health care providers. To be a "never event" an incident must fulfil the following criteria:-

- The incident has clear potential for or has caused severe harm / death.
- There is evidence of occurrence in the past, i.e. it is a known source of risk.
- There is existing national guidance and/or national safety recommendations on how the event can be prevented and support for implementation.
- Occurrence can be easily defined, identified and continually measured.
- A "never event" list can be found on the Department of Health website https://www.england.nhs.uk/wp-content/uploads/2015/03/never-evnts-list-15-16.pdf

3.4 How all Incidents and Near Misses Involving Staff, Patients and Others are Reported

A Reporting Guide designed to direct staff through the electronic incident reporting system can be found on the Risk Management Intranet page.

An incident is reported via the electronic incident reporting system accessed through the Trust's intranet homepage. All incidents should be reported within 24 hours of occurrence.

The reporter completes an incident form and the following sections must be completed, and as such have been made mandatory:

- Reporter Details.
- Date of Incident.
- Time of Incident.
- Details of the Subject of the Incident.
- Where the Incident Happened.
- Description of Incident.
- Incident Category / Cause.
- Immediate Action Taken.

Should there at any time be a problem with the electronic incident reporting system then the Risk Management Department has supplies of paper incident reporting forms for staff to complete as part of the Business Continuity Plan.

Assigning of Incidents

The assignment of an incident for investigation is done via an electronic notification. Each department has a notification group of managers that have been agreed by each of the Divisions. This ensures the incident is communicated to the appropriate manager to investigate, manage and subsequently close. The assigned manager will investigate the incident and grade the actual impact as 'near miss' or on a score of 1-5 in accordance with the National Patient Safety Agency (NPSA) Incident Consequence and Likelihood Scoring Process (Appendix 2)

In addition the Quality Managers / Governance Leads will receive notifications of all incidents relevant to their Division and the Risk / Specialist Managers will receive notification of any incident in their relevant incident categories.

Quality Managers / Governance Leads are responsible for informing the Risk Management Department of any changes or updates to the notifications list for their Division.

3.4.1 Process for the Identification of a Serious Incident (SI)

In the case of a red incident (likely to warrant an impact score of 4 or 5) it is necessary to report not only online by the web page but also by contacting the Risk Management Department and informing one of the Risk Managers of the serious incident.

The incident will be: -

- Reviewed by a member of the Clinical Governance / Risk Management Team.
- Ensure the incident is placed on the Safeguard Incident System and merged into the 'live' system.
- Given a category and colour coded according to severity (impact)

- If the severity (impact) of the incident is red (4 or 5) the Risk Management Team will highlight the possibility of an SI / adverse event and liaise with the Executive Leads.
- The Executive Team will agree the category of investigation, Category A, B, C or D and a Case Manager, Investigation Officer or Risk Specialist Manager will be assigned to lead an investigation (see New Serious Incident Process Flow Chart - Appendix 3).
- An initial investigation meeting will take place in accordance with the terms of reference relevant to the category of incident.
- The Risk Management Team will report the Serious Incident to the Lead Clinical Commissioning Group via the Strategic Executive Information System (StEIS) as soon as the incident has been classified as triggering the SI reporting procedure and deemed to meet the StEIS reporting criteria.

3.4.2 Reporting a Serious IT and Information Security incident

The Information Governance Department is responsible for ensuring that all Serious Incidents for IT and Information Security are input onto the Trust's Incident Reporting System and escalated to the Head of Information Governance, Senior Information Risk Owner (SIRO) and the Risk Management Team.

The Information Governance Officer will maintain a log of all incidents and ensure that monthly reports are sent to the Head of Information Governance to escalate where appropriate to the SIRO and Risk Management Team.

This log must contain at least:

- a unique identifier
- a title for the incident
- date of incident
- location of incident
- severity rating
- a Serious Incident Requiring Investigation Checklist (SIRI)

All Serious Incidents for IT and Information Security (that score a level 2 or above using the SIRI Checklist) must be input into the Information Governance Toolkit (IGT) within 5 working days. The Department of Health (DoH) and Information Commissioner's Office (ICO) should also be informed. Please refer to the Checklist Guidance for Reporting, Managing and Investigating Information Governance and Cyber Security Incidents Requiring Investigation.

3.4.2 Process for Recalling the Patient

Where it is identified that a patient should be recalled following investigation of a serious incident, the responsible clinician has the responsibility for co-ordinating the recall process.

The responsible Clinician will:

- Identify lead specialist(s) health professional who will speak to the individual patients to be recalled.
- To identify an agreed script for the lead specialist(s) health professional to follow when speaking to the patients to be recalled.
- To establish a helpline during office hours.
- Duty Manager / Duty Director to be informed of the agreed script and patients to be recalled in case of the need for further support / advice outside office hours.
- To ensure the Communications Department are aware of any media issues that may arise from patients being recalled.
- Inform any relevant parties where a patient is involved in a national screening programme.
- Inform NHS England Lancashire Team.
- Speak to the patient(s) on the telephone.
- Send a follow up letter to support the information provided to the patient(s) on the telephone.
- Diarise clinics as soon as possible for those patients who need to be recalled.
- Run clinics in the evening and weekends as necessary to accommodate the patient(s).
- Invite the patient(s) to attend clinic with a relative or friend if they wish.
- Offer the patient(s) counselling if required.
- Contact the relevant General Practitioner to inform them of the situation.
- Provide the patient(s) with contact details for specialist nurse, therapist or Consultant lead.

3.5 How Should an Incident Be Graded and How Should It Be Investigated

3.5.1 Grading of the Incident

The Trust adopted the NPSA Incident Consequence and Likelihood Scoring Process as evidenced in Appendix 2. The NPSA key functions transferred to the NHS Commissioning Board Special Health Authority in 2012.

3.5.2 Different Levels of Investigation Approximate to the Severity (Impact) of the Event(s)

All incidents should be investigated as follows:

The assigned manager (as per Section 3.1.8 of this policy) will investigate the reported incident and determine the following:

- The underlying causes or events.
- The actions taken to prevent reoccurrence or any change/s in practice.
- Recommendations and lessons learned.
- The outcome.

The assigned manager will record their findings on the incident manager's form via the electronic incident reporting system. The assigned manager will the score the incident based on the actual impact of harm to the subject of the incident (as per Section 3.5.1 of this policy.) In the case of the incident having an actual impact score of Near Miss, Level 1 or Level 2 the assigned manager completes the investigation as above within 20 days of the incident occurrence.

In the case of the incident having an actual impact score of Level 3, Level 4 or Level 5 the assigned manager will undertake additional investigation in the form of a Root Cause Analysis (RCA) via the electronic incident system. The assigned manager will identify the following:

- Care or service delivery problem(s).
- Contributory factors.
- Root cause/s.
- Involvement and support of the injured party.
- Involvement and support of staff.
- Lessons learned.
- Recommendations.
- Arrangements for shared learning.

The assigned manager will submit the RCA to the Risk Management Department within 30 days of the incident occurrence. The Service Manager, Matron or Locality Lead appropriate to the incident category will quality check the RCA and upon approval the incident will be completed.

The only exception to the completion of an RCA on the electronic system is that of Infection Control incidents. An RCA will be undertaken by the Infection Prevention Team based on the Department of Health guidelines and a copy forwarded to the Risk Management Department upon completion. The Risk Management Department will attach the document to the electronic incident record.

Stage 2, 3 or 4 Pressure Ulcers will require an RCA checklist completing (see Tissue Viability/Pressure Ulcer Risk Assessment, Management/Prevention/Treatment and Reporting Procedure – CORP/PROC/642).

In addition to the above any incident with an actual impact score of Level 4 or Level 5 will be managed as a Serious Incident (SI) and an investigation team will be identified, comprising of an independent and impartial Case Manager and Investigation Officer. The

investigation team will produce a SI report, utilising the new Serious Incident process guidance contained in Appendix 4.

It is the responsibility of the Case Manager of the Investigation Team to ensure that the Serious Incident Report is submitted to the Safety Panel, within the allocated timeframe, in order to meet the StEIS submission timescale. The Safety Panel will monitor and approve all Serious Incident Reports and action plans, prior to sign off by the Chief Executive. (See appendix 4 for Roles and Responsibilities of the Serious Incident Team and Safety Panel and for the Safety Panel's Terms of Reference).

3.5.3 Trust Management and the Investigation of a Serious Incident (SI)

3.5.3.1 When Is An Untoward Incident a Serious Incident (SI)?

Whilst all incidents should be reported, some are more serious than others and should be treated as serious incidents. Deciding whether an Untoward Incident should be treated in this way is a matter of judgement, which should be considered by all concerned in the reporting chain, but generally incidents with an actual impact score of Level 4 or Level 5 will be deemed as serious.

In broad terms, serious incidents are events in healthcare where the potential for learning is so great, or the consequence to patients, families and carers, staff or organisations are so significant, that they warrant using additional resources to mount a comprehensive response. Serious incidents can extend beyond incidents which affect patients directly and include incidents which may indirectly impact patient safety or an organisation's ability to deliver ongoing healthcare.

The occurrence of a serious incident demonstrates weaknesses in a system or process that need to be addressed to prevent future incidents leading to avoidable death or serious harm to patients or staff, future incidents of abuse to patients or staff, or future significant reputational damage to the organisations involved. Serious incidents therefore require investigation in order to identify the factors that contributed towards the incident occurring and the fundamental issues (or root causes) that underpinned these. Serious incidents can be isolated, single events or multiple linked or unlinked events signalling systemic failures within a commissioning or health system.

There is no definitive list of events/incidents that constitute a serious incident however the definition below sets out circumstances in which a serious incident must be declared. Every incident must be considered on a case-by-case basis using the description below.

- Unexpected or avoidable death, this includes suicide / self-inflicted death.
- Unexpected or avoidable injury that has resulted in serious harm
- Unexpected or avoidable injury to one or more people that requires further treatment by a healthcare professional in order to prevent the death of the service user or serious harm.
- Actual or alleged abuse; sexual abuse, physical or psychological ill-treatment, or acts of omission which constitute neglect, exploitation, financial or material abuse, discriminative and organisational abuse, self-neglect, domestic abuse, human

trafficking and modern day slavery where healthcare did not take appropriate action / intervention to safeguard against such abuse occurring or where abuse occurred during the provision of NHS funded care.

- This includes abuse that resulted in (or was identified through) a Serious Case Review (SCR), Safeguarding Adult Review (SAR), Safeguarding Adult Enquiry or other externally-led investigation, where delivery of NHS funded care caused / contributed towards the incident.
- A Never Event – all Never Events are defined as serious incidents although not all Never Events necessarily result in serious harm or death. See Never Events Policy and Framework for the national definition and further information.
- An incident (or series of incidents) that prevents, or threatens to prevent, an organisation's ability to continue to deliver an acceptable quality of healthcare services, including (but not limited to) the following:
    - Failures in the security, integrity, accuracy or availability of information often described as data loss and/or information governance related issues (see Appendix 2 for further information);
    - Property damage;
    - Security breach / concern;
    - Incidents in population-wide healthcare activities like screening13 and immunisation programmes where the potential for harm may extend to a large population;
    - Inappropriate enforcement / care under the Mental Health Act (1983) and the Mental Capacity Act (2005) including Mental Capacity Act, Deprivation of Liberty Safeguards (MCA DOLS);
    - Systematic failure to provide an acceptable standard of safe care (this may include incidents, or series of incidents, which necessitate ward / unit closure or suspension of services; or
- Activation of Major Incident Plan (by provider, commissioner or relevant agency)
- Major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare or an organisation.

If in any doubt advice should be sought from the Risk Management Department.

To decide if the incident is to be treated as a SI the person in charge at the time must liaise with the Directorate Manager / Duty Manager. If the SI occurs during normal working hours the Division should inform the Risk Management Department immediately via telephone. If the SI occurs outside of normal working hours the Division / Duty Manager should inform the Director on Call. Stakeholders who are involved in an incident must be informed immediately and involved in the investigation. Other interested parties may need to be informed.

If an SI occurs and as a consequence there may be a possibility that media would be alerted to the incident it may be necessary for the Trust to be fully prepared for these eventualities. Therefore the following procedure must be instigated.

3.5.3.2 In Normal Working Hours

- The incident should be reported as per Section 3.4 of this policy and must be reported by telephone to the Risk Management Department.
- The Risk Management Department will make a decision to inform the Director of Nursing and Quality and/or the Medical Director or appointed deputies of the incident immediately. However, the Risk Management Department may request further information from area concerned, in order to make this decision.
- Within the 48 hour period following preliminary review of the incident a decision would be made by the Director of Nursing and Quality and/or the Medical Director or Deputy, that an SI had occurred. The Risk Management Team would then report the incident on StEIS within 2 working days from the time the incident is identified as an SI. The lead Clinical Commissioning Group would be informed via StEIS within 2 working days.
- Following reporting of an SI on StEIS, the Risk Management Team will provide the lead Clinical Commissioning Group with a 72 hour review report, via the NHS Midlands and Lancashire Commissioning Support Unit.

3.5.3.3 Out of Hours

- The Acute Response Team would normally be informed first of an incident occurring in the out of hours period. The Duty Manager would be contacted immediately and the incident reported as per Section 3.4 of this policy.
- The Duty Manager will inform the Risk Management Department at the earliest opportunity.
- The Duty Manager will inform the Duty Director (Executive on Call).
- The Duty Director (Executive on Call) will inform the Director of Nursing and Quality and/or the Medical Director the following day where the process for investigation as in normal working hours would commence.

3.5.3.4 Investigation Procedure when a Serious Incident (SI) is Determined

- All SI investigations will have a member of the Clinical Governance / Risk Management Department supporting and contributing to the root cause analysis to ensure unbiased external input.
- Any SI investigation will be completed within 60 working days from the date of the incident unless an extension is requested and this is approved by the Lead Clinical Commissioning Group.
- The investigation will be led or supported by staff that have had training in root cause analysis.
- All category A and B serious incidents will be investigated by an independent and impartial Case Manager and Investigation Officer. Category C incidents will be managed by the Deputy Director of Nursing and Quality or the Assistant Director of

Nursing and Quality. Category D serious incidents will be managed within Division. (See new SI process flow chart – appendix 3)

- The full investigatory report will be submitted to the Risk Management Department for sign off in accordance with the new agreed new Serious Incident process. (See appendix 4).
- The Divisional Team where the incident occurred will implement an action plan, following completion of the investigation report. The Safety Panel will agree the action plan and monitor the implementation of actions / recommendation identified.
- An investigation file will be opened so that all documented evidence can be filed, on the completion of the action plan. Only when all evidence is received by the Risk Management team and filed will be the investigation be closed.
- In the case of the SI being StEIS reportable the finalised report will be submitted to the Lead Clinical Commissioning Group, via the NHS Midlands and Lancashire Commissioning Support Unit.

3.5.3.5 Media Relations

All enquiries from the media relating to the incident must be directed to the Press and Public Relations Department who will arrange for the appropriate response. The Press and Public Relations Manager will prepare all press statements in conjunction with the Risk Management Team. The Nominated Director will have the responsibility to ensure that this is completed, and the Chief Executive or nominated Director will approve the press statements prior to their release.

3.6 Investigation Record Keeping

A contemporaneous record of all the events must be initiated from the time that a Serious Incident is declared. The Risk Management Team will be responsible for compiling an investigation folder which will contain: -

- The incident report and investigation report including any RCA.
- Copies of health records if required. Health records may need to be copied if they are required for ongoing treatment.
- Interview records and prepared statements dated, timed and signed (Appendix 5).
- Interview timetable.
- All entries in the folder must be legible, timed, dated and signed.

The investigation folder must be kept secure at all times. Update reports will be provided for the Chief Executive as required. All information within the file will be disclosable and the folder should be titled “This folder has been prepared in anticipation of litigation”. This should be signed and dated. On completion of the investigation the investigation file will be stored and filed in the Risk Management Department.

The Information Governance Team are responsible for ensuring that Information Security and IT incidents are documented and retained and stored securely for audit review where necessary.

3.7 Process for Following up Relevant Action Plans

As part of the investigation of a reported incident, recommendations will be identified. These recommendations will form an action plan for monitoring either locally, via the Risk Management Department or the Safety Panel, dependent on the level of incident.

3.7.1 Actual Impact Score 'Near Miss', Level 1 and Level 2

These incidents are classified as low risk and do not require an action plan to be formulated. The Divisions will monitor the trends from these incidents on a bi-monthly basis via the Learning from Incidents and Risk Committee. However stage 2 pressure ulcer incidents will require a checklist RCA to be completed via the Safeguard Incident Reporting System.

3.7.2 Actual Impact Score Level 3, Level 4 and Level 5

These action plans are monitored by the appropriate Division at the Divisional Governance Meetings. In addition, for Serious Incidents, the action plans are monitored by the Safety Panel and Risk Management Department. The Learning from Incidents and Risks Committee will monitor the implementation, completion and auditing of action plan recommendations, through the Division's bi-monthly reporting to the Committee.

3.7.3 Serious Incidents (SI's)

The monitoring of recommendations/action plans for Serious Incidents (SI's) is undertaken by the Safety Panel and Risk Management Team. An organisation wide overview is monitored by the Quality Committee and the Trust Board. All StEIS reportable incidents are monitored by the Lead Clinical Commissioning Group.

3.8 How the Trust Shares Safety Lessons with Internal and External Stakeholders

The Trust process for involving and communicating with internal and external stakeholders to share safety lessons is:

3.8.1 Adequate and timely feedback is key to ensuring lessons are learned and applied into everyday practice.

The Trust will use the following methods to ensure this:

- Serious Incident (SI) lessons learned will be agreed by the Safety Panel and will be disseminated locally by the Division involved in the incident. Divisions to provide learning articles to the Risk Management Team for inclusion in the Trust Lessons Learned newsletter for wider organisational learning.
- Lessons learned from incidents are reviewed and discussed at the LIRC Committee on a bi-monthly basis and through the Health, Safety and Security Committee.

- Medical induction days will be used as a means of disseminating lessons learned.
- The Integrated Complaints, Litigation, Incidents and Patient experience Report (CLIP) is produced quarterly, collating information and learning from the previous 3 months. This report is approved by the LIRC Committee and is disseminated to Divisions and to the local Commissioning Leads.
- High level enquires received within the organisation are reported and shared through the Senior Governance Management Team and the Quality Committee.

Serious issues and key lessons learned from the investigation of Complaints, Litigation, Incidents and Patient experience that need to be communicated immediately will be done so in the form of a Risk Alert Memo, which must be communicated at all ward handovers for the period of one week.

3.8.2 How the Organisation Reports Incidents to Internal and External Stakeholders to share safety lessons

Adequate and timely feedback is key to ensuring lessons are learned and applied into everyday practice, please refer to Appendix 9 for a list of possible external bodies/other interested parties to be informed. The following methods will be used to ensure this:

- All patient safety incidents are reported through the National Reporting and Learning System (NRLS). A six monthly benchmarking report is produced by the NRLS and is disseminated through LIRC and the Lessons Learned newsletter.
- All Serious Incidents that meet the StEIS reporting criteria are reported to the lead local Commissioner through StEIS, the Strategic Executive Incident System. All Serious Incident reports are published on the Risk Management site accessed through the Trust's Intranet.
- All Never Events are reported to StEIS, the CQC, the lead local Commissioner and NHS England. All Never Event reports are published on the Risk Management site accessed through the Trust's Intranet.
- The integrated Complaints, Litigation, Incidents and Patient experience (CLIP) report is produced on a quarterly and annual basis and presented to the Learning from Incidents and Risk Committee and shared with Divisional staff and local Commissioner Leads. The CLIP report is also published on the Risk Management site of the Trust's Intranet.
- Information Security and IT incidents are reported locally and also to the Health Informatics Committee regularly.

3.9 Advice Available to Staff in the Event Of Being Called as a Witness

In the event of a member of staff being called as a witness to give evidence at either an inquest or trial, a representative from the Trust's Legal Department will meet with the individual witnesses to advise them of the purpose and format of the proceedings, how to give evidence and on the legal representation available to them, depending on the circumstances of their involvement. The Legal Representative will also advise staff on the

availability and source of external advice. Further details are outlined in the Handling Clinical Negligence and Personal Injury Claims Policy (CORP/POL/007).

3.10 Duty of Candour

The Trust has a commitment to patient safety and being open and honest following patient safety incidents, complaints and claims. The Trust also has a duty to promote a culture of openness and truthfulness as a prerequisite to improving the safety of patients, staff and visitors as well as the quality of healthcare systems. The culture of "Being Open" should be fundamental in relationships with and between patients, the public, staff and other healthcare organisations.

The standard NHS contract includes a contractual Duty of Candour for providers from 1st April 2013. In addition there is also a statutory Duty of Candour Regulation 20 which applies to all healthcare providers and services registered with the Care Quality Commission (CQC) which came into force from 27 November 2014. The contractual and regulatory duties mean the Trust should:

- Use definitions of moderate harm, severe harm and death (level 3, 4 and 5 incidents) that warrant a patient or family being informed an incident has occurred. This initial notification should be done face to face with the patient/carer or relative, with consent, if possible within 10 working days of the incident being reported. A sincere expression of apology must be provided and the conversation must be recorded either in the medical records or using a meeting template, contained within Corp/Pol/538).
- Provide a step by step explanation of what happened and explain that a review/investigation of the events will take place.
- The patient and/or carer must be offered written notification (including a sincere apology) of the incident. The offer must be documented whatever the outcome.
- Full written documentation of any letters, discussions and meetings must be maintained and attached to the incident on the Safeguard Incident reporting system. The response of the patient/carers should also be recorded. If meetings are offered but declined this must also be recorded. All follow up letters to patients / relatives must be approved for release by the Medical Director.
- Any emerging information (whether during the investigation or after the investigation) must be offered and recorded.
- All documented communication under relating to Duty of Candour should be attached to the incident report on the Safeguard Incident Reporting system.

For full information, guidance and templates for Duty of Candour please refer to CORP/POL/538 – Patient Safety Including Being Open and Duty of Candour Policy.

3.11 Process for Reporting To External Agencies

The Trust has a duty to report to external agencies as follows;

3.11.1 National Reporting and Learning System (NRLS)

The Risk Management Department will ensure that all closed patient safety incidents are reported through the National Reporting and Learning System on a weekly on a weekly basis.

3.11.2 Clinical Commissioning Groups

The Risk Management Department will report any StEIS reportable Serious Incident to the lead Commissioning Group without delay and no later than 2 working days after the incident is identified. Incidents falling into any of the serious incident categories listed below should be reported immediately to the relevant commissioning organisation upon identification. This should be done by telephone as well as electronically.

- Incidents which activate the NHS Trust or Commissioner Major Incident Plan:
- Incidents which will be of significant public concern:
- Incidents which will give rise to significant media interest or will be of significance to other agencies such as the police or other external agencies.

3.11.3 Coroner

In the case of an unexpected or unexplained death the Coroner must be informed by a member of the medical staff in accordance with CORP/POL/093 Referral to the Coroner.

3.11.4 Police

Where it appears there may be a criminal element to an incident or a suicide, the Local Security Management Specialist must inform the Police within 24 hours of occurrence and the incident must be managed as a Serious Incident. Incidents involving low level theft will not be managed as a Serious Incident.

3.11.5 Health and Safety Executive

The Health and Safety Team will ensure that all RIDDOR reportable incidents are reported to the Health and Safety Executive via the electronic report form within 15 days of the incident occurrence.

3.11.6 Medicines and Healthcare Products Regulatory Agency (MHRA)

The assigned manager will ensure that all medical devices MHRA reportable incidents are reported to the Medicines and Healthcare Products Regulatory Agency via the electronic report form (http://www.mhra.gov.uk /) within 15 days of the incident occurrence.

The Pathology Department will ensure all Serious Hazards of Transfusion (SHOT) incidents are reported to the MHRA via the Serious Adverse Blood Reactions and Events (S.A.B.R.E) electronic system in accordance with the framework for the Safe Dealing of a Blood Transfusion Service within the Trust (CORP/PROC/449).

3.11.7 Department of Health

The Radiology Department will ensure that all Ionising Radiation (Medical Exposure) Regulations 2000 reportable radiation incidents are reported to the Department of Health and the Care Quality Commission via email within 3 days of occurrence.

3.11.8 Environmental Health

The Microbiology Department will ensure all incidents involving Salmonella and Legionnaires are reported to Environmental Health.

The Catering Department will ensure all incidents of food poisoning or suspected food poisoning are reported to the Environmental Health Service by telephone.

3.11.9 NHS Litigation Authority

The Legal Department will ensure that all incidents that meet the NHS Litigation Authority Reporting Criteria are reported as per the Handling Clinical Negligence and Personal Injury Claims Policy - CORP/POL/007).

3.11.10 Medicines Regional Quality Centre

The Pharmacy Department will ensure that all incidents involving faulty drug products are reported to the Regional Quality Control Centre (North West Quality Control) within 1 month of occurrence.

3.11.11 Information Commissioners

See section 3.4.2 Reporting a Serious IT and Information Security incident.

3.12 Training of Staff in Line with the Training Needs Analysis

Training of staff is undertaken in line with the Trust's Mandatory Risk Management Training Policy CORP/POL/354.

3.13 Process for Monitoring Compliance

The process for monitoring compliance is outlined in Appendix 8 and 9.

4 ATTACHMENTS	
Appendix Number	**Title**
Appendix 1	Incident Decision Tree
Appendix 2	Incident Consequence and Likelihood Scoring Process
Appendix 3	Flow chart for Serious Incident Process
Appendix 4	New Serious Incident Investigation Process
Appendix 5	Preparation of Factual Accounts of Version of Events
Appendix 6	Levels of Systems-Based Investigation Recognised In The NHS – (NHSE Serious Incident Framework 2015)

4 ATTACHMENTS	
Appendix Number	**Title**
Appendix 7	Informing External Bodies/Other Interested Parties
Appendix 8	Process for Monitoring Compliance – Incident Reporting (3.2.2)
Appendix 9	Process for Monitoring Compliance – Investigations (3.2.5)
Appendix 10	Equality Impact Assessment Form

5 PROCEDURAL DOCUMENT STORAGE (HARD AND ELECTRONIC COPIES)
Electronic Database for Procedural Documents
Held by Procedural Document and Leaflet Coordinator

6 LOCATIONS THIS DOCUMENT ISSUED TO		
Copy No	**Location**	**Date Issued**
1	Intranet	02/10/2017
2	Wards, Departments and Service	02/10/2017

7 OTHER RELEVANT / ASSOCIATED DOCUMENTS	
Unique Identifier	**Title and web links from the document library**
	Safeguard Risk Management System http://fcvmsrv020/safeguard-bfw/index.aspx?sid=%20
CLIN/GOV/PLAN/001	Patient Safety and Risk Management Department Business Continuity Plan http://fcsp.xfyldecoast.nhs.uk/trustdocuments/Documents/CLIN-GOV-PLAN-001.docx
CLIN/GOV/PROC/002	Safeguard Web Incidents Training Guide (Merging Of Incidents and Uploading to NPSA/SIRS) Standard Operating Procedure http://fcsp.xfyldecoast.nhs.uk/trustdocuments/Documents/CLIN-GOV-PROC-002.docx
CORP/POL/007	Handling Clinical Negligence and Personal Injury Claims http://fcsp.xfyldecoast.nhs.uk/trustdocuments/Documents/CORP-POL-007.docx
CORP/POL/093	Referral Of Deaths To The Coroner http://fcsp.xfyldecoast.nhs.uk/trustdocuments/Documents/CORP-POL-093.docx
CORP/POL/116	Infection Prevention in the Acute Setting http://fcsp.xfyldecoast.nhs.uk/trustdocuments/Documents/CORP-POL-116.docx
CORP/POL/155	Systematic Approach to Managing Clinical Incidents, Complaints and Claims http://fcsp.xfyldecoast.nhs.uk/trustdocuments/Documents/CORP-POL-155.docx
CORP/POL/178	Information Security Policy http://fcsp.xfyldecoast.nhs.uk/trustdocuments/Documents/CORP-POL-178.docx
CORP/POL/214	Freedom to Speak Up (Whistleblowing Policy) http://fcsp.xfyldecoast.nhs.uk/trustdocuments/Documents/CORP-POL-214.docx

7 OTHER RELEVANT / ASSOCIATED DOCUMENTS	
Unique Identifier	**Title and web links from the document library**
CORP/POL/354	Mandatory Risk Management Training http://fcsp.xfyldecoast.nhs.uk/trustdocuments/Documents/CORP-POL-354.docx
CORP/POL/538	Patient Safety Including Being Open and Duty of Candour http://fcsp.xfyldecoast.nhs.uk/trustdocuments/Documents/CORP-POL-538.docx
CORP/POL/547	Risk Management Policy http://fcsp.xfyldecoast.nhs.uk/trustdocuments/Documents/CORP-POL-547.docx
CORP/PROC/449	Framework for the Safe Delivery of a Blood Transfusion Service http://fcsp.xfyldecoast.nhs.uk/trustdocuments/Documents/CORP-PROC-449.docx
CORP/PROC/642	Tissue Viability / Pressure Ulcer Risk Assessment, Management / Prevention / Treatment and Reporting http://fcsp.xfyldecoast.nhs.uk/trustdocuments/Documents/CORP-PROC-642.docx
Intranet Page ~ Web Based Incident Reporting / Root Cause Analysis	http://fcsp.xfyldecoast.nhs.uk/C/clinical-governance/riskmanagement/Pages/IncidentReporting.aspx

8 SUPPORTING REFERENCES / EVIDENCE BASED DOCUMENTS
References In Full
Crown. (1983). Mental Health Act 1983. Available: http://www.legislation.gov.uk/ukpga/1983/20/contents . Last accessed 25/09/2017.
Crown. (2000). The Ionising Radiation (Medical Exposure) Regulations 2000. Available: http://www.legislation.gov.uk/uksi/2000/1059/contents/made . Last accessed 25/09/2017
Crown. (2005). Mental Capacity Act 2005. Available: http://www.legislation.gov.uk/ukpga/2005/9/contents . Last accessed 25/09/2017.
Health and Safety Executive. RIDDOR - Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013. Available: http://www.hse.gov.uk/riddor/ . Last accessed 25/09/2017.
NHS England Serious Incident Framework (2015) - Supporting learning to prevent recurrence. Available: https://www.england.nhs.uk/wp-content/uploads/2015/04/serious-incidnt-framwrk-upd.pdf
NHS England Revised Never Events Policy and Framework (2015) Available: https://www.england.nhs.uk/wp-content/uploads/2015/04/never-evnts-pol-framwrk-apr.pdf
NHS England. NHS standard contract 2017/18. Available: https://www.england.nhs.uk/nhs-standard-contract/17-18/
MHRA. Medicines & Healthcare products. Available: https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency
National Patient Safety Agency. (2008). A risk matrix for risk managers. Available: http://www.nrls.npsa.nhs.uk/resources/?entryid45=59833&q=0%c2%acrisk%c2%ac&p=1 . Last accessed 25/09/2017.

9 CONSULTATION / ACKNOWLEDGEMENTS WITH STAFF, PEERS, PATIENTS AND THE PUBLIC		
Name	**Designation**	**Date Response Received**
Colin Norris	Health & Safety Officer	September 2017
Dawn Goodall	Head of Legal	September 2017
Peter Hudson	Clinical Nurse Specialist, Blood Bank	September 2017
Sharon Mawdsley	Acting Nurse Consultant, Infection Prevention	September 2017
Liane Moorhouse	Clinical Risk Manager	September 2017
Heather Atkinson	Information Governance Specialist	September 2017
Robert Ward	Mental Capacity/DOLS Lead	September 2017

10 DEFINITIONS / GLOSSARY OF TERMS	
Adverse events / Near Misses	These are incorporated in the one phrase, 'adverse incident'. An adverse event is when an unsafe act or omission has occurred in the course of a process. The adverse event may or may not cause actual unintended or unexpected harm, loss or damage. A near miss is where a chain of events/unsafe acts, potential leading to an incident, where in some way detected and thwarted prior to the penultimate harm act, but could have done.
Authorised User	A person who is authorised to use the Safeguard Risk Management System and has been issued a Username and Password.
Duty of Candour and Being Open	This is a term used to describe a communication process to patients and or their carers when moderate or major harm has occurred as a direct result of an incident whilst under the care of the Trust. Senior clinical staff will decide when to instigate the Duty of Candour and Being Open process and will ensure appropriate documentation is completed on the Trusts' incident reporting form and within the patient's health record.
CLIP	Complaints, Litigation, Incidents and Patient experience Report
Death	The death must relate to the incident rather than to the natural course of the patients illness or underlying condition.
DOC	Duty of Candour
DoH	Department of Health
GMC	General Medical Council
Harm	Is defined as 'injury (physical or psychological), disease, suffering, disability or death'. In most instances, harm can be considered to be unexpected if it is not related to the natural cause of the patient's illness or underlying condition.
Hazard	Is something, i.e. an object, an unsafe act, an unsafe process, that has the potential to cause harm, loss or damage
HSE	Health and Safety Executive
ICO	Information Commissioner's Office
IT	Information Technology
LIRC	Learning from Incidents and Risk Committee
MHRA	Medicines and Healthcare Products Regulatory Agency

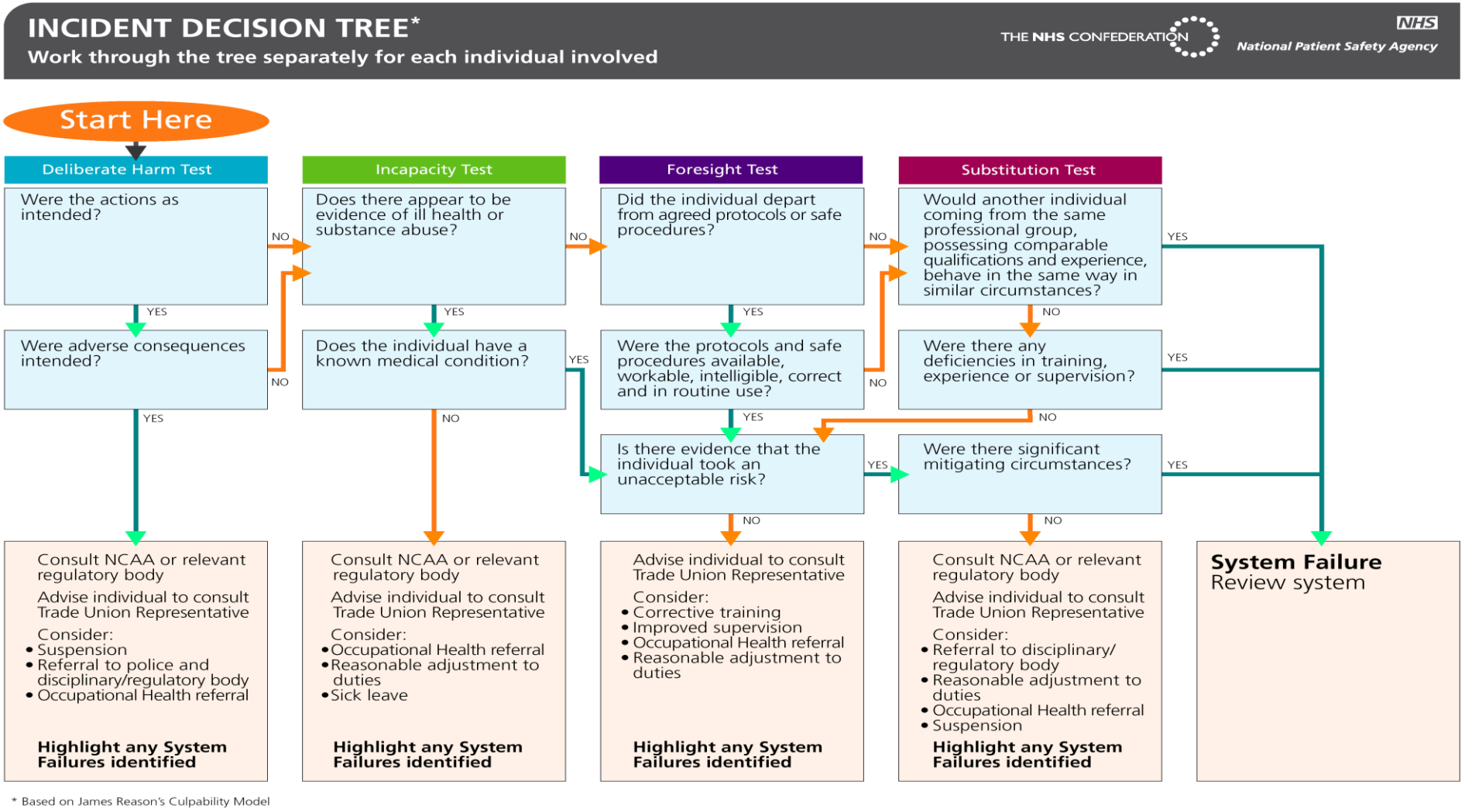
10 DEFINITIONS / GLOSSARY OF TERMS	
MRSA	Methicillin-Resistant Staphylococcus Aureus
National Patient Safety Agency (NPSA)	The National Patient Safety Agency is part of the NHS established in 2001 with a mandate to identify issues relating to patient safety and to find appropriate solutions.
National Reporting and Learning System (NRLS)	Is administered by the NPSA to complement local reporting arrangements and does not replace local reporting. The NRLS is an incident reporting database for recording incidents directly reported to it by individuals and is also connected in to the Trust's local incident database to track incident trends and solutions for sharing across the NHS in an anonymised format.
Never Events	NHS England has defined a Never Event as a serious and largely preventable patient safety incident, which should not occur if the available preventative measures have been implemented. A Never Event may or will result in severe harm or death to a patient and/or the public. NHS England has developed a core list of 14 Never Events which mostly link to acute providers of healthcare for 2015/16. The current list of Never Event incidents are as follows: • Wrong Site Surgery. • Wrong implant/prosthesis • Retained foreign object post-procedure • Mis-selection of a strong potassium containing solution • Wrong route administration of medication • Overdose of insulin due to abbreviations or incorrect device • Overdose of methotrexate for non-cancer treatment • Mis-selection of high strength midazolam during conscious sedation • Failure to install functional collapsible shower or curtain rails (mental health) • Falls from poorly restricted windows • Chest or neck entrapment in bedrails • Transfusion or transplantation of ABO incompatible blood components or organs • Misplaced Naso or Orogastric Tube not detected prior to use • Scalding of patients
NMC	Nursing and Midwifery Council
Open and Fair	Is term that is often used in conjunction with incident reporting. It is impossible to completely remove the chance that the fault may lie with an individual but the Trust makes it clear that an event will be properly investigated before the organisation concludes what caused it to occur.

10 DEFINITIONS / GLOSSARY OF TERMS	
Patient Safety Incident	Any unintended or unexpected incident (s) that could have or did lead to harm for one or more persons receiving NHS funded healthcare. Example: Patient given Paracetamol instead of aspirin. (This incident actually occurred). Patient safety incident' is an umbrella term which is used to describe a single incident or a series of incidents that occur over time.
Patient Safety Incident (Level of Severity: No Harm)	A patient safety incident that caused no harm but was not prevented (impact not prevented). Example; the wrong drug was given to the patient but no harm came to the patient.
Patient Safety Incident (Prevented)	Any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to patients receiving NHS funded health care. Example; the wrong blood transfusion was taken to the patient but was not given.
RIDDOR	Reporting of Injuries, Diseases and Dangerous Occurrences Regulations
Risk	Is the chance or likelihood of harm, loss or damage
Risk Assessment	The use of quantitative or qualitative measures to determine the level of risk associated with the hazard.
Risk Management	Is the process by which risks are reduced, managed or controlled to an acceptable level.
Risk Register	This is a management tool that lists all the identified hazards and the results of their analysis and evaluation. Information on the status of the risk is also included. These details can then be used to manage the risk to within acceptable levels. The risk register is an important component of the organisations Risk Management framework. Where suppliers and/or partners are involved, it is essential to have a shared understanding of risks and agreed plans for managing them please refer to the Risk Management Strategy.
Root Cause Analysis (RCA)	A root cause analysis (RCA) is a problem solving methodology for discovering the real, or root cause(s) of problems, or difficulties identified via a range of activities, including adverse incident management. RCA tools and techniques such as failure modes and effects analysis, control or barrier analysis and fault tree analysis are all approaches that can be used to analyse the robustness and reliability of systems and processes and are therefore proactive RCA tools. Following an adverse incident, a retrospective analysis is undertaken of the sequence of events leadings to it. Dependent on the type of incident and its severity, a structured investigation culminating in a report of the investigation's findings, conclusions and recommendations may be required. Any issues that may involve individual fault are removed from this exercise at the beginning and dealt with on a one to one basis alongside this process, or outside of the process through Human Resources policies and procedures.
S.A.B.R.E	Serious Adverse Blood Reactions and Events
SAR	Safeguarding Adult Review

10 DEFINITIONS / GLOSSARY OF TERMS	
SCR	Serious Case Review
Serious Incident (SI)	In broad terms, serious incidents are events in health care where the potential for learning is so great, or the consequences to patients, families and carers, staff or organisation are so significant, that they warrant using additional resources to mount a comprehensive response. Serious incidents can extend beyond incidents which affect patients directly and include incidents which may indirectly impact patient safety or an organisation's ability to deliver ongoing care. The occurrence of a serious incident demonstrates weaknesses in a system or process that need to be addressed to prevent future incidents leading to avoidable death or serious harm to patients or staff, future incidents of abuse to patients or staff, or future significant reputational damage to the organisations involved. Serious incidents therefore require investigation in order to identify the factors that contributed towards the incident occurring and the fundamental issues (or root causes) that underpinned these. Serious incidents can be isolated, single events or multiple linked or unlinked events signalling systemic failures within a commissioning or health system.
SIRO	Senior Information Risk Owner
SHOT	Serious Hazards of Transfusion
SI	Serious Incident
StEIS	STrategic Executive Information System

11 AUTHOR / DIVISIONAL / DIRECTORATE MANAGER APPROVAL			
Issued By	Helena lee	**Checked By**	Simone Anderton
Job Title	Governance, Risk & Patient Safety Manager	**Job Title**	Deputy Director of Nursing & Quality
Date	20/09/2017	**Date**	22/09/2017

APPENDIX 1: INCIDENT DECISION TREE



APPENDIX 2: INCIDENT CONSEQUENCE AND LIKELIHOOD SCORING PROCESS

Table 1 Consequence scores

Choose the most appropriate description for the identified risk from the left hand side of Table 1, then work along the columns in the same row to assess the severity of the risk on the scale of 1 to 5 to determine the consequence score, which is the number given at the top of the column.

Table 1	Consequence Score (severity levels) and examples of descriptions				
	1	2	3	4	5
Description	**Negligible**	**Minor**	**Moderate**	**Major**	**Catastrophic**
Impact on the safety of patients, staff or public (physical / psychological harm)	Minimal injury requiring no/minimal intervention or treatment. No time off work	Minor injury or illness, requiring minor intervention Requiring time off work for >3 days Increase in length of hospital stay by 1-3 days	Moderate injury requiring professional intervention Requiring time off work for 4-14 days Increase in length of hospital stay by 4-15 days RIDDOR/agency reportable incident An event which impacts on a small number of patients	Major injury leading to long-term incapacity/disability Requiring time off work for >14 days Increase in length of hospital stay by >15 days Mismanagement of patient care with long-term effects	Incident leading to death Multiple permanent injuries or irreversible health effects An event which impacts on a large number of patients
Quality / complaints / audit	Peripheral element of treatment or service suboptimal Informal complaint/inquiry	Overall treatment or service suboptimal Formal complaint (stage 1) Local resolution Single	Treatment or service has significantly reduced effectiveness Formal complaint (stage 2) complaint Local resolution	Non-compliance with national standards with significant risk to patients if unresolved Multiple complaints/ independent	Totally unacceptable level or quality of treatment/service Gross failure of patient safety if findings not acted on

APPENDIX 2: INCIDENT CONSEQUENCE AND LIKELIHOOD SCORING PROCESS					
		failure to meet internal standards Minor implications for patient safety if unresolved Reduced performance rating if unresolved	(with potential to go to independent review) Repeated failure to meet internal standards Major patient safety implications if findings are not acted on	review Low performance rating Critical report	Inquest/ombudsman inquiry Gross failure to meet national standards
Human resources /organisational development/ staffing/ competence	Short-term low staffing level that temporarily reduces service quality (< 1 day)	Low staffing level that reduces the service quality	Late delivery of key objective/ service due to lack of staff Unsafe staffing level or competence (>1 day) Low staff morale Poor staff attendance for mandatory/key training	Uncertain delivery of key objective/service due to lack of staff Unsafe staffing level or competence (>5 days) Loss of key staff Very low staff morale No staff attending mandatory/ key training	Non-delivery of key objective/service due to lack of staff Ongoing unsafe staffing levels or competence Loss of several key staff No staff attending mandatory training /key training on an ongoing basis
Statutory duty / inspections	No or minimal impact or breech of guidance/ statutory duty	Breech of statutory legislation Reduced performance rating if unresolved	Single breech in statutory duty Challenging external recommendations/ improvement	Enforcement action Multiple breeches in statutory duty Improvement notices	Multiple breeches in statutory duty Prosecution Complete systems change required

APPENDIX 2: INCIDENT CONSEQUENCE AND LIKELIHOOD SCORING PROCESS					
			notice	Low performance rating Critical report	Zero performance rating Severely critical report
Adverse publicity/ reputation	Rumours Potential for public concern	Local media coverage – short-term reduction in public confidence Elements of public expectation not being met	Local media coverage – long-term reduction in public confidence	National media coverage with <3 days service well below reasonable public expectation	National media coverage with >3 days service well below reasonable public expectation. MP concerned (questions in the House) Total loss of public confidence
Business objectives/ projects	Insignificant cost increase/ schedule slippage	<5 per cent over project budget Schedule slippage	5–10 per cent over project budget Schedule slippage	Non-compliance with national 10–25 per cent over project budget Schedule slippage Key objectives not met	Incident leading >25 per cent over project budget Schedule slippage Key objectives not met

APPENDIX 2: INCIDENT CONSEQUENCE AND LIKELIHOOD SCORING PROCESS					
Finance including claims	Small loss Risk of claim remote	Loss of 0.1–0.25 per cent of budget Claim less than £10,000	Loss of 0.25–0.5 per cent of budget Claim(s) between £10,000 and £100,000	Uncertain delivery of key objective/Loss of 0.5–1.0 per cent of budget Claim(s) between £100,000 and £1 million Purchasers failing to pay on time	Non-delivery of key objective/ Loss of >1 per cent of budget Failure to meet specification/ slippage Loss of contract / payment by results Claim(s) >£1 million
Service/business interruption Environmental impact	Loss/interruption of >1 hour Minimal or no impact on the environment	Loss/interruption of >8 hours Minor impact on environment	Loss/interruption of >1 day Moderate impact on environment	Loss/interruption of >1 week Major impact on environment	Permanent loss of service or facility Catastrophic impact on environment

Table 2 Likelihood score (L)

What is the likelihood of the consequence occurring?

Use Table 2 to determine the likelihood of this incident occurring.

Table 2

Likelihood Score	1	2	3	4	5
Description	**Rare**	**Unlikely**	**Possible**	**Likely**	**Almost certain**
Frequency How often might it / does it happen	This will probably never happen/recur	Do not expect it to happen / recur but it is possible it may do so	Might happen or recur occasionally	Will probably happen / recur but it is not a persisting issue	Will undoubtedly happen / recur, possibly frequently

APPENDIX 2: INCIDENT CONSEQUENCE AND LIKELIHOOD SCORING PROCESS

For a detailed discussion about consequence and likelihood see the instructions for use detailed below.

Table 3 Risk scoring = Consequence x Likelihood (C x L)

Calculate the risk score by multiplying the Consequence by the Likelihood = Risk Score

Table 3

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

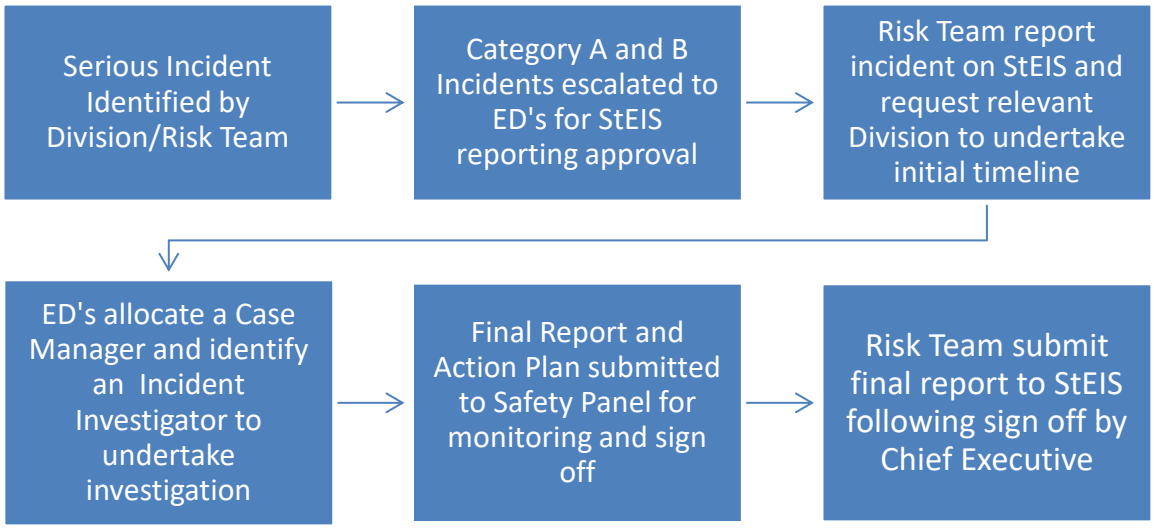
1 – 3	Low risk
4 – 6	Moderate risk
8 – 12	High risk
15 – 25	Extreme risk

Instructions for use

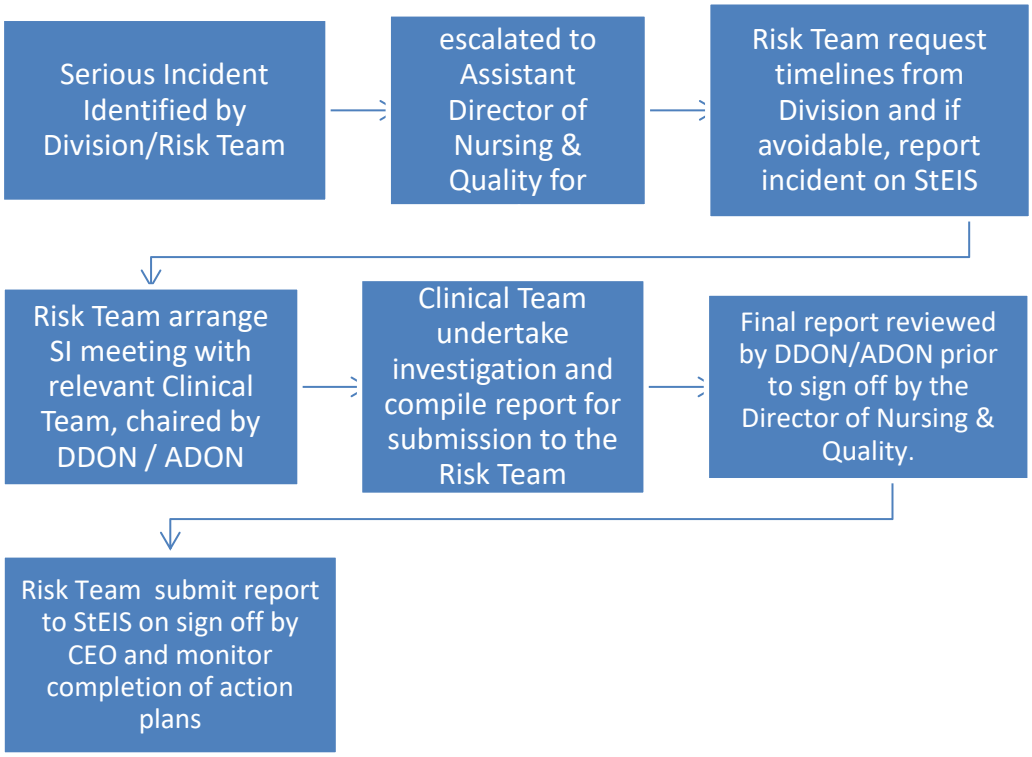
- Define the risk(s) by considering the adverse consequence(s) that might arise from the risk.
- Use table 1 to assess the severity of the risk(s) on a scale of 1 to 5 to determine the consequence score.
- Use table 2 to determine the likelihood score(s) of this incident occurring.
- Calculate the risk score by multiplying the consequence score by the likelihood score.
- Identify the level at which the risk will be managed in the organisation, assign priorities for remedial action, and determine whether risks are to be accepted on the basis of the colour.

APPENDIX 3: FLOW CHART FOR SERIOUS INCIDENT PROCESS

<u>Category A and B</u> - Most Serious, i.e. Never Events and all other StEIS reportable SI's excluding category C incidents.



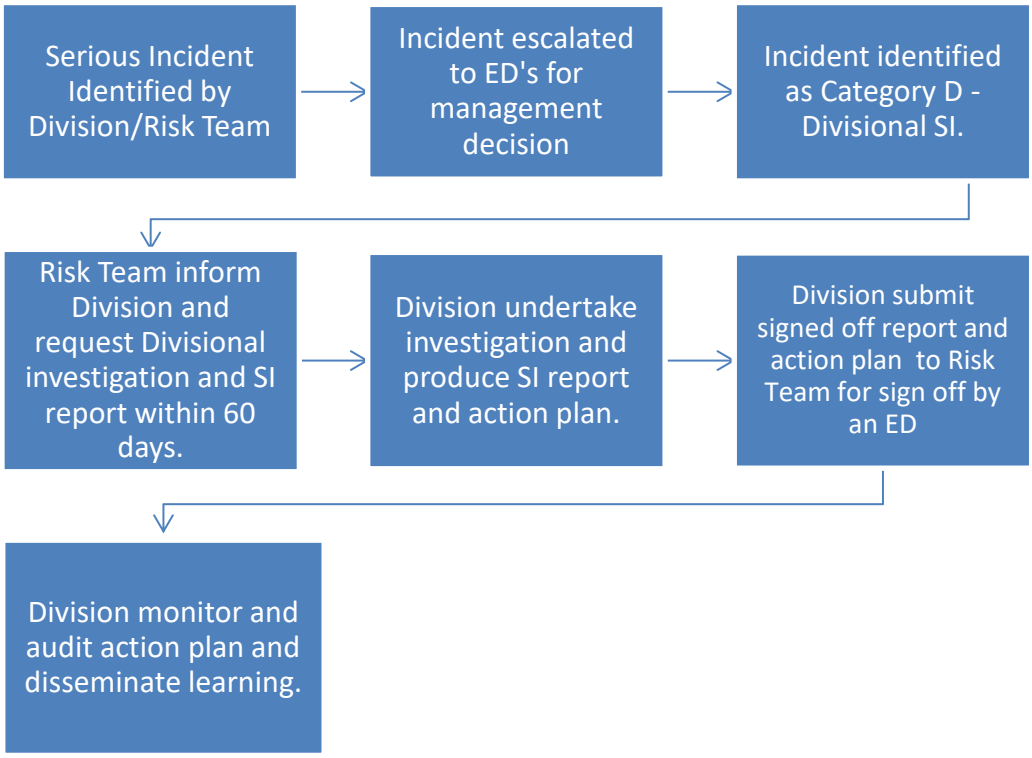
<u>Category C</u>: Falls with fracture, avoidable stage 3 and 4 Pressure Ulcers



If Category C incidents are identified as being 'unavoidable', an appropriate RCA/Check List will be completed through the Safeguard Incident Reporting system, as per current Trust Policy for Falls and Pressure Ulcers.

APPENDIX 3: FLOW CHART FOR SERIOUS INCIDENT PROCESS

<u>Category D</u>: Incidents which do not meet the StEIS reportable criteria under the NHS Serious Incident Framework (2015), but where there are serious concerns raised and lessons to be learned.



TIMEFRAMES

All Serious Incidents must be investigated and a report completed and signed off by all parties within 60 working days of the incident being identified as an SI. StEIS reportable Serious Incidents must be submitted to StEIS within 60 working days from reporting on StEIS. Never Event incident investigations are expected to have a rapid turn-around due to the seriousness of the incident and the expectations of stakeholders.

LESSONS LEARNED

All categories of Serious Incidents must be followed up by a Lessons Learned article, in the Trust format, for dissemination locally by the Division and Trust Wide through the Lessons Learned Newsletter by the Risk Team.

APPENDIX 4: NEW SERIOUS INCIDENT INVESTIGATION PROCESS

Serious Incident Investigation Report – Completion Guide

This guide provides a basic indication of the information expected to be contained within each section of the investigation report. It also provides a summary of the respective roles and responsibilities of both the Case Manager and the Investigating officer.

Front Cover

The front cover of the report must detail the following information:

- Incident UIR number(s)
- SEIS reference number e.g. 2017/12450
- Incident Description, this description is provided when the incident is initially registered as a SI - for example Information Governance or Medication Error
- Incident date
- Case Manager (usually Divisional Director/Head of Department/Senior Clinicians)
- Investigation Officer
- Report Date
- Version Number *
- Divisional and Executive sign off

* If the case is the subject of a Coroner's Inquest – please indicate "Final Draft Version".

Contents

Please ensure that you update the page numbering on the contents page on completion of each version of the report.

Section 1: Introduction and Background

<u>Description of the incident and consequences</u>

This should be a brief summary of the incident including the impact of the incident to the patient, staff and the organisation and why the investigation was necessary. For example: a lady with asthma sustained brain damage following IV administration of a drug to which she was known to be allergic.

<u>Any other relevant factors/background information</u>

This should include relevant patient's medical history and recent attendances at healthcare providers or clarification of care provided at patient's own home. A brief description of the service type, size, clinical team, care type should also be included.

<u>Terms of Reference</u>

In this section you should outline the specific problems to be addressed and the objectives of the investigation, for example:

- To establish patient / carer involvement in the setting of the terms of reference
- To establish the facts i.e. what happened (effect), to whom, when, where, how and why (root causes)
- To establish whether failings occurred in care or treatment
- To look for improvements rather than to apportion blame
- To establish how recurrence may be reduced or eliminated
- To formulate recommendations and an action plan
- To provide a report and record of the investigation process & outcome
- To provide a means of sharing learning from the incident (LIRC etc.)
- To identify routes of sharing learning from the incident

Executive Summary

This should set out a summary of the incident, the purpose of the report, and the main findings and conclusions of the investigation team.

Investigation Team

It is important that at least one member of the investigation team has completed the Trust's Investigation / Root Cause Analysis training (RCA); a full list of trained officers is maintained by the Risk Management Team.

In this section you should name the investigation team and whether they have received Investigation/RCA training.

Pre-Investigation Initial Severity Rating

Indicate here the initial severity rating – as recorded on the UIR.

Section 2: Investigation

Information and evidence gathered

This should describe how the team went about finding the information used within the investigation, for example review of case notes, correspondence, lab investigations, clinical and national guidelines etc.

Staff Interviewed

Please list the name and designation of all staff interviewed as part of the investigation, also indicate whether they were witnesses to the incident, directly involved or staff experts used to provide additional information such as interpretation of reports or clinical opinions. Statements taken should also be indicated.

APPENDIX 4: NEW SERIOUS INCIDENT INVESTIGATION PROCESS

Documentation Reviewed

List all the documentation that has been reviewed during the investigation: case notes particularly consent forms, were the risks to a procedure explained? Also consider reviewing correspondence, lab investigations, radiological reports/ observation charts (particularly NEWS)/fluid balance, clinical guidelines and national guidance (e.g. NICE). Consider also SOPs, policies /procedures/training schedules/ staff rotas; equipment logs, patient information that may have been provided to the patient prior to the procedure/ product information or any or CDs/ DVDS which may have been viewed. Other similar incidents should also be identified and reviewed.

Other Evidence reviewed

Review equipment / machinery / Environment / Staffing levels (locums/agency staff) where the incident occurred.

RCA Methodology utilised

The investigating team must record the method of root cause analysis used in the investigation (e.g. '5 Whys'/ Fishbone/ 'Cause and Effect' charts/ 'Barrier Analysis', etc.

Guidance should be sought using the publication: 'Six Steps to Root Cause Analysis' (3rd Edition) provided to all investigating officers who have undertaken RCA training)

Whichever RCA tool(s) are employed in the process of the investigation, these must be retained with all other documentation to ensure there is a complete and comprehensive record of events and the investigation.

All completed SI reports and associated appendices must be forwarded to the Risk Team to be stored in the relevant folder. These reports may be called upon in the future by coroners, potential litigants, commissioners etc.

Section 3: Findings

Findings

This will be the largest section of the report and will set out what the investigation discovered during the investigation. The Chronology of Events (Appendix 1) should be referred to in this section

Contributory Factors

Use the Contributory Factors list (Appendix 2) to determine the key factors for each case/care management concern.

Root Causes

Identify the root causes for each case/care management concern – these should be meaningful and not sound bites such as 'communication failure' – and there should be a clear link between root cause and effect on the patient

APPENDIX 4: NEW SERIOUS INCIDENT INVESTIGATION PROCESS

Mitigating Factors

Any factors regarding the organisation or individuals which may be relevant at this stage, for the reader to follow. 'Set the scene' at the time of the incident where known. This may include factors such as the condition of the patient before the incident; the activity of the unit; dependency of other patients; numbers and skills of staff; or environmental factors. By completing this section it may be easier to analyse the root causes and contributory factors following the investigation

Inconsistencies identified in the report

If so, these should be outlined and explained including why a particular version of events was selected.

Notable practice identified

This is where points in the incident or investigation process where care and/or practice had an important positive impact and may provide learning opportunities e.g. exemplar practice, involvement of the patient, staff openness etc.

Learning Points

This is where you need to identify any learning points identified from the investigation.

Risks to the organisation

These may be considered to be litigious, reputational, corporate, clinical, financial, health and safety or a risk to employee relations. The case manager and investigator officers should describe what they believe by inference or by fact, providing full explanations/justifications.

Section 4: Communications

Details of Duty of Candour notifications with persons affected by the incident:

Please document what information has been communicated and to whom particularly patient/NOK/carers including dates and state if the matter is concluded or requires further follow up etc.

It is essential to establish contact with the patient or family or carer. Please document what information has been communicated and to whom particularly patient/NOK/carers including dates and state if the matter is concluded or requires further follow up etc.

After the conclusion of the report, this must be shared with the patient/family/carer as appropriate and a meeting should be offered to explain the report and the findings. We must be open and honest and apologise where appropriate using the Trust's 'Patient Safety Including Being Open and Duty of Candour' Policy (CORP/POL/537) available on the intranet.

Intended feedback to the patient/family/carer should be included in the report's action plan where appropriate.

APPENDIX 4: NEW SERIOUS INCIDENT INVESTIGATION PROCESS

Details of feedback given to staff involved

- Outline Issues of concern
- Be open and honest and support staff
- Develop and agree action plan
- Comment if everyone is in agreement/happy with the outcome of the investigation.
- Lessons learned and actions to be shared with the Risk Management Team, Safety Panel, LIRC, Divisional Board, Divisional Governance Committee and Clinical Policy Group.
- Follow-up audit of actions taken.

Intended feedback to staff should be included in the report's action plan where appropriate.

Trainee Involvement

Should a junior doctor, trainee nurse or allied health professional be involved in the investigation their relevant educational supervisor/practice placement facilitator/supervisory support link must be informed at the start of the investigation.

Health and Safety Executive/Coroner Involvement

If the incident required reporting to the HSE or if the incident involved an unexpected death please include details of any involvement and reports which need to be provided.

Issues to be reported to the Learning and Development Department

Are there any lessons to be learnt about our system for training and education that needs to be reported to the Learning and Development Department.

Intended feedback should be included in the report's action plan where appropriate.

Arrangements for sharing lessons learned within Division or wider Trust

Describe how the learning from the incident has been or will be shared within the Division or Trust (as appropriate) for example through presentation to speciality forums/board (LIRC etc.). A Lessons Learned article for each SI should be produced and sent to the Risk Team for the Trust's Lessons learned Newsletter.

Intended feedback should be included in the reports action plan where appropriate.

Human Resource Involvement

If disciplinary action is warranted it is not necessary to provide details within this report, however you should indicate whether a separate HR investigation is going to be initiated.

Other

Any other parties involved for example NWAS, other Trusts, Primary Care, Public Health, the Police, Safeguarding, etc.

APPENDIX 4: NEW SERIOUS INCIDENT INVESTIGATION PROCESS

Section 5: Conclusions and Recommendations

Conclusions

Investigating Officers should refer back to the Terms of Reference of the investigation and should determine whether, following the findings, the investigation is conclusive and what the conclusions are. For example that a process or procedure was not followed, or an individual behaved inappropriately.

Recommendations

Recommendations must be SMART and supported by the Case Manager:

- S - Be Specific about what you want to achieve, do not be ambiguous and communicate clearly.
- M - Ensure your result is Measurable. Have a clearly defined outcome and ensure this is measureable (KPIs).
- A- Make sure it is Appropriate. Is it an Achievable outcome?
- R- Check that its Realistic, it must be possible taking account of time, ability and finances.
- T- Make sure it is Time restricted

These should relate to the findings and conclusions of this investigation. Examples of recommendations include: Training; Introduction/updating of policies and procedures; Initiation of disciplinary procedures

Recommendations should relate back to the root causes, they should be clear but not detailed, detail belongs in the action plan. The number of key recommendations should be kept to a minimum wherever possible.

Post-Investigation Impact Rating

A final closing impact score for the incident must also be agreed at this time.

Manager responsible for monitoring completion of the action plan

All category A and B serious incident investigations are monitored until completion by the Trust Safety Panel. Responsibility for completion of the action plan should not remain with the investigation team as best practice dictates that this team should be independent of the area under investigation.

At the conclusion of the investigation and in conjunction with the Case Manager and if appropriate the Divisional Director/ ADON a nominated officer (usually the relevant Head of Department or Clinical Lead / Directorate Manager) should be allocated overall responsibility for ensuring the action plan (and audit plan) is completed as intended – the Case Manager or identified lead will be asked to attend the Safety Panel to provide progress updates.

APPENDIX 4: NEW SERIOUS INCIDENT INVESTIGATION PROCESS

Appendices:

Appendix 1: Chronology of Events

This section should enclose a brief summary of relevant events including not only those that are the subject of the investigation but also the relevant key events of the investigation itself (e.g. dates commenced, dates of interview with each witness etc.).

Appendix 2: Contributory Factors Analysis

This section identifies the major contributory factors. Place an 'X' in each tick box which is deemed appropriate**.**

Appendix 3: Action Plan

The action plan will be produced by the relevant Division, following completion of the Incident Report, **not** by the Investigation Officer. The action plan is to be a separate document from the report, but can be added as an appendix.

The action plan should detail the actions to be taken to address the recommendations from the report (in addition to any outstanding feedback to patients/staff etc.).

Each action should be referenced and be related back to a recommendation, actions should be SMART (see section 5 – Recommendations).

For each action you should also state whether the action point requires an audit, this should be 'Yes' or 'No'.

The action plan will be reviewed and monitored by the Safety Panel.

Appendix 4: Audit Plan

This section of the report explains how assurance will be provided that agreed actions have become embedded and led to changes in practice.

Frequently action points will be included in one audit, in which case several action points can be grouped together. The audit plan should describe the audit to be undertaken, who has responsibility for that audit and the date the audit is expected to be completed. The clinical audit registration reference (received when audits are officially registered with the Clinical Audit department) should also be included. Similar Serious Incident investigation actions should be grouped together for auditing purposes to prevent an over burden of audits.

There will however be some actions that are not auditable or are already included in existing Trust audits and do not require an additional audit to be undertaken. This should be explained in the audit plan under the section 'reason why audit is not required'.

Audits from Serious Incident action plans should be monitored through the relevant Divisional Governance processes and reported through the LIRC Committee.

APPENDIX 4: NEW SERIOUS INCIDENT INVESTIGATION PROCESS

Other Appendices

These should be referenced within the contents page and contain information that is relevant to the investigation, but has no place in the main body of the report. Typical appendices include:

- A list of staff and designations who have provided witness/event statements
- Copies of the interview questions used and guidance given to interviewees about the investigation process.
- Copies of documents reviewed during the investigation process
- Any methodology tools used

Serious Incident Investigations – Roles and Responsibilities

Role of the Executive/Corporate Team:

- Agrees the appropriate level of investigation for the identified incident (A, B or C) and informs the relevant Division
- Provides the Division with a timescale in which to investigate their incident and produce a report in readiness for submission to the Safety Panel for review, prior to sign off.
- Agrees and informs the responsible Case Manager for the investigation
- Agrees and informs the allocated Investigation Officer
- Disseminates the report to the Division for learning and compilation of the action plan.
- Monitors the completion of the action plan.

Role of the Case Manager:

- Agrees the scope and terms of reference for the investigation
- Determines the timescale for the report to be received from the Investigation Officer
- Ensures timescales are maintained / met
- Reviews draft report and recommendations
- Accepts and signs off the first draft report
- Takes overall responsibility for the report.
- If the Case Manager does not accept the report then they can request further details or investigations
- Is available for advice / support
- The Case Manager will attend the Safety Panel meeting with the Investigation Officer

APPENDIX 4: NEW SERIOUS INCIDENT INVESTIGATION PROCESS

Role of Investigation Officer:

- The Investigation Officer will take direction for the investigation from the Case Manager.
- The Investigation Officer will undertake the investigation utilising appropriate root cause analysis tools. Information and facts should also be obtained through undertaking conversations and interviews, obtaining written information and statements, reviewing local policies and procedures and national guidelines, undertaking internet based research, utilising peer review papers and accessing specialist advice where the 'advisor' is not already on the investigation team.
- The Investigation Officer will produce the SI report and discuss the draft report with the Case Manager who may ask for further investigation and further details maybe required to support the recommendations made by the Investigating Team.
- Once the report is agreed and signed off by the Case Manager, the Investigating Officer should submit the final draft report to the Risk Team for review by the Safety Panel.
- The Investigation Officer will attend the Safety Panel meeting to present the report and receive feedback from the Safety Panel.
- The Investigation Officer will not be responsible for the resultant action plan, which will be the responsibility of the relevant Case Manager / Divisional Clinical Lead / Directorate Manager / Head of Department / Matron, as appropriate.

Investigation and Report Timescales:

All untoward incidents should be reported on the Safeguard System within 24 hours of the incident occurring. Level 3 RCA incident investigations should be completed within 30 days of reporting.

When an incident is reported on StEIS, the Trust has 60 working days in which to complete the investigation and submit a fully signed off RCA report. If the incident is the subject of a Coroner's Inquest, the report will be signed off as a "Final Draft" prior to the Inquest, in the event of any further learning identified by the Coroner.

The Risk Team will provide each clinical team with a timescale in which to investigate their incident and produce a report in readiness for submission to the Safety Panel for review, prior to sign off.

Safety Panel Membership:

- Medical Director (Chair) / Deputy Medical Director
- Director of Nursing & Quality (Acting Chair) / Deputy Director of Nursing & Quality
- Governance, Risk & Patient Safety Manager / Clinical Risk Manager
- CCG Quality Representatives

- Legal Team Representative
- Admin Support

Role of the Safety Panel:

The Safety Panel will consider the following when reviewing the SI Report:

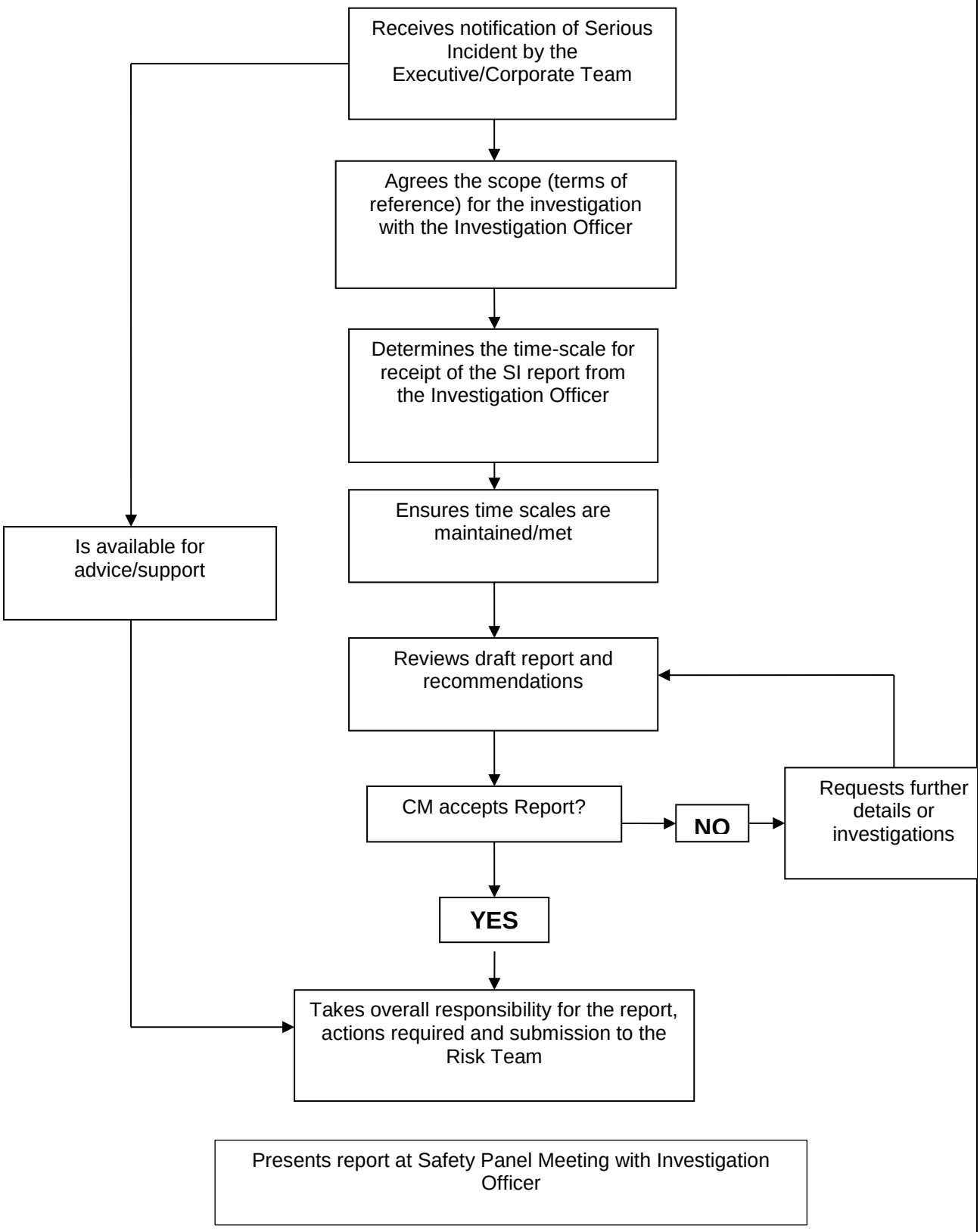
- Do the recommendations made address the range of identified root causes (is there a clear link between the recommendations and the investigation?) and do the actions meet SMART criteria?
- Have sources of assurance been identified, e.g. clinical audit, to evidence the effectiveness of stated actions? Has the report been agreed by the relevant Division?
- Overall is there evidence that the report has sufficient detail/content to have confidence in the findings of this incident as presented in this report?
- Has duty of candour been applied in this case?
- Have staff involved in the incident received feedback?
- If a junior doctor is involved has the educational supervisor/medical education been notified?
- Is the terminology in the report understandable to a lay person?
- Has the patient or their family's input been included into the report?
- Has the report been completed within the Trust's timescales for investigation of incidents, if not, what were the reasons?

The Safety Panel will consider the following when reviewing the Action Plan:

- Has the investigation report been shared with the patient/family?
- Is there evidence of actions being completed satisfactorily?
- Does audit evidence indicated provide sufficient coverage in terms of sample used and timescale to provide adequate assurance that changes have become embedded?
- Does audit evidence indicated provide reassurance that the intended quality improvements are now in place and are being adhered to?
- Has the action plan now been fully completed and are the panel satisfied to finally close the incident investigation?
- Are arrangements in place for on-going audits to provide periodic assurance of continued compliance through the LIRC Committee?

APPENDIX 4: NEW SERIOUS INCIDENT INVESTIGATION PROCESS

Role of the Case Manager



APPENDIX 5: PREPARATION OF FACTUAL ACCOUNTS OF VERSION OF EVENTS

Statements should be prepared if requested by the Serious Incident Investigation Team or by the Risk Management Team.

1. Version of events must be factual covering the witness' own actions and what they observed of the incident.

2. It is inappropriate for a witness to seek to blame others in their version of events, and similarly it is inappropriate for one party to apologies to another party in a witness statement.

3. It must be emphasized that the versions of events should be purely factual and not contain the witnesses' opinions or speculations as to why something may have gone wrong.

4. When preparing a version of events the following must be included within the statement:

    a) Full name

    b) Qualifications at the time of the incident

    c) Post held at time of incident

    d) A factual chronological account of the witness' involvement with the incident including a transcription of all entries in the health or other records made by the witness i.e. what the witness did and what they saw.

APPENDIX 6: LEVELS OF SYSTEMS-BASED INVESTIGATIONS RECOGNISED IN THE NHS - (NHSE SERIOUS INCIDENT FRAMEWORK 2015)				
Level	**Application**	**Product/ outcome**	**Owner**	**Timescale for completion**
Level 1 **Concise internal investigation**	Suited to less complex incidents which can be managed by individuals or a small group at a local level	Concise/ compact investigation report which includes the essentials of a credible investigation	Provider organisation (Trust Chief Executive/relevant deputy) in which the incident occurred, providing principles for objectivity are upheld	Internal investigations, whether concise or comprehensive must be completed within 60 working days of the incident being reported to the relevant commissioner All internal investigation should be supported by a clear investigation management plan
Level 2 **Comprehensive internal investigation** (this includes those with an independent element or full independent investigations commissioned by the provider)	Suited to complex issues which should be managed by a multidisciplinary team involving experts and/or specialist investigators where applicable	Comprehensive investigation report including all elements of a credible investigation	Provider organisation (Trust Chief Executive/relevant deputy) in which the incident occurred, providing principles for objectivity are upheld. Providers may wish to commission an independent investigation or involve independent members as part of the investigation team to add a level of external scrutiny/objectivity	
Level 3 **Independent investigation** Required where the integrity of the investigation is likely to be challenged or where it will be difficult for an organisation to conduct an objective investigation internally due to the size of organisation or the capacity/ capability of the available individuals and/or number of organisations involved	Required where the integrity of the investigation is likely to be challenged or where it will be difficult for an organisation to conduct an objective investigation internally due to the size of organisation or the capacity/ capability of the available individuals and/or number of organisations involved.	Comprehensive investigation report including all elements of a credible investigation	The investigator and all members of the investigation team must be independent of the provider. To fulfil independency the investigation must be commissioned and undertaken entirely independently of the organisation whose actions and processes are being investigated.	6 months from the date the investigation is commissioned

APPENDIX 7: INFORMING EXTERNAL BODIES/OTHER INTERESTED PARTIES

The Serious Incident Investigation Team must consider which other interested parties may need to be informed. These may include:-

- General Practitioners
- Clinical Commissioning Groups
- Other Trusts
- Quality Care Commission
- Mental Health Commission
- Patient Relations
- Patient Forum
- National Health Service Litigation Authority, via the Legal Team
- Police
- Coroner
- Home Office
- Social Services
- Medicines and Health Care Products Regulatory Authority
- Health and Safety Executive
- Child Protection Services
- Safeguarding Boards
- Health Protection Agency
- Trust Legal Team
- Local Supervising Authorities for a Maternal death
- Council Authorities

This list is not exhaustive and there may be other agencies that need to be informed.

APPENDIX 8: PROCESS FOR MONITORING COMPLIANCE – INCIDENT REPORTING (3.2.2)							
Minimum requirement to be monitored		**Process for monitoring e.g. audit**	**Responsible individual/ group/ committee**	**Frequency of monitoring**	**Responsible individual/ group/ committee for review of results**	**Responsible individual/ group/ committee for development of action plan**	**Responsible individual/group/ committee for monitoring of action plan and Implementation**
a)	Duties	Audit	Risk Management Team	Annually	Risk Management Team Learning from Incidents and Risks Committee	Risk Management Team	Risk Management Team Learning from Incidents and Risks Committee
b)	How all incidents and near misses involving staff, patients and others are reported	Audit	Risk Management Team	Annually	Risk Management Team Learning from Incidents and Risks Committee	Risk Management Team	Risk Management Team Learning from Incidents and Risks Committee
c)	How the organisation reports incidents to external agencies	Audit	Risk Management Team	Annually	Risk Management Team Learning from Incidents and Risks Committee	Risk Management Team	Risk Management Team Learning from Incidents and Risks Committee
d)	How staff can raise concerns, for example, whistle blowing, open disclosure etc.	Audit	Risk Management Team	Annually	Risk Management Team Learning from Incidents and Risks Committee	Risk Management Team	Risk Management Team Learning from Incidents and Risks Committee

APPENDIX 9: PROCESS FOR MONITORING COMPLIANCE – INVESTIGATIONS (3.2.5)							
Minimum requirement to be monitored		**Process for monitoring e.g. audit**	**Responsible individual/ group/ committee**	**Frequency of monitoring**	**Responsible individual/ group/ committee for review of results**	**Responsible individual/ group/ committee for development of action plan**	**Responsible individual/group/ committee for monitoring of action plan and Implementation**
a)	Duties	Audit	Risk Management Team	Annually	Risk Management Team Learning from Incidents and Risks Committee	Risk Management Team	Risk Management Team Learning from Incidents and Risks Committee
b)	Organisations expectations in relation to staff training as identified in the Training Needs Analysis	Audit	Learning and Development Manager	Annually	HR, OD and Teaching Governance Committee	Learning and Development Manager	HR, OD and Teaching Governance Committee
c)	Different Levels of Investigation appropriate to the severity of the event	Audit	Risk Management Team	Annually	Risk Management Team Learning from Incidents and Risks Committee	Risk Management Team	Risk Management Team Learning from Incidents and Risks Committee
d)	How the Organisation shares safety lessons with internal and external stakeholders	Audit	Risk Management Team	Annually	Risk Management Team Learning from Incidents and Risks Committee	Risk Management Team	Risk Management Team Learning from Incidents and Risks Committee
e)	How action plans are followed up	Audit	Risk Management Team	Annually	Risk Management Team Learning from Incidents and Risks Committee	Risk Management Team	Risk Management Team Learning from Incidents and Risks Committee

APPENDIX 10: EQUALITY IMPACT ASSESSMENT FORM

Department	HR Directorate – Learning and Development	**Service or Policy**	Untoward Incident and Serious Incident Reporting Procedure	**Date Completed:**	22 September 2012

GROUPS TO BE CONSIDERED

Deprived communities, homeless, substance misusers, people who have a disability, learning disability, older people, children and families, young people, Lesbian Gay Bi-sexual or Transgender, minority ethnic communities, Gypsy/Roma/Travellers, women/men, parents, carers, staff, wider community, offenders.

EQUALITY PROTECTED CHARACTERISTICS TO BE CONSIDERED

Age, gender, disability, race, sexual orientation, gender identity (or reassignment), religion and belief, carers, Human Rights and social economic / deprivation.

QUESTION	**RESPONSE**		**IMPACT**	
	Issue	Action	Positive	Negative
What is the service, leaflet or policy development? What are its aims, who are the target audience?	The Untoward Incident and Serious Incident Reporting Procedure details the Trust's process for the reporting of and investigation of all untoward incidents and serious incidents occurring within the Trust.		Yes – Compliance with this policy will ensure the reporting and investigation of all untoward incidents and the sharing of lessons learned from these incidents.	
Does the service, leaflet or policy/ development impact on community safety • Crime • Community cohesion	The policy is relevant to the safety of all staff within the Trust and in the community.		Yes	
Is there any evidence that groups who should benefit do not? i.e. equal opportunity monitoring of service users and/or staff. If none/insufficient local or national data available consider what information you need.	No. This policy should ensure a positive impact across all groups of staff and patients.		Yes	
Does the service, leaflet or development/ policy have a negative impact on any geographical or sub group of the population?	No		Yes	
How does the service, leaflet or policy/ development promote equality and diversity?	Defines the standardised process to be followed in the event of an untoward incident.		Yes	
Does the service, leaflet or policy/ development explicitly include a commitment to equality and diversity and meeting needs? How does it demonstrate its impact?	The Policy includes a completed EA which provides the opportunity to highlight any potential for a negative / adverse impact.		Yes	
Does the Organisation or service workforce reflect the local population? Do we employ people from disadvantaged groups	Our workforce is reflective of the local population.		Yes	
Will the service, leaflet or policy/ development i. Improve economic social conditions in deprived areas ii. Use brown field sites iii. Improve public spaces including creation of green spaces?	No	N/A	N/A	
Does the service, leaflet or policy/ development promote equity of lifelong learning?	No	N/A	N/A	

APPENDIX 10: EQUALITY IMPACT ASSESSMENT FORM

Does the service, leaflet or policy/ development encourage healthy lifestyles and reduce risks to health?	The procedure identifies the process in relation to reporting, investigating and learning from incidents which occur within the Trust which will result in improving the safety of our patients and staff.	Persons working within the Trust are provided with adequate training in order to ensure understanding of the process to be followed.	Yes	
Does the service, leaflet or policy/ development impact on transport? What are the implications of this?	No	N/A	N/A	
Does the service, leaflet or policy/development impact on housing, housing needs, homelessness, or a person's ability to remain at home?	This policy will have an impact on all members of staff working in the Trust and patients in their care.		Yes	
Are there any groups for whom this policy/ service/leaflet would have an impact? Is it an adverse/negative impact? Does it or could it (or is the perception that it could exclude disadvantaged or marginalised groups?	The Policy promotes access to information for all members of staff in the Trust.	N/A	Yes	
Does the policy/development promote access to services and facilities for any group in particular?	No	N/A	N/A	
Does the service, leaflet or policy/development impact on the environment • During development • At implementation?	No			

ACTION:			
Please identify if you are now required to carry out a Full Equality Analysis	~~**Yes**~~	**No**	**(Please delete as appropriate)**

Name of Author: **Signature of Author:**	Helena Lee	**Date Signed:**	22/09/2017
Name of Lead Person: **Signature of Lead Person:**	Helena Lee	**Date Signed:**	22/09/2017
Name of Manager: **Signature of Manager**	Simone Anderton	**Date Signed:**	22/09/2017