Cumbria Partnership NHS
NHS Foundation Trust

Incident and Serious Incidents that Require Investigation (SIRI) Policy

Document Summary

To ensure that Cumbria Partnership NHS Foundation Trust communicates openly and honestly with patients, significant others carers and staff following incidents which have caused harm.

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Important Note:
The Intranet version of this document is the only version that is maintained.

Any printed copies should therefore be viewed as "uncontrolled" and, as such, may not necessarily contain the latest updates and amendments.

Contents

1. INTRODUCTION

Incident Management underpins the Risk Management and Board Assurance and escalation for Cumbria Partnership Trust (CPFT).

It is a fundamental tool of risk management, the aim of which is to collect information about adverse incidents, including near misses.

The Trust wishes to ensure that when an incident or serious incident occurs:

- ✓ There are systematic measures in place for safeguarding service users, carers, staff, the public, property, NHS resources and reputation.
- ✓ That the organisation learns from adverse incidents and in doing so prevents further harm.

The following policy and procedure and additional guidance outlines the requirements for staff and managers in relation to the management of incidents and Serious Incidents which Require Investigation (SIRI).

Incidents in relation to Safeguarding, Whistle Blowing and Fraud should be managed in accordance with the Trust's specific policies for these areas.

Disciplinary action in relation to incidents and SIRI may be considered if one or more of the following apply:

- There is a breach of criminal law
- Professional misconduct has been identified
- There are repeated unsafe occurrences in relation to the same individual
- In the view of the Trust or professional body the action causing the incident was not acceptable practice
- There is evidence that attempts were made to conceal the incident or tamper with any evidence.

2. SCOPE

This policy applies to all Trust services and to all Trust-employed staff, staff working in integrated teams, full-time and part-time clinical, agency, locum, non-clinical staff, patients, visitors and others who may be affected by incidents and SIRI that occur in connection with the Trust's activities.

3. PURPOSE

The overall purpose of this policy/procedure document is to provide a framework to assist Directors, Departments, Care Groups and individual staff to understand their responsibility and accountability when incidents occur, how these are reported, investigated and managed within the Trust.

This will ensure that:

- ✓ We meet our statutory obligation in protecting the health and safety of individuals (patients, carers, public and staff);
- ✓ Where incidents occur, we will take action and learn from the incident to ensure that steps are taken to prevent reoccurrence;
- ✓ Incidents that result in significant harm to either an individual and/or the Trust are managed appropriately to reduce further risk of harm and provide assurance that such incidents are fully investigated and lessons are learnt.

4. DEFINITIONS AND GRADING

4.1 Reportable Incidents

An Incident is defined as an untoward event which causes or has the *potential* to cause any of the following:

- Harm to an individual
- Financial loss to an individual or the Trust
- Damage to the property of an individual or the Trust
- Disruption to services provided by the Trust
- Damage to the reputation of the Trust

This definition also encompasses all prevented incidents i.e. where none of the above occurred either by good fortune or due to the intervention of staff. These can also be referred to as " near miss" incidents.

Further details and examples of risk grading is shown in Appendix D

4.2 Electronic Incident Reporting

All incidents are reported electronically via the intranet using the Ulysses Risk Management System.

4.3 Being Open and the Duty of Candour

Regulation 20 of the Health and Social Care Act 2008 (Regulated Activity) Regulations 2014, introduced a statutory ***Duty of Candour*** for the NHS. This was a direct response to recommendations outlined in the Francis Inquiry report into Mid Staffordshire NHS Foundation Trust. The intention of this regulation is to ensure that providers are open and transparent with

people in relation to care and treatment, and specifically when things go wrong with care and treatment, and that they provide people with reasonable support, truthful information and an apology.

Individual health professional bodies also incorporated the Duty of Candour into their own standards. As such, those professionals will also be accountable to their own professional body.

Patients and/or their families (as appropriate) should be promptly informed **within 10 working days** about patient safety incidents that, as a result of acts or omissions in the care provided, result in **moderate harm, severe harm or death (see appendix D for harm definitions)** and receive appropriate apologies, be kept informed of investigations and be supported.

The relevant details which apply to the Duty of Candour are reported in the Manager Report section of Ulysses and full details of the process associated with the Duty of Candour is shown in the Trust's policy:

4.4 Serious Incident Requiring Investigations (SIRI)

The NHS England Serious Incident Framework (2015) sets out the guidance as to the process and timescales to be followed for a Serious Incident Requiring Investigation (SIRI). There will be other incidents that do not meet the Framework requirements but which are still serious and these will be investigated and reported outside of the SIRI Framework.

Under the Framework serious incidents in health care are events where the potential for learning is so great or the consequences to patient, families or carers, staff or the organisation are so significant that they require attention to ensure that these incidents are identified, investigated and most importantly trigger actions to prevent them occurring again in the future.

As outlined in the NHS England Serious Incident Framework (2015) there is now no definitive list of serious patient safety incident, however a serious incident in health care could include:

- Acts and/or omissions occurring as part of NHS-funded healthcare (including in the community) that result in:
    - Unexpected or avoidable death of one or more people. This includes suicide/self-inflicted death; and
    - homicide by a person in receipt of mental health care within the recent past;
- Unexpected or avoidable injury to one or more people that has resulted in serious harm;
- Unexpected or avoidable injury to one or more people that requires further treatment by a healthcare professional in order to prevent:
    - 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 section 5.5)

- 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;
    - Property damage;
    - Security breach/concern;
    - Incidents in population-wide healthcare activities like screening 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

4.5 Never Events

If an incident is classified as a Never Event, it will be classified as a SIRI. NHS England provides a list of Never Events, which are serious and largely preventable incidents. Once an incident has been declared as a SIRI then the Quality, Safety and Safeguarding team will determine whether a Never Event has occurred.

The following information shows the Never Event list (January 2018) as defined by NHS England:

1. Wrong site surgery
2. Wrong implant/prosthesis
3. Retained foreign object post-procedure
4. Mis – selection of a strong potassium containing solution
5. Wrong route administration of medication
6. Overdose of Insulin due to abbreviations or incorrect device
7. Overdose of methotrexate for non-cancer treatment
8. Mis – selection of high strength Midazolam during conscious sedation
9. Failure to install functional collapsible shower or curtain rails
10. Falls from poorly restricted windows
11. Chest or neck entrapment in bedrails
12. Transfusion or transplantation of ABO-incompatible blood components or organs
13. Misplaced naso- or oro-gastric tubes
14. Scalding of patients
15. Unintentional connection of a patient requiring oxygen to an air flowmeter

4.6 Near Misses

Any event that has occurred, but which was not anticipated or planned, which did not actually lead to harm, loss or damage, but under different circumstances could have done. A near miss can still be considered as a SIRI. Deciding whether or not a near miss should be classified as a serious incident should therefore be based on an assessment of risk that considers:

- The likelihood of the incident occurring again if current systems/process remain unchanged; and
- The potential for harm to staff, patients, and the organisation should the incident occur again.

This does not mean that every near miss should be reported as a SIRI but, where there is a significant existing risk of system failure and/or serious harm, the serious incident process should be used to understand and mitigate that risk.

4.7 Data Incidents

The scope of an Information Governance Serious Incident Requiring Investigation (IG SIRI) is as follows:

- This type of incident will typically breach one of the principles of the General Data Protection Regulation and/or the Common Law Duty of Confidentiality.
- This includes unlawful disclosure or misuse of confidential data, recording or sharing of inaccurate data, information security breaches and inappropriate invasion of people's privacy.
- Personal data breaches which could lead to identity fraud or have other significant impact on individuals.
- Applies irrespective of the media involved and includes both electronic media and paper records relating to staff and service users.
- A Cyber-related incident is anything that could (or has) compromised information assets within Cyberspace. All IG and Cyber SIRI (level 2 and above) are reported through the Data Security and Protection Toolkit incident reporting system by the Data Protection Officer after review and agreement from the Data Protection Officer and/or Caldicott Guardian. In addition Level 2 and above IG and Cyber SIRIs are reported to the Information Commissioner's Office. The Data Protection Officer will provide advice and assistance to the Incident Leads for SIRIs that contain IG/Cyber Security elements, and will liaise with the ICO (Information Commissioner) on behalf of the Trust

Under the General Data Protection Regulations (Law now but enforceable from 25 May 2018), it is critical that organisations are prepared to respond to security breaches in respect of personal data. Under the Regulation, a personal data breach is not merely marked by the loss of data to an outside party, but is more broadly defined: "personal data breach means a breach of security leading to accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise processed" (GDPR Article 4, Clause 12). Incident management is the process by which the ongoing impacts of such breaches are minimised. It entails recognising that an incident has occurred, responding to the immediate and long term concerns, and tracking the incident to ensure that the steps taken are effective.

Notification - The General Data Protection Regulation has specific rules regarding when and how an incident must be reported to the Information Commissioner's Office and to the affected data subjects (staff or patients).

The Trust is required to notify the Information Commission of a personal data breach as soon as the Trust becomes aware that a personal data breach has occurred and without undue delay and where feasible, not later than 72 hours after having become aware of it (Article 33 (1)(GDPR - Recital 85). Staff must report all breaches immediately within 72 hours and those involving personal data marked as "information governance" so that these can be coded in line with statutory guidance.

The information governance team can provide guidance and advice on all personal data incidents and assist with the Head of Information Governance (as the Data Protection Officer) acting as the intermediary with the Information Commissioners Office.

4.8 RIDDOR Incidents

The Reporting of Injuries Diseases and Dangerous Occurrences Regulation 1995 (HSE 1999). RIDDOR defines the type of incident, diseases and occurrences that must be reported to the Health and Safety Executive (HSE) to comply with statutory requirements. These are listed in full on the HSE website www.hse.gov.uk .

4.9 Initial Brief Clinical Reviews / 72 Hour Report'

An initial brief clinical review should be undertaken when a patient safety incident resulting in moderate or greater harm has occurred. The clinical team should complete the appropriate Brief Clinical Report/72 hour report, based on the reported incident form on Ulysses, the aim of this initial review is to:

- Confirm the details of the incident including the level of harm, that the patient was in our care and that the harm was (or was possibly) as a result of an act or omission in the care we provided.
- Identify and provide assurance that any necessary immediate action to ensure the safety of the staff, patients and public is in place;
- Determine whether the Duty of Candour needs to be applied

Where it is not clear, help to determine whether the incident is a SIRI and, if so, propose the appropriate level of investigation and provide draft Terms of Reference for the investigation.

If the incident is to be a declared a SIRI this must be decided and reported to the CCG within 48 hours of the incident be reported. The individual care groups will have their own arrangements for ensuring that this timescale is met. If it is subsequently decided that the incident is not a SIRI then a request will be made to the CCG to downgrade the incident.

The 72hr report should be completed in full, and be as accurate as to what is known at the time. This will ensure that there is no delay in the sign off process for 72hr reports for commissioners. Local monitoring and audit of the completeness of 72hr reports will take place on a regular basis.

4.10 Level of SIRI Investigation

There are three levels of SIRI investigation, as outlined by NHS England, which are:

- ***Concise***: suited to less complex incidents which can be managed by individuals or small groups at a local level. ***The investigation should be completed within 60 working days of the incident being reported as a SIRI.***

- ***Comprehensive***: suited to complex issues which should be managed by a multidisciplinary team involving experts and/or specialist investigators where applicable. ***The investigation should be completed within 60 working days of the incident being reported as a SIRI.***

- ***Independent:*** 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. ***The investigation should be completed within 6 months of the incident being reported as a SIRI.***

The Care Group Associate Director of Nursing (ADN) and/or Associate Medical Director (AMD) or equivalent Associate Director of Support Services is responsible for agreeing the level of investigation that is required.

4.11 Involvement of multiple care groups

Where there is a SIRI which relates to 2 or more care groups then the ADN/AMD for the Care Groups should work together to agree which care group will take the lead for coordinating the investigation and the completion of action plan.

SIRI investigation reports involving multiple care groups will be reviewed at the Central SIRI panel so as to reduce the amount of duplications from this information being presented at the individual Care Group SIRI Panel.

4.12 Structured Judgement Reviews

As a systemic quality and safety check, and to minimise the possibility of a missed opportunity of learning more widely from deaths, random reviews using evidence based methodology will be conducted on a sample of deaths that have been deemed as falling within the category of not requiring investigation.

In addition to investigations and reviews carried out in accordance with the CPFT Incident and SIRI Policy, the Mortality Reporting and Surveillance Group will request that reviews are carried out within the Care Groups of a random selection of patient deaths that have been deemed by the Care Group as not requiring reviews. This will typically be patient deaths that have been deemed as falling within the natural, expected deaths category. The review results will be made available to the Care Groups and the Mortality Reporting and Surveillance Group to enable thematic reviews.

All reported deaths not meeting the criteria for completion of a 72hr report or SIRI investigation to be reported monthly to the Mortality Reporting & Surveillance Group (MRSG). The MRSG will select a random sample of reported deaths and notify Care Groups for completion of a review. There will be a maximum of 5 reviews required to be completed per care group each quarter period.

4.13 Involvement of multiple providers

Often more than one provider is involved in the care and service delivery in which the serious incident has occurred. The organisation that identifies the serious incident is responsible for alerting other providers to the incident, as required in order to initiate discussions about subsequent action. In CPFT other organisations will be alerted by the Care Group Associate Director of Nursing. Through these discussions we should confirm who will be the lead investigating organisation for the SIRI and also which organisation it is appropriate to report the serious incident to the CCG via the STEIS system.

Where possible organisations should work together to develop a single investigation report. Commissioners should help to facilitate discussions relating to who the most appropriate organisation is to coordinate the investigation.

4.14 Pressure Ulcers

The European Pressure Ulcer Advisory Panel (EPUAP) defines a pressure ulcer as a localised injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear (NPUAP-EPUAP, 2009):
http://www.epuap.org/guidelines/Final_Quick_Prevention.pdf
Pressure ulcers are categorised from 1 - 4 category definitions (and ungradable) as can be seen in the EPUAP guidelines.

- *All pressure ulcers that occur in CPFT care or patients referred to the Trust services who have suffered pressure damage without any referral communication to the CPFT teams are reported onto the Trust's Ulysses risk management system as an incident;*
- *Those high harm pressure ulcers e.g. Grade 3 & 4 pressure ulcers and/or pressure harm that is potentially or may manifest to serious harm or is extensive are also reported via the Ulysses system, in addition a RCA /clinical review is carried out by local team leads to identify the root cause or any contributory factors, and used as patient care evaluation and team learning and ongoing development of safe practice identifying both good practice and any acts, omissions of care.*
- *Any pressure ulcer incidents could be escalated to be reported and investigated as a SIRI if the incident meets both local and national definitions. These would be identified from the investigation as from the above 2 points*

4.15 Incidents involving national screening programmes

The characteristics specific to screening programmes means that safety incidents require special attention and management, for example:

- There is potential for safety incidents in screening programmes to affect a large number of individuals/users of the service. This means that seemingly minor local incidents can have a major service and population impact.

Where an incident involves any National Screening Programme, the appropriate Quality Assurance Reference Centre, Public Health England and/or the local Commissioner must be informed. This notification will be provided through the central Quality, Safety and Safeguarding Team in conjunction with the appropriate Care Group Associate Director of Nursing.

All screening incidents must be reported via the Trust's risk management system, Ulysses. If the incident is suspected or known to be a serious incident then the clinical team must complete the national screening incident provider form and this is then sent to the Quality Assurance Reference Centre. Further guidance can be obtained from 'Managing Safety Incidents in NHS Screening Programmes' (NHS Screening Programmes – updated August 2017) https://phescreening.blog.gov.uk/2017/08/21/managing-safety-incidents-guidance-update/

All serious screening incidents will be reported on the national STEIS system by the Quality, Safety and Safeguarding Team.

4.16 Categorisation of Deaths

Type of Death	Description
Expected Natural (Within Expected Timeframe) **(EN1)**	A death that was expected to occur in an expected time frame e.g. terminal illness or in palliative care services and where an end of life care plan has been agreed. These deaths **will not** require a 72 hour review and would not be investigated further but may be included in a mortality review
Expected Natural (Earlier than expected timeframe) **(EN2)**	A death that was expected but was not expected to happen in that timeframe e.g. service user had terminal cancer but who dies much earlier than anticipated. These deaths **may** require a 72 hour review. Each will require clinically informed judgement to determine requirement.
Unexpected Natural (Natural unavoidable) **(UN1)**	Unexpected death which is from natural causes e.g. sudden cardiac condition or stroke. These deaths **may** require a 72 hour review. Each will require clinically informed judgement to determine requirement.
Unexpected natural (Natural but avoidable) **(UN2)**	Unexpected deaths which are from natural causes but which didn't need to be e.g. alcohol dependency or where there have been care delivery concerns identified These deaths **will** require a 72 hour review and dependent on the findings some will require further investigation
Unexpected unnatural **(UU)**	Unexpected deaths which are from unnatural cause e.g. suicide, homicide abuse or neglect These deaths **will** require a 72 hour review and comprehensive investigation

The Associate Director of Nursing from the care groups will be responsible for ensuring that incidents related to deaths are signed off by a member of the Care Group Senior Leadership Team, or a nominated deputy, as appropriate.

4.17 Death in custody

This section refers to any death within police and prison setting, and therefore within CPFT relates primarily to the health care services provided by CPFT at Haverigg Prison, Millom.

As set out in the NHS England Serious Incident Framework any death in custody will be referred by the Governing Governor at Haverigg prison to the Prison and Probation Ombudsman (PPO) who are responsible for carrying out the relevant investigations.

A death in custody within Haverigg should be reviewed for consideration of requiring a full SIRI type investigation. As with all serious incidents the completion of the 72 hour clinical review report, should in part be used as a decision making tool to understand whether it is appropriate to move tothe completion of either a concise or comprehensive SIRI type investigation. Any internal investigation should help to support the identification of any learning points, in parallel to the PPO external investigation.

In circumstances where the cause of death is unknown and/or where there is reason to believe the death may have been avoidable or unexpected i.e., not caused by the natural course of the patient's illness then the death must be reported to commissioner and therefore in this case to NHS England. Any death in custody which occurs in Haverigg and when a patient is receiving care from CPFT services should be reported on STEIS. As there are multiple health care providers delivering care within this setting it should be agreed earlier within this process who the lead organisation for the SIRI and STEIS reporting are.

If required, commissioners can help to facilitate these discussions.

All completed SIRI type investigation reports should be sent to Associate Director of Nursing for the Specialist Care Group as well as NHS England (as the appropriate commissioner). Completed SIRI for Haverigg should be reviewed at the multidisciplinary/multiagency clinical governance meetings, which are chaired by the Governing Governor as well as being ratified at the central CPFT SIRI panel meeting.

4.18 Coronial process

Her Majesty's Coroner is notified of all deaths. When a death is unexpected, violent or unnatural, the Coroner will decide whether to hold a post-mortem and, if necessary, an inquest. When a person dies in the custody of the legal authorities, including detention under the Mental Health Act, and those patients who have a deprivation of liberty authorisation in place, an inquest must be held.

The Coroner's court is a court of law, and accordingly the Coroner may summon witnesses to attend and give evidence. It is a legal requirement to attend, and failure to do so may result in a charge of contempt of court.

SIRI's are on an occasion identified for the first time when the Coroner notifies the Trust of an unexpected death. The incident must be reported in Ulysses in order to generate an incident number.

The Coroner may raise a Prevention of Future Death Report (Regulation 28) following an inquest and it may be at this stage that a serious incident is raised. If the Coroner issues a 'Prevention of Future Death Report' letter, and the death was not previously investigated as a serious incident, then this must be escalated and the SIRI process followed.

5 DUTIES

5.1 Roles and Responsibilities

The following details the individual and departmental roles and levels of responsibility for incident and Serious Incident Requiring Investigation (SIRI) management within the organisation including: the Trust Board, Trust committees / groups, managers and all staff.

5.2 Chief Executive

The Chief Executive is accountable and responsible to the Board for ensuring that resources, policies and procedures are in place to ensure the effective reporting, recording, investigation and treatment of incidents. In practice the Chief Executive may delegate the day-to-day responsibility for this to the Chief Nurse.

5.3 Chief Nurse

The Director of Quality and Nursing is the nominated Director responsible for ensuring that the Trust has appropriate arrangements in place for the management of incident reporting and associated investigation. The Director of Quality and Nursing will chair the Central SIRI Panel Meetings.

5.4 Director of Quality and Nursing and Medical Director

The Medical Director and Director of Quality and Nursing are responsible for ensuring that their respective professional groups are compliant with this policy and associated procedures in identifying, reporting and investigating incidents. This includes a responsibility to ensure professional practice obligations are maintained, learning is shared and any necessary changes implemented following the investigation of incidents.

They will also provide professional advice and contribute to the decision making processes to identify serious incidents.

5.5 Deputy Director of Quality and Nursing

Key task for this role, include:

Ensuring appropriate notification of incidents to relevant internal and external stakeholders, agencies and regulatory bodies.

Notifying the Chief Executive, Executive Directors, Non-Executive Directors and all other relevant stakeholders, of unexpected death or other serious incidents that may attract media attention.

Providing appropriate advice and support to the Care Group Senior Leadership Teams to enable the accurate identification, reporting and investigation of serious incidents.

5.6 Executive Directors

All executive directors are responsible for ensuring incident reporting arrangements as described in this policy are implemented throughout their service areas.

5.7 Care Group Senior Leadership Team

Care Group Associate Directors of Nursing (ADN), Associate Medical Directors (AMD) and Associate Director of Operations (ADO) are accountable for the quality and safety of the services provided within their division.

Each Care Group ADN, AMD and ADO has responsibility therefore to ensure the principles and practice described in policy is embedded within their Care Group through clear communication with all staff in their Care Group and effective Clinical Governance and operational management arrangements.

5.8 Associate Directors of Nursing

This is a key role for the effective management of both incident and SIRI management, which includes:

- The ADNs will provide assurance that all incidents reported through Ulysses are reviewed, actioned and closed as soon as is viable (ideally within 72 hours) by their Senior Managers.
- In conjunction with the Associate Director of Operations and Associate Medical Director Care Group the ADNs will identify any on-going risks and escalate these appropriately through the risk register and the established clinical governance processes.
- The ADN will identify any incidents which fall (or may fall) within the criteria for a SIRI. They will work closely with the Deputy Director of Quality and Nursing to ensure that a Directors Notification is completed for all SIRI investigations.
- Instigating serious incident investigations and other internal investigations/reviews in line with this policy and published best practice guidance.
- Ensuring an effective quality assurance process is in place to monitor the quality of investigations, associated reports and action plans prior to submission to the Board of Directors or designated sub-committee, and commissioning body.
- Chairing the Care Group SIRI panel and attendance at the Central SIRI Panel.
- The Associate Directors of Nursing will lead on specific work streams related to the clinical needs of the Care Group to support its current and future service delivery.
- Ensuring evidence is collected and appropriately stored to validate the implementation of recommendations and actions arising from serious incidents.
- Support the Lead Investigating Officers in terms of providing feedback on the investigation to the patient and/or family members.
- Lead on specific work streams related to the clinical needs of the Care Group to support its current and future service deliver. Initiatives will be derived from areas where SIRIs or other adverse events indicate that improvements in clinical standards in relation to the quality and safety of patient care are required.

5.9 Care Group Quality and Safety Leads

Support the Care Group Associate Directors by:

- Managing the Care Group SIRI panel and associated processes;
- Supporting the allocation of Investigating Officers for SIRI and coordinate the work with other care groups and external organisations where it is felt that it would be beneficial for a joint SIRI to be conducted.
- Supporting the quality assurance of all SIRI prior to sign off;
- Leading and facilitating learning lessons events, with support from the Learning Lessons Facilitators;
- Ensuring an effective tracking system is in place so that progress against action plans arising from serious and other grades of incident can be monitored and reported to Care Group Clinical Governance.
- Ensuring the completion of the 72 hour clinical review report and associated Terms of reference;
- Where required, undertaking the investigation of complex and comprehensive SIRI.

5.10 Learning Lessons Leads

The Learning Lessons Leads will support the care group by:

- Embedding a culture of learning and continuous improvement across teams;
- Leading and facilitating learning lessons events and the subsequent improvement actions from these events (as appropriate);
- Coaching and training of staff to increase the confidence and competence in relation to

undertaking SIRI.
- Providing expert advice regarding the Duty of Candour Legislation, including training for staff;
- Hold a small case load of complex and comprehensive investigation, which are agreed in-conjunction with the care group.

5.11 Head of Clinical Governance

The Head of Clinical Governance has delegated day-to-day management responsibility for the Trust's electronic incident management system together with all other systems related to the recording, analysis and tracking of incidents, serious incidents and associated action plans. The Head of Clinical Governance must:

- Ensure an effective tracking system is in place so that progress against action plans arising from serious and other grades of incident can be monitored and reported to Quality and Safety Committee.

- Ensure systems are fit for purpose and capable of producing the information required by the Board and its sub-committees, executives and all other senior managers of the Trust in a timely way.

- Analyse incident data to produce performance, management and assurance reports including quarterly thematic analysis of serious incidents to the Quality and Safety Group.

- Ensure that following declaration of a SIRI, the Quality, Safety and Safeguarding Team will inform the appropriate commissioning body and record the incident on the electronic Strategic Executive Information System (STEIS).

- Ensuring an effective tracking system is in place so that progress against action plans arising from serious and other grades of incident can be monitored and reported on to the Board of Directors.

5.12 Clinical Governance Administrator

This post holder as part of their role will:

- Work closely with the Care Group to ensure the timely declaration and reporting of SIRI;
- Provide email communication to the appropriate senior managers within the organisation when a SIRI has been declared;
- Report all SIRI which meet the criteria to the CCG and NHS England via the Executive Information System (STEIS);
- Maintain central records in relation to all SIRI;
- Provide monthly assurance and performance data on SIRIs;
- Coordinate Freedom of Information request which relate to SIRIs
- Provide monthly reports to the Medical Revalidation Team of the name of the Responsible Doctor for where the safety incident occurred.

5.13 Clinical Risk and Safety Manager

The Clinical Risk and Safety Manager delegated day-to-day management responsibility for the Trust's electronic incident management system together with all other systems related to the recording, analysis and tracking of incidents and serious incidents.

The Clinical Risk and Safety Manager must:

- Oversee the provision of education, training and information for all staff so that they are aware of the incident reporting procedure and the mechanism of grading incidents.
- Review all incidents entered on a daily basis and provide advice to the Lead Incident and Risk Coordinator regarding required data amendments/queries and highlight/discuss any incidents/risks and areas of concern directly with the senior manager of the identified team and provide expert advice on the management of these incidents
- Work collaboratively with clinicians and managers, using developed analytical skills, to identify incident management priorities both straddling the whole or parts of the organisation and pertinent to particular clinical areas or departments.
- Support our operational services to ensure that patients and or their relatives/carers are appropriately informed in line with the Being Open policy and the Duty of Candour legislation, and accurately report in our Risk Management system

5.14 Lead incident and Risk Coordinator

The Lead incident and Risk Coordinator will:

- Administer the system and ensure that all staff have access to the system, and that the functionality of the system meets the requirements of the Trust;
- Provide guidance and support to all staff through delivery of Standard Operating Procedures (SOP), education, training and information;
- Coordinate Freedom of Information request which relate to incidents;
- Will provide information to the National Patient Safety Agency (NPSA) by ensuring all patient safety incidents are reported through the National Reporting and Learning System (NRLS);
- Ensure information is forwarded to the relevant external agency where appropriate.
- Highlight and escalate individual incidents or trends of incidents to Care Groups and Clinical Risk and Safety Manager
- Will ensure all such systems are kept up to date with the latest software releases, and that changes and improvements are shared with systems users as appropriate.

5.15 Head of Engagement and Communication

The Head of Engagement and Communications will, in liaison with appropriate Care Group Associate Director of Nursing, facilitate and coordinate any communications with the media in accordance with the Trust's Media Relations Protocol.

5.16 Role of Nominated Associate Director(s)/ Directors (including On-Call Senior Managers)

Any Director who is made aware of a Serious Incident Requiring Investigation (SIRI), or the Director on call, will inform the Care Group Associate Director of Nursing of a Serious Incident Requiring Investigation (SIRI) as appropriate.

The Care Group Associate Director of Nursing and the Deputy Director of Quality and Nursing are all informed of SIRI through the Ulysses notification system.

The Director of Nursing, Chief Operating Officer, Medical Director, Head of Communication and Clinical Governance Manager are all notified of a SIRI through the Directors Notification process.

5.17 Investigating Officers (IOs)

In the event of a SIRI, the Care Group Associate Directors of Nursing (ADN)/ Clinical Governance Team will identify, preferably two, appropriately experienced and/or trained lead IOs. The IOs will be provided with:

- Clear terms of reference (as set out in the 72 hour report) within which to conduct the investigation.
- "Guidance for SIRI investigators" that sets out the expectations and process to be followed
- The SIRI template report to be used.
- The name of the SIRI Panel to which the draft report should be presented and the date of the meeting that ensures that the approved report is completed and sent to the CCG within the 60 day target.
- The contact details of the family liaison person.
- The contact details of the investigation liaison person from the care group.

The IOs will:

- Facilitate a Root Cause Analysis (RCA) investigation and compile a report.
- Wherever possible, and appropriate, a learning lessons review event should be held reducing the need for individual interviews and optimising the learning from the incident.
- All SIRIs will require an investigation and report. The IOs should gain assurance that all staff involved in the incident and who may be interviewed, are receiving the appropriate support, including junior doctors.
- Attend the appropriate SIRI panel (either central or care group) to present findings from the investigation;
- Following approval from the Care Group and/or Associate Medical Director (AMD), the IOs feeds back findings to the relevant staff group to maximise the opportunities for learning.
- The IOs are expected to complete concise or comprehensive investigations within 60 working days from the incident being reported.
- The lead IO (with the nominated family liaison person) will communicate with the patient/family/carer at the outset of the investigation, informing them of the incident and invite them to make a contribution.
- A copy of the final approved report will be available for a patient and or family members in line with the Trust's Being Open policy and the requirement for Duty of Candour.
- The findings from the SIRI investigation should be discussed in person (if possible and requested) with the patient and or family member. These meetings should be support by the nominated family liaison person

5.18 Head of Information Governance

The Head of Information Governance as the organisation's Data Protection Officer, is responsible for assessing all Information Governance and Information Security incidents and assigning the appropriate risk level as per national guidance. They will follow up incidents to ensure appropriate actions have been taken by line managers.

The Head of Information Governance will assist with or undertake incident reviews as appropriate in relation to Information Governance and Information Security Incidents.

The Head of Information Governance will provide advice to assist panels investigating Information Governance and Information Security Incidents in determining the most appropriate way to action

the recommendations.

The Head of Information Governance needs to be involved properly and in a timely manner, in all issues which relate to the protection of personal data (article 38 – GDPR Requirement). The Head of Information Governance will:

1. Cooperate with the supervisory authority (e.g. Information Commissioners Office) (article 39 (1)(d))
2. Act as a contact point for the supervisory authority on issues relating to personal data breaches.

5.19 Caldicott Guardian

The Trust Caldicott Guardian is the Medical Director and is responsible for ensuring the protection and use of patient identifiable information, ensuring it is only shared with those who have a justified need and that it is shared through safeguarded routes.

The Caldicott Guardian will provide advice as appropriate to assist panels investigating Information Governance and Information Security Incidents involving patient identifiable data and in determining the most appropriate way to action the recommendations.

5.20 Named Nurse for Safeguarding

The Named Nurses for Safeguarding are responsible for ensuring the reporting framework for Safeguarding operates and supports the incident reporting policy. The post holder must ensure that all Safeguarding incidents are reviewed and escalated in accordance with external Safeguarding procedures and takes part in any investigation where Safeguarding is believed to be a factor.

5.21 Accountable Officer for Controlled Drugs

The Accountable Officer for Controlled Drugs is the Medical Director, in this role they will ensure that any serious incident involving Controlled Drugs is reported to the Cumbria Local Intelligence Network (LIN) and the police where necessary.

Ref Controlled drugs policy POL001/013/001.

5.22 All Managers

Managers at all levels within the Trust are responsible for:

- ✓ Encouraging an ‘open and just’ culture within their service area;
- ✓ Ensuring all staff who report incidents receive an acknowledgement that encourages a positive reporting and risk management culture;
- ✓ Ensuring incident reporting arrangements are implemented within their service areas;
- ✓ Following an incident, take immediate action within the scope of their remit to prevent recurrence and/or eliminate or reduce any identified risks i.e. make the individual or environment safe;
- ✓ In the event of an SIRI or potential SIRI, make appropriate notifications to internal stakeholders such as executive directors, Care Group ADN and the Quality, Safety and Safeguarding Team and following the process map at (Appendix E).
- ✓ Conduct local investigation into all reported incidents at the appropriate and proportionate level;
- ✓ Conduct a risk assessment and notify their line manager of identified risks highlighted

by an incident or near miss, where risks cannot be reduced to an acceptable level;
- ✓ Provide immediate and appropriate support to staff, patients and families following incidents;
- ✓ Sign off completed incident forms for incidents and near misses within their service within 48 hours ensuring that incident report forms and appendices are completed with appropriate information;
- ✓ Use information from reported incidents, including analyses of themes and trends, to inform the undertaking and review of risk assessments for their service areas;
- ✓ Ensure an appropriate individual(s) within their service area is nominated to sign off incident forms in their absence.

5.23 All staff

- ✓ Report all incidents and near misses as soon as is practical, preferably within 24 hours via the Trust's electronic incident management system, Ulysses;
- ✓ Ensure the details of any incident are contemporaneously and objectively reported in the patient's clinical record; in line with the Trusts healthcare record keeping standards
- ✓ Raise any concerns about situations that led to, or could lead to, an incident or a near miss with their line manager or Quality and Safety Lead or the Learning Lessons Facilitator;
- ✓ Actively participate in any subsequent incident investigation such as: providing a written account of the incident; attending multidisciplinary fact-finding and feedback meetings.
- ✓ Attend a Coroner's inquest on behalf of the Trust if called to do so.

The Trust will make available appropriate support to those staff involved in a traumatic incident, where this is required.

6.1 Quality and Safety Committee

The Quality and Safety Committee will receive quarterly reports of all incidents within the Trust including Serious Incident Requiring Investigations (SIRI) and ensures that all incidents have been investigated appropriately and thoroughly. This Committee ensures that lessons learnt have been shared appropriately across the Trust.

6.2 SIRI Panel Meetings

The final draft SIRI investigation report will be considered for approval at either the Central SIRI Panel or the Care Group SIRI Panel.

6.3 Central SIRI Panel

The membership of the Central SIRI Panel includes:

- Chief Nurse (Chair)
- Deputy of Quality and Nursing (Vice Chair)
- Medical Director
- Director of Operations
- Associate Directors of Nursing (Care Groups)
- Clinical Safety Manager, North Cumbria CCG
- Head of Clinical Governance

The function of this meeting is:

- Provide senior level scrutiny of the SIRI investigation;

- Approve final SIRI report and agree circulation;
- Set additional lines of inquiry if required;
- Agree lessons learned and actions required;
- Agree the process for dissemination and implementation of actions required to improve safety and services;
- receive assurance re implementation and completion of required improvement;
- Ensure approved SIRI reports are provided to the Quality & Safety Committee in timely manner;
- Provide quarterly reports to Cumbria Commissioning Group(s) re SIRI process;
- Assurance function for care groups; a sample of SIRI reports signed off at care group level are reviewed;
- Identify and learn from themes.

SIRI investigations which meet the following criteria & samples from care groups:

- Never events;
- Inpatient unexpected deaths (both mental health inpatient and community hospitals)
- Any serious incident which relates to neglect or harm (willful or reckless) by a member of staff;
- Serious case reviews
- Domestic homicides
- SIRI related to prison health care services
- SIRI which involve to two or more care groups
- Serious incidents which relates to national screening programmes.
- Serious incidents relating to corporate issues, such as Information Governance.

6.4 Care Group SIRI Panels

Individual care groups have developed and implemented similar processes to mirror the Central SIRI panel, however these meetings are undertaken by each of the care groups for the majority of SIRI which do not fall within the above criteria i.e., unexpected death in community services or serious falls within inpatient services. The rationale for the two tier approach to the SIRI investigation approval process includes:

- Encourage more timely approval of investigation reports;
- For care groups to be responsible for the effective management of the SIRI process and have ownership of any learning points or actions;
- To ensure any learning points are close to the front line services;
- Support the investigator to build confidence in presenting their findings. Build confidence for the investigator to present their findings.

7. Process and arrangements for reporting all incidents

The process to assist all staff reporting or investigating an incident is detailed below. Should the incident be identified as a potential SIRI, the process map at Appendix E should be used.

The process map is designed to provide a quick but comprehensive guide to those reporting and those providing an immediate response to an incident as well as others who may be involved in incidents, such as: the executive team, ADN, Quality and Safety Leads, those responsible for a patient's care, named contact for patient/family/carer liaison, investigating officers, the executive team and the Quality, Safety and Safeguarding Team.

7.1 Immediate response following an incident or near miss event

Not all incidents are serious nor cause harm. Staff should therefore take a proportionate

response according to the impact of the incident and level of harm caused. In order to maximise learning from all incidents however, even those that have not caused harm or are 'near miss' incidents, should be reported via the Ulysses system.

In all instances, the first priority of anyone involved in an incident is to ensure the needs of individuals affected are attended to, including any urgent clinical care that may reduce the harmful impact. The risk of recurrence should be considered immediately and actions taken to mitigate in advance of any investigation.

Where relevant, a safe environment must be re-established, all equipment or medication quarantined, labelled and isolated, and all relevant documentation copied and secured to preserve evidence to facilitate the investigation and learning. To maintain product liability, no piece of equipment should be returned to the manufacturer for repair/examination until the Trust has carried out all necessary tests on the equipment as suggested by the MHRA.

- The needs of patients and their family/carers must be made the first priority.
- Relevant documentation should be copied and secured to preserve evidence and facilitate investigation and learning.
- If there is a suggestion that a criminal offence has been committed, the organisation should contact the police.

If the incident is a potential SIRI, notification must be made to the appropriate Associate Director of Nursing or their Support Services equivalent i.e., Deputy Director of Nursing. The ADN or Quality and Safety Lead will then alert Deputy Director of Quality and Nursing who will review, declare and coordinate external reporting arrangements.

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

7.2 Reporting the incident – local level

Managers of all service areas will have arrangements in place to ensure this policy is implemented. This includes ensuring that all members of staff have received the appropriate training to enable them to identify and report incidents using the Trust's incident management system. All incidents must be reported as soon as practical, preferably within 24 hours.

The Trust uses the Ulysses web based electronic incident system for the reporting and management of all incidents.

All relevant sections of the incident form are to be completed, including:

- ✓ The details of who were involved
- ✓ What happened
- ✓ Incident grading
- ✓ Level of harm
- ✓ Details of the local investigation
- ✓ The local immediate actions taken and further actions necessary

Any member of staff can complete an electronic incident report for incidents and near misses involving them, a colleague, a patient, visitor or contractor, or any other person or agency affected by the Trust's activities. The incident report is to be prepared by the member of staff who first became aware of the incident. Managers or a person they nominate in their absence will acknowledge the incident via the electronic reporting system.

The purpose of this is to recognise the incident occurred, ensure that appropriate follow-up to the incident is undertaken, including investigation at the appropriate level and satisfactory

closure on the Ulysses system. Incomplete incident forms and incidents 'open' beyond the agreed timescale for investigation will be followed up by the Clinical Risk and Safety Team with the manager of the department where the incident was reported.

7.3 Incident documentation

Details of a patient safety incident must be recorded contemporaneously and objectively within the patient's individual record. Incident forms however are a management document and copies must not be filed in clinical records. Incident reports are disclosable documents in the event of a claim against the Trust. It is therefore essential that facts only, not opinions, be documented. It should be noted that completion of an incident form does not constitute an admission of liability of any kind.

7.4 Reporting potentially serious incidents

All managers will ensure notifications of unexpected deaths and all other serious incidents or potential serious incidents are made as soon as possible after the event to the Care Group ADN or the Deputy Director of Quality and Nursing or the on call manager, if the incident occurs out of hours.

If a serious incident or Never Event occurs out of hours, during a weekend or bank holiday, the manager on call will be contacted immediately by the person in charge of the area where the incident occurred, and will be responsible for informing the Silver on call who will in turn inform the Gold on-call.

7.5 Incidents of fraud or suspected fraud

In the event of fraudulent or suspected fraudulent activity, the Local Counter Fraud Specialist is to be notified immediately. Reference must be made to the Trust's Counter Fraud policy for guidance on how to report and manage this category of incident.

7.6 Incidents of violence and aggression

Any incident where physical contact was made with a member of staff in a violent or aggressive manner must be reported, including incidents where the clinical condition of a patient may be a factor. Refer to the Prevention of Management of Violence and Aggression (PMVA) policy, for further guidance.

8. NOTIFICATIONS

8.1 Notification to internal and external stakeholders, agencies and regulatory bodies

Upon receipt of a completed incident report, the Quality, Safety and Safeguarding Team (QSS) will ensure the appropriate internal and external stakeholders; agencies and regulatory bodies are informed as appropriate.

All identified serious incidents must be notified to the relevant bodies without delay and within two working days of the incident occurring (see Appendix E). It is the role of the QSS Team to ensure that incidents and serious incidents are reported to:

- NHS England via the National Reporting and Learning System (NRLS);
- Care Quality Commission (CQC) as required by the Health and Social Care Act 2008;
- Monitor as the Trust's licensing authority;
- The Trust's commissioners via the Strategic Executive Information System (STEIS) within the required timescales.
- Cumbria Clinical Commissioning Group(s)

- Mortality and Surveillance Group within CPFT
- Other NHS Trusts

Appendix A, sets out the full external reporting requirements for NHS provider organisations.

8.2 Never Events

In the case of a never event, all reporting documentation must clearly indicate 'Never Event' throughout.

- If a never event occurs out of hours, at weekends or bank holidays, the reporter must inform their line manager and they will inform the Bronze On-call Manager, who will then inform Silver On-call. The Silver on call Manager will then inform the executive Gold on call.
- The executive on call will confirm via e-mail to the Director of Quality and Nursing, Deputy Director of Quality and Nursing, Deputy Director of Quality and Nursing, Associate Director of Nursing (for the appropriate care group) and the Clinical Governance Manager.

9. INVESTIGATING THE INCIDENT

All incidents and near misses will be subject to a level of investigation proportionate to their severity. The appropriate manager will grade all incidents according to the severity of the incident and likelihood of recurrence.

Local responsibility for investigations:

9.1 All Incidents

Where an incident is graded no or low harm, the member of staff in charge of the area where the incident occurred is required to investigate the circumstances.

Findings and learning from local incidents will then be recorded in the appropriate field on the Ulysses system alongside the incident. The local manager is responsible for ensuring all changes are made and learning shared with staff in response to incidents to reduce the risk of recurrence. The lessons learned section is now mandatory on the Ulysses system, to encourage reporting. A monthly report is then provided to the QSL's for review of Lessons learned across the Trust. All incidents should be review at the appropriate Care Group Clinical Governance Meeting/ or equivalent meeting in Corporate Support Services.

If it is assessed that a moderate or above harm from a patient safety incident has occurred then the Duty of Candour process should be applied and consideration if the incident should be reported as SIRI.

9.2 Serious Incidents Requiring Investigation (SIRI)

The initial investigation should aim to identify why the incident occurred. Depending on the initial grading and findings from a local investigation, a decision will be made as to whether further investigation is required. The initial decision as to whether an incident is a SIRI must be taken and noted to the CCG within 48 hours. The initial investigation should be completed within 72 hour (3 working days of the incident being reported) (see Appendix E).

Root cause analysis (RCA) investigation report

In the case of SIRI investigations the lead investigating officer is responsible for completing a draft report using the appropriate Trust template that will be provided to them when allocated the investigation.

If a serious incident has also been subject to an inquest then the coroner's conclusion must be included in the final report if available at the time of writing.

There are three levels of SIRI investigation, as outlined by NHS England, which are:

- **Concise:** suited to less complex incidents which can be managed by individuals or small groups at a local level. The investigation should be completed , and final reports submitted to the CCG within 60 working days of the incident being reported.
- **Comprehensive:** suited to complex issues which should be managed by a multidisciplinary team involving experts and/or specialist investigators where applicable. The investigation should be completed, and final report submitted to the CCG, within 60 working days of the incident being reported.
- **Independent:** 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. The investigation should be completed, and final report submitted to the CCG, within 6 months of the incident being reported**.**

10. LEARNING FROM INCIDENTS

10.1 Learning lessons

One of the key aims of the serious incident reporting and learning process is to reduce the risk of recurrence. The timely and appropriate dissemination of learning following an SIRI or other incidents is core to achieving this and to ensure that these lessons are embedded in practice.

10.2 Definition of learning in the context of patient safety

Action plans should describe the ways in which learning from the individual incident will be disseminated.

Action Plans will be maintained on Ulysses and used to assess progress in their implementation, primarily by the individual clinical teams and care group, but also centrally by the Lead Learning Lessons Facilitators.

Audits will be conducted to strength test the learning/changes required from the serious incident to ensure improvements are being maintained. Learning from a patient safety incident should be a collaborative, decentralised and reflective process that draws on experience, knowledge and evidence from a variety of sources.

- ✓ Organisational learning can be demonstrated by sustainable changes and improvements in process, policy, systems and procedures relating to patient safety.
- ✓ Individual learning can be demonstrated by sustainable changes and improvements in behaviour, beliefs, and attitudes and knowledge of workers at the front line of service delivery.

10.3 Examples of learning

Examples of learning following a patient safety related incident include:

- ✓ Changes to strengthen controls within systems and processes that will reduce the

potential occurrence or impact of future incidents. This may include for example, modification to patient safety tools, changes to falls risk assessments or drug administration protocols or collective ways of working to reduce the potential for incidents, errors or omissions. This may include for example making changes to handover routines that standardise the way in which information is exchanged, or changes to the way in which MDT meetings are conducted.

- ✓ Sharing solutions to address identified incident root causes and contributory factors that may be relevant to other teams, services or organisations.

10.4 Disseminating learning

There are a number of ways in which learning from a serious or critical incident might be disseminated within the Trust to improve patient safety and reduce the risk of recurrence. Examples of communication methods might include but are not limited to:

- ✓ Learning reviews and events i.e., Oxford Learning Events
- ✓ Presentations and discussion at staff/team meetings
- ✓ E-bulletins and newsletters
- ✓ Trust intranet site
- ✓ Trust public web site
- ✓ Public board papers
- ✓ Notice boards
- ✓ E-mail/internal alert mechanisms
- ✓ Reports to Quality and Safety Committee and Clinical Governance Forums
- ✓ Incorporation into risk management, incident reporting and investigation training i.e. using case studies
- ✓ Local conferences, seminars and workshops
- ✓ Periodic serious incident and incident summary reports

10.5 Analysis of incidents

The incident reporting tool which is linked to the electronic incident management system (Ulysses) enables data from reported incidents to be analysed for themes, trends or patterns.

Incident data will form part of the Trust's aggregated analysis of risk management information. Aggregated analysis involves the collation and analysis of information from different sources such as:

- Incidents
- Serious incidents
- Complaints and PALs
- Claims
- Inquests
- Patient surveys and other feedback
- Clinical audit results

Analysis of incident data is a standing item on clinical governance agendas throughout the organisation.

10.6 Risk Assessment

Incident and near miss event information will be utilised by managers when conducting or reviewing risk assessments, in accordance with the Trust's Risk Management Policy.

11. COMMUNICATION

11.1 Patients and/or family/carers

In the case of serious incidents, to include all patient safety incidents that result in moderate harm, severe harm or death, every step must be taken to ensure that the patient and their family or carers are informed at the earliest opportunity in line with the Trust's Being Open Duty of Candour Policy.

It is essential that someone with the necessary understanding of the situation, as well as the appropriate ability to take responsibility, establish contact. This could be:

- Chief Nurse
- Medical Director
- Deputy Director of Quality and Nursing
- Associate Directors of Nursing
- Associate Medical Director
- Care Group Quality and Safety Leads
- Together with the lead investigating officer if identified at this stage
- Network Managers
- Clinical Directors

The Trust representative from the above list should ensure that any questions or concerns raised by patients, relatives or carers are shared with the lead investigating officer and incorporated into the investigation. Staff should understand that an apology when something goes wrong does not constitute an admission of liability.

11.2 Sharing the report with patients/families/carers

At the point of raising the SIRI, the Care Group will formally identify the contact person best suited to speak to the patient and family to inform them of the pending investigation and subsequent findings.

Senior staff involved in the early communication with the patient, family or carers will inform them that the final report will be offered to them. They will be informed that the report is anonymised in order to assist in the appropriate dissemination of learning and to maintain confidentiality. In certain circumstances it may be appropriate to share an executive summary rather than the report in its entirety. It will be required to establish the appropriate arrangements for the sharing of the report and this may require a further meeting.

11.3 Communication with staff

All staff should receive feedback on incidents they have reported. It is the responsibility of the local manager (or their nominated deputy) to provide feedback to the person who reported the incident, thanking them for highlighting the issue, and informing them of the action(s) taken following the event. The Clinical Risk and Safety Team will provide, upon request, a summary of reported incidents to managers to assist in this process.

11.4 Media involvement following an incident

It is the responsibility of the Quality, Safety and Safeguarding Team to inform the Communications Manager in the event of a SIRI. All media enquiries received by individual members of staff must be referred to the Communications team who will respond on behalf of the Trust. The Trust will not notify the media before staff, patients, relatives or the public have been informed. If necessary, staff should refer to the Trust's Communications Policy.

11.5 Hotline arrangements

In the case of an incident that has affected a large number of individuals who may need either to be contacted by, or who may need to contact the Trust, a dedicated hotline will be set up that is coordinated by the Communications Department and supported by the Resilience Manager. The Communications Department will publish information to staff, patients and the public by the appropriate route. When setting up such arrangements, the Communications Department will need to give consideration to the following:

- Management responsibility
- Media management
- Phone lines
- Internet and intranet information
- Staffing
- Capacity to manage calls over time
- Documentation
- Record keeping
- IT/e-mail and postal arrangements

12. Losses and Compensation Claims

Staff or patients, who have incurred any financial loss due to the theft or damage of clothing or belongings whilst on Trust premises, may wish to claim for the loss. The Trust will not compensate for items that could be covered through normal household contents insurance that covers personal loss. Nor will the Trust accept responsibility for patients' items that were not handed in for safe-keeping. Circumstances however where an ex-gratia payment to cover minor damages to clothing or belongings during an incident may be appropriate.

Reimbursement expenses via ex gratia payments will be met from the budget of the service area reporting the loss but all compensation/loss forms must be approved by the Care Group Associate Director of Operations and the Legal Team before payment is made.

13. Training

All staff must receive relevant guidance and training to help them identify report and investigate incidents appropriate to their role. Healthcare provider organisations are required to include the reporting and management of incidents as part of staff induction and ongoing training.

Attendance at training will be recorded and reported via the Trust's governance and monitoring framework for training.

14. Monitoring Compliance with this policy

The table below outlines the Trusts' monitoring arrangements for this policy/document. The Trust reserves the right to commission additional work or change the monitoring arrangements to meet organisational needs.

Aspect of compliance or effectiveness being monitored	**Monitoring method**	**Individual responsible for the monitoring**	**Frequency of the monitoring activity**	**Group / committee which will receive the findings / monitoring report**	**Group / committee / individual responsible for ensuring that the actions are completed**
Effectiveness of SIRI investigation process	Review and audit of SIRI investigation reports	Central SIRI panel	Monthly	Quality and Safety Committee – quarterly monitoring report	Quality and Safety Committee – quarterly monitoring report
Timely sign off of incident reports	Incident reporting tool audit	Care Group Quality and Safety Leads	Monthly	Care Group Clinical Governance Meeting	Care Group Clinical Governance Meetings

15.1 Related Trust Policies

- Risk Management Policy
- Duty of Candour Policy
- Prevention and Management of Violence and Aggression (PMVA) policy
- Health and Safety Policy
- Claims Policy
- Security Policy
- Raising Concerns Policy
- Capability Policy
- Disciplinary Policy
- Fraud Policy
- Raising Concerns
- Safeguard Framework Policy
- Learning From Deaths Policy

APPENDIX A – Notification to internal and external stakeholders

Internal and/or External stakeholders need to be notified of incidents/events. Who these stakeholders are depends on the circumstances of the incident/event, and the people involved.

Internal stakeholders include the Trust's Executive Directors, Board, Non- Executives, specialist advisers, as well as all managers and individuals within the trust. Quality, Safety and Safeguarding Team notify appropriate internal stakeholders upon receipt of the incident report form. It is also expected that local managers will have made contact with all relevant internal stakeholders in the event of an SIRI.

A. Notifications to the regulator (CQC, Monitor)

- Healthcare provider organisations are required to notify the appropriate regulator about incidents that indicate, or may indicate, risks to ongoing compliance with the registration requirements, or that lead, or may lead, to changes in the details about the organisation in the regulator's register

- Most of the requirements for the CQC, as defined in current regulations guidance, are met by providing incident reports to the NRLS. The NRLS will forward relevant information to the CQC.

Reporting of Unauthorised Absences (AWOL) of people detained or liable to be detained under the Mental Health Act 1983 (CQC Regulation 17)

- Only services that are designed as low, medium or high security are required to notify CQC of any unauthorised absences of people detained or liable to be detained under the Mental Health Act 1983

- All CPFT Mental Health Inpatient Wards are categorised as general level security and therefore – we are not required to report incidents of AWOLs separately to the CQC. The reporting of these incidents will be completed through the standard process which is via the Ulysses system.

Deaths of detained patients (CQC Regulation 17)

- Services are required to notify the CQC directly when any patients dies while detained or liable to be detained under the Mental Health Act. The Quality, Safety and Safeguarding are able to support services with the completion of the appropriate forms for this information to be submitted to the CQC. Staff should contact 01228 608385
- Staff can find further information: www.cqc.org.uk/organisations-we-regulate/registered-services/notifications

Young person placed on adult psychiatric units (CQC Regulation 18 (2) (h))

- Providers of psychiatric wards whose service is normally intended for someone over 18 years must notify the CQC directly about the placement of a child or young person where the placement last for a continuous period of longer than 48 hours.
- The Quality, Safety and Safeguarding are able to support services with the completion of the appropriate forms for this information to be submitted to the CQC. Staff should contact 01228 608385. Staff can find further information: www.cqc.org.uk/organisations-we-regulate/registered-services/notifications

Reporting certified treatment (CQC Regulation 18)

- Under Section 61 of the MHA requires that, where a patient has received treatment certified by a panel under Section 57 or a Second Opinion Appointed
- Doctor under Section 58 or 62A, a report on the treatment and the patient's condition must be given by the approved clinician in charge of the patient's treatment to the CQC
- These reports are generally required when a patient's detention is renewed (for patients subject to a CTO this report is only required at the renewal of the order if they have received treatment certified by SOAD recalled) following a second opinion or when the CQC requires one.
- The format of this report can be found on www.cqc.org.uk/organisations-we-regulate/registered-services/notifications. There is a separate form for Section 57 treatment which can be requested from MHAEnquires@cqc.org.uk
- The CPFT MHA Legislation Unit are also able to support staff with the completion of these forms.

B. Reporting to the Health and Safety Executive (HSE)

- The HSE is responsible for the enforcement of the Health and Safety at Work Act 1974 (HSWA) and ensuring that "risks to people's health and safety from work activities are properly controlled"
- Serious incidents may need to be reported under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR)
- Further information on reporting is available at http://www.hse.gov.uk/riddor/report.htm

C. Reporting to the police

- The police are likely to investigate incidents where there is evidence, or suspicion of, a criminal offence having been committed, e.g. if an incident has arisen from or involves criminal intent, or gross negligence
- In the first instance the incident should be reported within the organisation in the normal way and to the commissioning body.
- Referral to the police should be undertaken by a senior member of staff in the reporting organisation.
- An unexpected death (where natural causes are not suspected) and all deaths of detained patients must be reported to the coroner by the treating clinician
- This should be done immediately, but recognising that, following an unexpected death, a serious incident may not be identified until the issuing of the coroner's report.

D. Reporting to Public Health England

PHE Centres:

- Where incidents have the potential to affect population health, the provider should seek advice from the local PHE Centre. Depending on the nature of the incident, other public health organisations such as local authorities may need to be involved.
- Such incidents will include those with a health protection component, such as failures in decontamination

- The PHECs' health protection staff will provide a risk assessment and advise on appropriate action

E. National screening programmes

- In the case of a serious incident in a screening programme, the NHS Commissioning Board Area Team Screening and Immunisation Lead is responsible for ensuring that the provider(s) respond to a serious incident in an appropriate and timely manner and take all necessary steps to mitigate any on-going risks .
- The provider organisation must report all potential incidents and serious incidents to the Regional QA Director or Regional QA Lead. The Quality Assurance team will undertake initial fact finding with the screening provider and advise on next steps

F. Reporting to the Medicines and Healthcare products Regulatory Agency (MHRA)

- Any serious incident involving medication or medical devices should be reported to the MHRA. Details on how to do this are at: www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/index

G. Reporting Health Care Associated Infection (HCAI) serious incidents

- The Health Protection Agency's guidance on Health Care Associated Infection Operational Guidance and Standards for Health Protection Units provides information on the steps that should be followed by providers in escalating concerns about the management of a HCAI situation, incident or outbreak and steps for informing commissioners and regulators about concerns. While this will need to be updated to reflect new responsibilities, the principles around recognising incidents, undertaking risk assessments and when to escalate serious HCAI situations/incidents and outbreaks remain valid. The guidance can be found at: www.hpa.org.uk/Publications/InfectiousDiseases/InfectionControl/1207hcaiopguidancestdsforHPUs

H. Caldicott, data protection and information governance

- When reporting serious incidents, providers must comply with Caldicott, data protection and information governance requirements.
- They should not refer to individuals by name or give other identifiable information, and should "restrict access to patient information within each organisation by enforcing strict need to know principles".
- In any circumstance where it may be necessary to identify an individual, the serious incident lead in the provider organisation must contact the senior member of the commissioner or local authority to discuss the incident and provide more detailed information

Reporting of Injuries, Diseases and Dangerous Occurrences (RIDDOR) Regulations 1995

Please refer to the Health and Safety Policy for more information.

APPENDIX B STEIS reporting categories

Categories

Abuse/alleged abuse of adult patient by staff
Abuse/alleged abuse of adult patient by third party
Abuse/alleged abuse of child patient by staff
Abuse/alleged abuse of child patient by third party

Accident e.g. collision/scald (not slip/trip/fall) meeting SI criteria
Adverse media coverage or public concern about the organisation or the wider NHS
Apparent/actual/suspected homicide meeting SI criteria
Apparent/actual/suspected self-inflicted harm meeting SI criteria
Blood product/ transfusion incident meeting SI criteria
Commissioning incident meeting SI criteria
Confidential information leak/information governance breach meeting SI criteria
Diagnostic incident including delay meeting SI criteria (including failure to act on test results)
Disruptive/ aggressive/ violent behaviour meeting SI criteria
Environmental incident meeting SI criteria
Failure to obtain appropriate bed for child who needed it
HCAI/Infection control incident meeting SI criteria
Incident affecting patient's body after death meeting SI criteria
Major incident/ emergency preparedness, resilience and response/ suspension of services
Maternity/Obstetric incident meeting SI criteria: baby*
Maternity/Obstetric incident meeting SI criteria: mother and baby*
Maternity/Obstetric incident meeting SI criteria: mother only
Medical equipment/ devices/disposables incident meeting SI criteria
Medication incident meeting SI criteria
Operation/treatment given without valid consent
Pending review (a category must be selected before incident is closed)
Pressure ulcer meeting SI criteria
Radiation incident (including exposure when scanning) meeting SI criteria
Screening issues meeting SI criteria
Slips/trips/falls meeting SI criteria
Sub-optimal care of the deteriorating patient meeting SI criteria
Substance misuse whilst inpatient meeting SI criteria
Surgical/invasive procedure incident meeting SI criteria
Treatment delay meeting SI criteria
Unauthorised absence meeting SI criteria
VTE meeting SI criteria
*To include foetus, neonate and infant

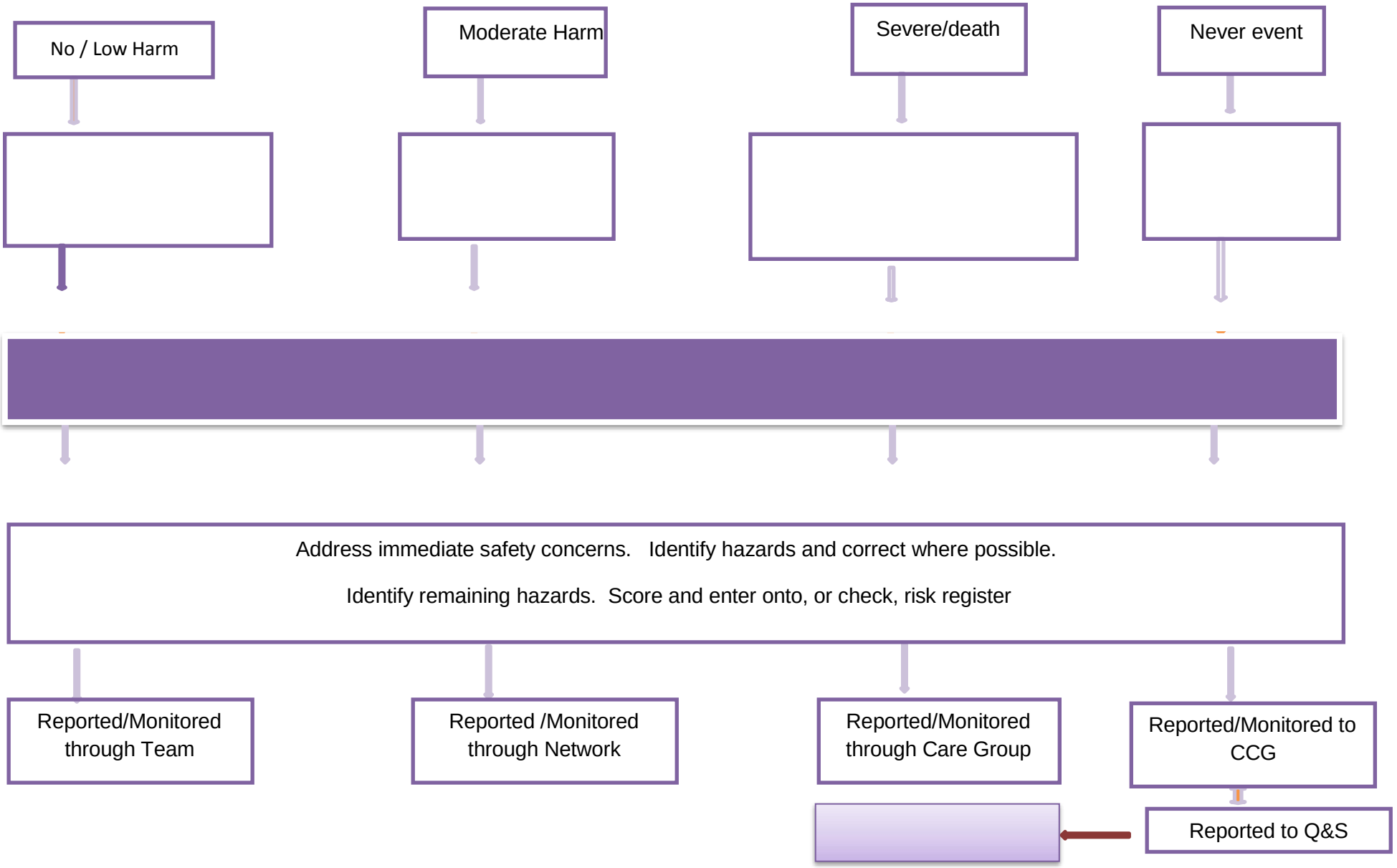
Notes regarding the reporting of Safeguarding and Child Death incidents on STEIS system:

Safeguarding: Within the reason for reporting there is the actual/alleged abuse category. There are also several incident types that relate to safeguarding issues and there is also the option to add when a SCR/SAR is required and when the LA have been informed. The correspondence history can be used to document information relating to correspondence between designated professionals/safeguarding leads. The immediate action box should also be used to provide information and assurance about action taken by relevant individuals. There is also the legal status box which should highlight those patients under DoLS etc., which may require further consideration.

Child death: is not included as an SI by definition as this may not always be the case. Wherever the SI criteria applies however (i.e. unexpected/potentially avoidable death) then the death should be reported as a serious incident and the relevant category selected in the reason for reporting field in STEIS. The incident type should be linked to the event that occurred i.e. surgical procedure, medication incident, sub-optimal care, self-inflicted harm etc. Often the incident type is unknown at the time of reporting unexpected/potentially avoidable deaths so this is why a 'pending' category has been included. This field should be amended and a relevant incident type selected as soon as possible or the incident should be downgraded if on further investigation it's identified the SI criteria do not apply. The age of the patient should be included within the STEIS report so it is possible to tell whether a child is involved.

APPENDIX C – Incident Notification and Sign off

Incident Notified



APPENDIX D - CATEGORIES OF REPORTED INCIDENT
THE INCIDENT REPORT FORM

Electronic Incident Reporting

1. Follow the link on the intranet home page 'Electronic Incident Reporting'. This will take you to the Ulysses web pages.

2. Login to Ulysses web pages using your usual network login username and password

3. Links to guidance notes and associated video links on how to use the electronic incident reporting system are listed on the Ulysses home.

2. CATEGORIES OF REPORTED INCIDENT

The process incorporates different levels of investigation appropriate to the significance of each reported incident in terms of actual impact and risk presented (in accordance with NPSA risk matrix & harm level descriptors). Examples of incidents falling into each of the categories are provided below.

Calculate the Incident Grading

Multiply the 'Likelihood' figure and the 'Consequences' figure to calculate the Grade score. For example, if the Likelihood was graded as 4 (likely) and the Consequences were graded as 3 (moderate), the Grading would be 4 x 3 = 12. This score will equate to a low, medium, moderate, or very high risk, as can be seen on the risk grading grid overleaf.

Consequences

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

Red	15-25	Very high risk
Orange	8-12	Moderate risk
Yellow	4-6	Low risk
Green	1-3	Very low risk

INCIDENT GRADING: GUIDELINES FOR STAFF

The Trust operates an established grading system based on a 1-5 scale for likelihood and consequence, known as the 5 x 5 matrix. Using this scale the lowest score is 1 and the highest score is 25. Incidents graded 15 or above are considered High Risk and are trigger a Serious Untoward Incident (SUI) investigation Initial Management Report, which may then lead onto a full SUI investigation (refer to flowchart at Appendix 1). The matrix operates on the following descriptors:-

Quantify the Potential for the Incident or Event to Happen Again if Nothing Changes

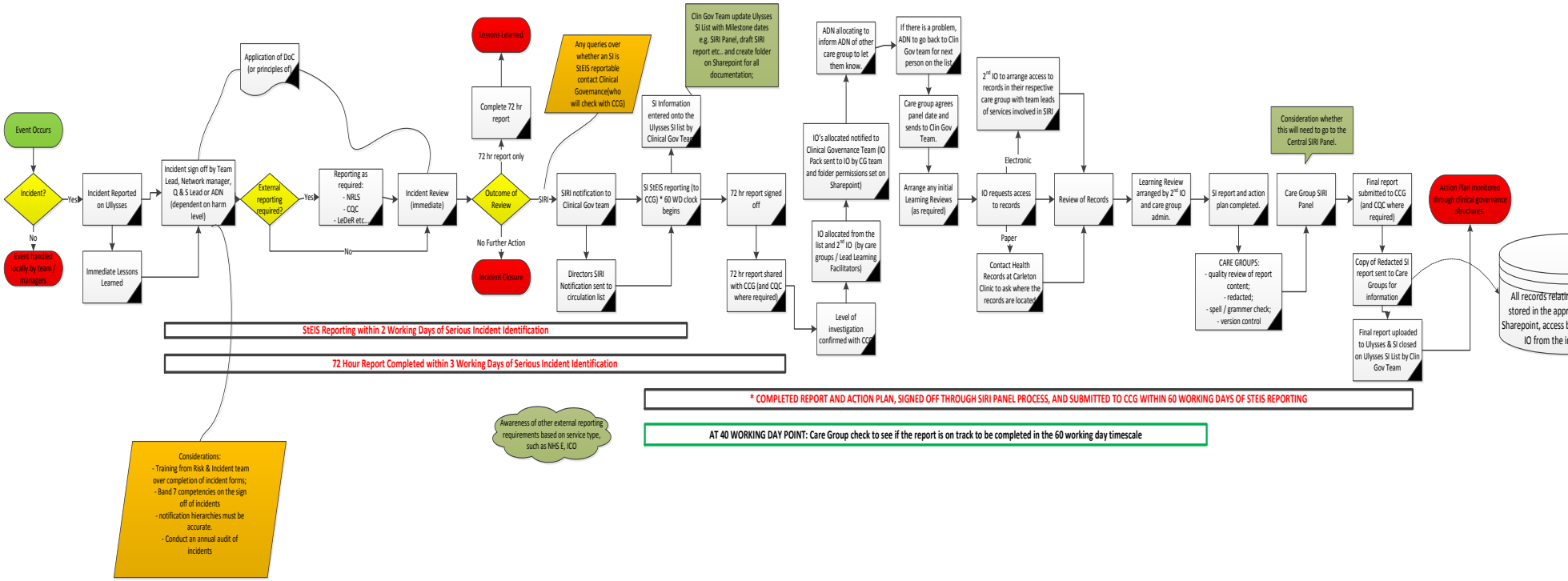
1	Rare	May only occur in exceptional circumstances
2	Unlikely	May occur at some time
3	Possible	Will occur from time to time
4	Likely	Will occur at some time in the near future
5	Almost Certain	Will occur at any time and reoccur frequently

Describe the ACTUAL OUTCOME of the incident or event based on the definitions shown below:

Potential/Actual Impact of an Risk Grading	Actual Outcome of Injury Extent	Potential Impact: Injuries - Level of Harm			Potential Impact: Non-Injury Impacts			
		Physical Injuries – EXCEPT from falls incidents	Physical injuries from Falls Incidents	Psychological Injury (distress)	Financial Impact	Impact on Health objectives	Compliance	Service Delivery
1	0 Near Miss	No physical harm	n/a	n/a	n/a	n/a	**n/a**	**n/a**
	1 Insignificant	No obvious injury, no treatment required	Fall occurred but with no harm to the patient	No psychological distress	Costs £10k and under.	No Significant effect on quality of care.	No effect on compliance issues	No effect on ability to deliver services
2	2 Minor	First Aid injury. No lost time. No permanent damage.	Harm requiring minor/first-aid level of treatment only	Minor distress - short term impact	Costs up to £100k.	Noticeable effect on quality of care	Compliance with statutory/mandatory requirements may be effected	Ability to deliver services may be effected
3	3 Moderate	Sprain, strain, burn. May require medical treatment. Lost time. Temporary incapacity (up to 1 week).	Harm is likely to require outpatient treatment, admission to hospital, surgery or a longer stay in hospital, but a full	Moderate distress, medium term impacts but full recovery is anticipated	Costs up to £500k	Significant effect on quality of care.	Compliance with statutory/mandatory requirements is likely to be effected	Ability to deliver services likely to be effected
4	4 Major	RIDDOR reportable incident. More than 7 days incapacity, loss of limb, fracture (not fingers or toes), crushing ,Exposure to Toxins. Permanent Incapacity.	Harm causing permanent disability; the patient is unlikely to regain their previous level of independence	Significant distress to a level which may have longer term impacts and which could adversely affect full recovery	Costs up to £5m	Patient care significantly impaired.	Compliance with statutory/mandatory requirements significantly impaired	Ability to deliver services is significantly impaired. Major disruption to service
5	**5 Catastrophic**	Multiple casualties with major injuries.	n/a	Extreme distress, to a level that triggers suicidal ideation	Costs over £5m.	Patient Care impossible.	Failure to meet statutory/mandatory requirements	Unable to deliver services
	6 Death	Fatality.	Death was the direct result of the fall	Death	n/a	n/a	n/a	n/a

APPENDIX E – Serious Incident Requiring Investigation Process (SIRI)

Please zoom in on this page to view image detail.



FV02 Sep 2017

APPENDIX F Guide for investigators

SECTION1 QUICK GUIDE FOR SIRI INVESTIGATORS

DECISION BY AN ASSOCIATE DIRECTOR / DIRECTOR CONFIRMING INCIDENT IS A SIRI
BASED UPON A REVIEW OF AN INCIDENT REPORTED IN ULYSSES WITHIN 48 HOURS OF INCIDENT OR FROM A 72 HOUR INCIDENT

STEP 1

ANONYMISED 72 R INCIDENT INVESTIGATION REPORT PROVIDED TO CCG& StEIS REPORTED BY

CARE GROUP/ CLINICAL GOVERNANCE TEAM **APPOINT (IDEALLY 2) TRAINED ROOT CAUSE ANALYSIS (RCA) INVESTIGATOR(S)** AND **PROVIDE THE INVESTIGATOR(S) WITH**:

1) **COMPLETED AND APPROVED 72 HOUR REPORT** (INCLUDING TERMS OF REFERENCE)
2) **FORMAT AND LATEST TEMPLATE OF REPORT TO BE USED** (CONCISE OR COMPREHENSIVE)
3) **DATE OF THE CARE GROUP/ CENTRAL SIRI PANEL THAT IS TO CONSIDER AND APPROVE THE COMPLETED SIRI REPORT** (INCLUDING COMPLETED ACTION PLAN)

STEP 2

INVESTIGATORS UNDERTAKE RCA INVESTIGATION AND PREPARE DRAFT REPORT BY:

1. **PLANNING THE INVESTIGATION**
2. **OBTAINING** THE INFORMATION SET OUT IN STEP 2
3. **SPEAKING TO PATIENT/ RELATIVES** TO GET THEIR PERSPECTIVE AND ANY CONCERNS OR POSITIVE OBSERVATION AND ANY ISSUES THEY WANT TO BE ADDRESSED AND INCLUDED IN THE TERMS OF REFERENCE (LINK TO DUTY OF CANDOUR)
4. **COMPLETING A TABULAR TIMELINE OF EVENTS**
5. **IDENTIFYING** THE INDIVIDUALS AND SERVICES INVOLVED
6. **OBTAINING** RELEVANT RECORDS, POLICIES, GUIDELINES ETC
7. **ARRANGING AND FACILITATING A STRUCTURED "LEARNING LESSONS" MEETING**TO CONFIRM THE INCIDENT DETAILS (INCLUDING **TABULAR TIMELINE**), IDENTIFY ANY ACTS OR OMMISSIONS THAT MAY HAVE CONTRIBUTED TO OR BEEN THE ROOT CAUSE OF ANY SERIOUS LAPSES IN CARE. (**USE FISHBONE DIAGRAM** AND **5 WHYS TOOLS**) AND AGREE LESSONS LEARNT AND ACTION TO BE TAKEN
8. **UNDERTAKE ANY OUTSTANDING** INTERVIEWS/ DOCUMENTATION REVIEWS
9. **DRAFT CONCISE/ COMPREHENSIVE REPORT**
10. **SHARE / DISCUSS INITIAL FINDINGS AND/ OR DRAFT REPORT** WITH THOSE INVOLVED (INCLUDING PATIENT OR FAMILY, IN ACCORDANCE WITH THEIR WISHES) AND REVISIT ISSUES/ AMEND REPORT AS NECESSARY.
11. **FINDINGS AGREED WITH, & ACTION PLAN COMPLETED BY, RELEVANT OPERATIONAL MANAGER(S)** & INCLUDED IN SIRI REPORT
12. **SUBMIT DRAFT** SIRI REPORT **FOR CARE GROUP QUALITY ASSURANCE REVIEW AND RECEIVE BACK**
13. **RETAIN EVIDENCE OF INVESTIGATION:** ELECTRONICALLY ON SECURE SHAREPOINT SITE (ACCESS PROVIDED BY CLINICAL GOVERNANCE TEAM) AND ANY PAPER RECORDS RETAINED ON FILE.

STEP 3

INVESTIGATOR(S) SUBMIT DRAFT SIRI REPORT FOR PRE-SIRI PANEL APPROVAL TO RELEVANT CARE GROUP SENIOR MANAGEMENT TEAM (SMT) OR CORPORATE SERVICES SMT AND INVESTIGATOR(S) AMEND DRAFT REPORT AS NECESSARY

STEP 4

INVESTIGATOR(S) SUBMIT DRAFT SIRI REPORT TO ADMINSTRATOR OF NOMINATED CARE GROUP/ CENTRAL SIRI PANEL 7 DAYS PRIOR TO THE PANEL MEETING DATE

STEP 5

INVESTIGATOR(S) PRESENT FINDINGS (5 MINUTES) TO SIRI PANEL MEETING, ANSWER ANY QUESTIONS AND AGREE ANY AMENDMENTS. INVITED SERVICE MANAGER(S) PROVIDE ASSURANCE THAT ACTIONS AGREED WILL BE IMPLEMENTED. **SIRI PANEL APPROVE** (OR INVESTIGATORS COULD BE ASKED TO REPRESENT AMENDED REPORT TO THE NEXT SIRI PANEL.

STEP 6

INVESTIGATOR(S) MAKE ANY AGREED CHANGES TO APPROVED REPORT AND INCLUDE THE DETAILS OF APPROVING PANEL AND COMPLETE THE FINAL PROOF READ AND ANONYMISATION CHECKS AND THEN SEND TO THE CLINICAL GOVERNANCE TEAM

STEP 7

FINAL PROOF READ & REDACTION CHECK BY CLINICAL GOVERNANCE TEAM AND ANONYMISED REPORT SUBMITTED TO CCG SUBMITTED TO CCG

STEP 8

IF DUTY OF CANDOUR APPLIES **INVESTIGATOR(S) (AND NOMINATED FAMILY LIASON PERSON) MEET WITH PATIENT TO REPORT THE OUTCOME** (IF THEY WISH) AND PROVIDE THEM WITH THE APPROVED SIRI REPORT.
(Covering letter to the report will be the FINAL DUTY OF CANDOUR LETTER where it applies).

STEP 9