South Western Ambulance Service NHS
NHS Foundation Trust

Serious and Moderate Harm Incident Policy

Incorporating the Duty of Candour and Never Events

Version:	2
Status:	Approved
Title of originator/author:	Patient Safety Manager
Name of responsible director:	Executive Director of Nursing and Governance
Developed/revised by group/committee and Date:	Quality Committee 14 April 2016 PRAG 20 April 2016
Approved by group/committee and Date:	Board of Directors 28 April 2016
Effective date of issue: **(1 month after approval date)**	May 2016
Next review date:	April 2019
Date Equality Impact Assessment Completed	TBC
Regulatory Requirement:	National Serious Incident Framework

responsive committed effective

Trust Policy Foreword

Code of Conduct and Conflict of Interest Policy - The Trust Code of Conduct for Staff and its Conflict of Interest and Anti-Bribery policies set out the expectations of the Trust in respect of staff behaviour. SWASFT employees are expected to observe the principles of the Code of Conduct and these policies by declaring any gifts received or potential conflicts of interest in a timely manner, and upholding the Trust zero-tolerance to bribery.

Compassion in Practice – SWASFT will promote the values and behaviours within the Compassion in Practice model which provide an easily understood way to explain our role as professionals and care staff and to hold ourselves to account for the care and services that we provide. These values and behaviours reflect the Trust's commitment to developing an outstanding service through the conduct and actions of all staff. SWASFT will encourage staff to demonstrate how they apply the core competencies of Care, Compassion, Competence, Communication, Courage, and Commitment to ensure our patients experience compassionate care.

Duty of Candour – SWASFT will, as far as is reasonably practicable, apply the statutory Duty of Candour to all reported incidents where the Trust believes it has caused moderate or severe harm or death to a patient. This entails providing the affected patient or next of kin (within strict timescales) with: all information known to date; an apology; an explanation about any investigation; written follow-up; reasonable support; and the outcome fed back in person (unless they do not want it). The only exception is where making contact could have a negative impact upon the next of kin. SWASFT employees are expected to support this process by highlighting (early) any incident where they believe harm may have been caused.

Equality Act 2010 and the Public Sector Equality Duty - SWASFT will act in accordance with the Equality Act 2010, which bans unfair treatment and helps achieve equal opportunities in the workplace. The Equality Duty has three aims, requiring public bodies to have due regard to: eliminating unlawful discrimination, harassment, victimization and any other conduct prohibited by the Act; advancing equality of opportunity between people who share a protected characteristic and people who do not share it; and fostering good relations between people who share a protected characteristic and people who do not share it. SWASFT employees are expected to observe Trust policy and the maintenance of a fair and equitable workplace.

Fit and Proper Persons – SWASFT has a statutory duty not to appoint a person or allow a person to continue to be an executive director or equivalent or a non-executive director under given circumstances. They must be: of good character; have the necessary qualifications, skills and experience; able to perform the work they are employed for (with reasonable adjustments); able to provide information required under Schedule 3 (Health and Social Care Act 2008 (Regulated Activities) Regulations 2014). The definition of good character is not the test of having no criminal convictions but instead rests upon judgement as to whether the person's character is such that they can be relied upon to do the right thing under all circumstances. This implies discretion for boards in reaching a decision and allows that people can change over time.

Health and Safety - SWASFT will, so far as is reasonably practicable, act in accordance with the Health and Safety at Work etc. Act 1974, the Management of Health and Safety at Work Regulations 1999 and associated legislation and approved codes of practice. It will provide and maintain, so far as is reasonable, a working environment for employees which is safe, without risks to health, with adequate facilities and arrangements for health at work. SWASFT employees are expected to observe Trust policy and support the maintenance of a safe and healthy workplace.

Information Governance - SWASFT recognises that its records and information must managed, handled and protected in accordance with the requirements of the Data Protection Act 1998 and other legislation, not only to serve its business needs, but also to support the provision of highest quality patient care and ensure individual's rights in respect of their personal data are observed. SWASFT employees are expected to respect their contact with personal or sensitive information and protect it in line with Trust policy.

NHS Constitution - SWASFT will adhere to the principles within the NHS Constitution including: the rights to which patients, public and staff are entitled; the pledges which the NHS is committed to uphold; and the duties which public, patients and staff owe to one another to ensure the NHS operates fairly and effectively. SWASFT employees are expected to uphold the duties set out in the Constitution.

Risk Management - SWASFT will maintain good risk management arrangements by all managers and staff by encouraging the active identification of risks, and eliminating those risks or reducing them to the lowest level that is reasonably practicable through appropriate control mechanisms. This is to ensure harm, damage and potential losses are avoided or minimized, and the continuing provision of high quality services to patients, stakeholders, employees and the public. SWASFT employees are expected to support the identification of risk by reporting adverse incidents or near misses through the Trust web-based incident reporting system.

CONTENTS

1 Introduction

1.1 South Western Ambulance Service NHS Foundation Trust (hereafter referred to as the Trust) is committed to meeting its objectives and protecting patients, staff, the public and other stakeholders against all kinds of risks. It has therefore adopted a Governance Strategy to which this policy contributes.

1.2 It is fundamental to the Trust's risk management system that Serious and Moderate Harm Incidents (SIs and MHs) are appropriately managed to learn lessons and avoid their future reoccurrence.

1.3 For the purpose of this policy the Trust has adopted NHS England's Serious Incident Framework, March 2015 which highlights some fundamental changes from the 2013 Framework. However continues to follow the ethos outlined by the National Patient Safety Agency in 2010.

1.4 In addition the Trust has undertaken compliance with the Statutory Duty of Candour. The Statutory Duty of Candour was introduced in 2014. This requires the Trust to be transparent and open with our patients informing them that a Patient Safety incident has occurred. Candour applies to both serious and moderate incidents. A definition of serious, moderate, adverse incidents and the Duty of Candour can be found in section 4.

1.5 Examples of Serious Incidents are set out at Appendix A.

1.6 Examples of Moderate Harm Incidents are set out in Appendix B.

2 Purpose

2.1 This policy establishes a procedural framework for dealing with Serious and Moderate Harm Incidents in order that:-

a) the possibility of a re-occurrence is minimised or eliminated; and/or

b) lessons are learnt leading to continuous quality improvement of service.

2.2 This policy outlines the statutory requirements of the Trust to in order to meet to meet the requirements of the Duty of Candour.

3 Scope

3.1 This policy covers all Serious and Moderate Harm Incidents and applies to all the Trust's employees, volunteers, non-executive directors, governors, patients, visitors, contractors, agency staff and other partner agency employees whilst on Trust business.

3.2 This policy applies to every part of the Trust's business including clinical care, human resources, ambulance operations, urgent care / 111 service, minor injury and treatment centres, accountability issues, fleet and equipment management, estates management, financial performance, corporate issues and strategic positioning.

3.3 Incidents that are not covered under the definition within this policy are managed within the Trust's Incident Reporting Policy.

3.4 This policy covers the Trust's statutory requirement to the Duty of Candour. The Statutory Duty of Candour applies to all patient safety incidents that are deemed of moderate or serious harm.

4. Definitions

Throughout this policy the following definitions will apply:-

4.1 **Serious Incidents (SI)** are defined as those that occur that have the potential to or actually impact patient safety or an organisations ability to deliver ongoing health care. Their occurrence demonstrates weaknesses in a system or process that need to be addressed to prevent future incidents leading to avoidable death or serious harm to patients or staff, future incidents of abuse to patients or staff, or future significant reputational damage to the organisations involved.

4.2 A serious incident has been defined by the NHS England, within the 2015 framework, as 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;

- 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

For clarity, the term '**incident'** in relation to the serious incident process is described as: 'an event or circumstance that could have resulted, or did result, in unnecessary damage, loss or harm such as physical or mental injury to a patient, staff, visitors or members of the public'.

4.3 **Moderate Harm (MH):** A patient safety incident that resulted in a moderate increase in treatment and that caused significant, but not permanent, harm to one or more patients. A moderate increase in treatment is defined as a return to surgery, an unplanned readmission, a prolonged episode of care, extra time in hospital or as an outpatient, cancellation of treatment, transfer to another area such as intensive care as a result of the incident or a scenario that causes or is likely to cause psychological harm for a continuous period of at least 28 days

4.4 **Adverse Incident (AI):** Any event or circumstance arising that could have or did lead to unintended or unexpected harm, loss or damage to any individual or the Trust. Adverse incidents may or may not be clinical and may involve actual or potential injury, mis-diagnosis or treatment, equipment failure, damage, loss, fire, theft, violence, abuse, accidents, ill health, near misses and hazards.

4.5 **Duty of Candour (DoC)**: A duty to be open with our patients, informing them of any moderate or serious patient safety incident in which they have been involved. When 'being open', the Trust should acknowledge the incident occurred, apologise to the patient or next of kin, and explain why the incident occurred and what actions will be put in place to try and prevent a recurrence.

4.6 **Never Events (NE)**: Are defined by NHS England within the national Never Events Policy and Framework as a particular type of Serious Incident that meet **all** of the following criteria:

- They are **wholly preventable**, where guidance or safety recommendations that provide strong systemic protective barrier **are available at a national level**, **and should** have been implemented by all healthcare providers.
- Each Never Event type **has the potential to cause serious patient harm or death**. However, serious harm or death is not required to have happened as a result of a specific incident occurrence for that incident to be categorised a Never Event.
- There is evidence that the category of Never Event **has occurred in the past**, for example through reports to the National Reporting and Learning System (NRLS), and a risk of reoccurrence remains.

4.7 **Quality Development Forum**

The Quality Development Forum reports to the Quality Committee and its' duties include:

- proactively highlighting areas of concern or poor practice and undertaking focused reviews, informed by other forums such as the Quality Committee and Clinical Effectiveness Group, to develop and influence Trust-wide quality improvements;
- approving updates to the Trust's Quality Strategy, and supporting its implementation;
- making recommendations for action to improve quality, ensuring those actions are implemented and disseminated throughout the organisation;
- referring and receiving recommendations for change to policy to appropriate Director;
- referring and receiving recommendations for change to the Trust annual training programme, via the Clinical Effectiveness Group;
- analysing and acting upon feedback from the external environment such as national groups.
- identifying and learning from areas of good practice, including undertaking and promoting use of PDSA (Plan, Do, Study, Act) cycles to assess their effectiveness;
- ensuring a positive and productive relationship with key learning forums such as Clinical Effectiveness Group, the Right Care team, and the Staying Well service
- establishing a positive and productive relationship with Operations to help drive forward quality improvement;
- learning from and acting upon staff and patient feedback;
- reviewing and supporting improvements in Clinical Supervision;
- identifying quality priorities to feed into CQUINs and the Quality Account;
- identifying and referring any new or changed risks;
- exploring and influencing cultural change within the Trust;
- holding a bi-annual meeting, with a larger membership, to consider work undertaken by the Group in the intervening period, as well as its effectiveness.

5 Principles

5.1 The Trust recognises that the outcome of investigations into Serious Incidents should be critically analysed by suitably qualified and experienced Trust staff and, where appropriate, shared with other NHS organisations. The assistance of expert advisers from outside the Trust may be sought when required.

5.2 The Trust recognises the importance of Being Open and has developed a Duty of Candour Procedure (Appendix C). The Duty of Candour Procedure sets out the processes for being open when a Serious or Moderate Harm patient safety incident occurs.

5.3 All staff have a duty to ensure that all potential and actual Serious and Moderate Harm Incidents are reported through the relevant reporting procedures. This includes complaints, accidents or incidents, information governance incidents, major incidents, health and safety issues, alleged clinical negligence or malpractice and alleged abuse of patients, staff and/or property/assets.

5.4 All Trust managers have an obligation to investigate and take appropriate action to ensure that the aims of this policy are met.

5.6 Where a potential or actual Serious Incident has occurred, the decision of the police or Local Counter Fraud Service to proceed or not with any related investigation, prosecution or other action will not necessarily have any bearing on any internal investigation and/or related management decision. The advice of the Executive Director of Nursing and Governance (the director with nominated lead responsibility for Serious Incidents) must be taken at the earliest opportunity when the Police become involved in a Trust matter and the guidance set out in the *'Memorandum of Understanding: Investigating patient safety incidents involving unexpected death or serious untoward harm'* published by the Department of Health, February 2006 (Appendix D), should be followed. For fraud and corruption matters the Deputy Chief Executive / Executive Director of Finance should be notified.

5.7 Where the Investigating Officer or Chair of any Serious Incident Review Meeting feels that the matter would be better dealt with under a different procedure (e.g. the incident may not be as serious as first thought or another Trust policy may be more appropriate for example, the Capability Policy) the matter may be referred for a different type or level of investigation under other Trust policies. This decision should inform future decision making when confirming Serious Incidents.

5.8 Where it is identified during a Serious or Moderate Harm Incident investigation that that any employment policies may apply to the incident, guidance should be sought from the Patient Safety Manager and / or Human Resource Business Partners. Any employment investigation should run alongside the Serious or Moderate Harm Incident investigation and, where practicable, be completed prior to the Serious Incident Review Meeting being convened.

5.9 There may be times following a clinical incident that results in serious or moderate harm, when Trust officers may consider the appropriateness of applying restrictions to the clinical scope of practice of clinical staff pending the outcome of an investigation. This is to ensure that concerns regarding clinical practice are dealt

with in a fair, transparent manner providing support to the individual clinician, whilst ensuring that patient safety is paramount and should comply with the requirements of the Capability Policy.

5.10 Records of all Serious and Moderate Harm Incidents will be recorded on a Trust Serious and Moderate Harm Incident Master Log maintained and monitored by the Patient Safety team.

5.11 The Trust is committed to learning from Serious and Moderate Harm incidents and will publish, share and disseminate lessons learned through Reflect and National Ambulance Forums.

6 Duties, Responsibilities and Reporting

6.1 Board of Directors

6.1.1 The Board of Directors is responsible for:-

a) ensuring appropriate structures are in place to manage Serious and Moderate Harm Incidents;

b) monitoring the effectiveness of this policy.

6.2 Chief Executive

6.2.1 The Chief Executive of South Western Ambulance Service NHS Foundation Trust has overall responsibility, on behalf of the Board of Directors, for ensuring the implementation of this policy throughout the organisation.

6.3 Executive Director of Nursing and Governance

6.3.1 The Executive Director of Nursing and Governance has lead responsibility for implementing and monitoring the Serious and Moderate Harm Incident process, including being one of the nominated chairs for Serious Incident Review Meetings and the over-arching decision maker for the confirmation of Serious and Moderate Incidents.

6.3.2 The Executive Director of Nursing and Governance can confirm a ‘Barn door’ Serious Incident without the requirement for it to follow the normal decision making process (See point 7.7).

6.4 **Directors and nominated Deputy Directors**

6.4.1 Directors and their nominated Deputy Directors are responsible for:-

a) implementation of this policy, on behalf of the Chief Executive;

b) ensuring that managers and staff co-operate in applying this policy;

c) when required making the over-arching decision as to whether an incident constitutes a serious or moderate harm incident requiring in-depth investigation, in the absence of the Chief Executive or Executive Director of Nursing and Governance;

d) nominating managers to investigate Serious Incidents;

e) chairing Serious Incident Review Meetings.

6.5 **The Head of Patient Safety and Risk**

6.6.1 The Head of Patient Safety and Risk is responsible for:-

a) the overall management of this policy;

b) ensuring the processes and procedures are correctly adhered to.

6.6 **The Patient Safety Manager**

6.6.1 The Patient Safety Manager is responsible for:-

a) the day to day management of this policy;

b) ensuring the review of all adverse incident reports and complaints highlighted by the Patient Experience Team to assess whether they are potential Serious or Moderate Harm Incidents;

c) the circulation of potential Serious or Moderate Harm Incidents to the Serious and Moderate Harm Incident Decision Making Group, together with supporting information, to facilitate an informed decision by the Group as to whether an incident constitutes a Serious Incident or Moderate Harm incident as defined in Section 4.

d) the arrangement of a weekly teleconference to present potential Serious or Moderate Harm Incidents to the Serious and Moderate Harm Incident Decision making group for decision;

e) the reporting of Serious Incidents on the STEIS system;

f) producing a 72 hour report for the South West Commissioning Support Unit or Lead Clinical Commissioning Group for each confirmed Serious Incident or as requested as per the format set out in Appendix E;

g) ensuring that the Trust's Communications Team are briefed on each confirmed Serious Incident by means of a briefing email;

h) ensuring that the Duty of Candour is applied to each Serious and Moderate Harm Incident;

i) advising on when a Serious Incident should be managed through a multi-agency approach or where it should be referred to an external lead organisation and liaising with the South West Commissioning Service or Lead Clinical Commissioning Group to facilitate this and be the main liaison for the Trust in these cases;

j) liaison with the South West Commissioning Service or Lead Clinical Commissioning Group (or other Commissioners as required) with regard to the status of confirmed Serious Incidents and managing any feedback on Investigation Outcome reports;

k) providing advice to Investigating Officers;

l) convening and attending Serious Incident Review Meetings;

m) sending a weekly update of the Serious Incident Review Meetings scheduled to the Non-Executive Directors (via the PA & Business Manager to Chairman and Chief Executive) and the South West Commissioning Support Unit or Lead Clinical Commissioning Group(s) ; and

n) maintaining and monitoring the Serious Incident and Moderate Harm Action Plans.

6.7 Serious Incident and Moderate Harm Decision Making Group

6.7.1 This Group will review and confirm Serious and Moderate Harm Incidents on a weekly basis via a teleconference.

6.7.2 The standing members of the Group will be the Patient Safety Manager (or nominated deputy), the Head of Governance (or nominated deputy) and the senior Clinician on call. There will be a minimum of two clinicians on the call.

6.7.3 Members of this group are required to:-

a) be aware of their responsibilities under this and other risk management policies;
b) attend teleconferences relating to the process as required;
c) ensure that they have full knowledge of the incidents being discussed;
d) provide a rationale to the Patient Safety Team for the decision made regarding an incident;
e) consider the requirement for reporting to regulatory bodies, any further immediate actions for instance restriction of practice or highlighting with any specific service line in order to raise issues in a timely fashion;
f) ensure staff are supported appropriately.

6.8 **Head of Departments**

6.8.1 Head of Departments are required to:-

a) be aware of their responsibilities under this and other risk management policies;

b) ensure their staff and professionals who work for, or who provide services to the Trust, are informed of this policy:

c) in accordance with Trust procedures, ensure that any action identified as a result of a Serious Incident is taken;

d) ensure that support is provided to any staff involved in a Serious or Moderate Harm Incident investigation;

e) nominate Investigating Officers, as required and ensure that these Investigating Officers are given sufficient time to undertake the investigation;

f) Quality Assure serious incident reports using the format outline in Appendix F.

6.9 **Line Managers**

6.9.1 Line managers are required to:-

a) be aware of their responsibilities under this and other risk management policies;

b) ensure their staff and professionals who work for, or who provide services to the Trust, are informed of this policy:

c) ensure that support is provided to any staff involved in a Serious or Moderate Harm Incident investigation;

d) nominate Investigating Officers, as required and ensure that these Investigating Officers are given sufficient time to undertake the investigation;

e) act as an Investigating Officer if nominated;

f) facilitate the attendance of their staff as required at Serious Incident Review Meetings through the rearrangement of working patterns.

6.10 **Quality Leads and Investigating Officers**

6.10.1 Quality Leads will act as the senior investigating officer within their operational locality.

6.10.2 Investigating Officers including Quality Leads will be nominated by the relevant Director or Head of Department and are responsible for:-

a) ensuring that Serious Incidents are investigated thoroughly in accordance with the Trust's Guide to Investigations and within 35 working days of the Serious Incident being confirmed or 35 days of a moderate harm incident being confirmed;

b) maintaining an incident investigation log using the proforma supplied as Appendix G.

c) notifying the Patient Safety Manager, as soon as possible, where it is not possible to meet the timescales specified in 6.9.2a of the reason for the delay and likely completion date;

d) instigating contact with families, in line with the being open timescales;

e) providing a 72 hour investigation update report, where required, for the Trust's Directors and Patient Safety Manager;

d) producing a full investigation report using the Trust's Serious Incident (based on the National Patient Safety Agency guidance) or Moderate Harm report template(s) and presenting their investigation report to a Serious Incident Review Meeting;

e) working alongside the Patient Safety Team to finalise the investigation report following the Serious Incident Review Meeting or quality assurance process.

f) ensuring staff receive the necessary support;

g) liaising with all parties involved in the investigation (including patients, patient representatives, external parties for example, the Police, Out of Hours GP Service, and employees), ensuring they are kept up to date on investigation progress;

h) identifying all parties, including staff and their line managers, to be invited to the Serious Incident Review Meeting and notifying the Patient Safety Administrator of who should be invited, at least 3 weeks in advance of the Review Meeting.

6.11 **All Employees**

6.11.1 All employees have a duty to comply with this policy and report adverse incidents and near misses within 24 hours of the incident occurring.

6.11.2 All employees have an obligation to co-operate with any Serious or Moderate Harm Incident investigation.

6.11.3 Employees involved in a Serious Incident will be invited to the Serious Incident Review Meeting and their line manager will be notified to help facilitate attendance and provide support

6.14 Employees involved in a Serious or Moderate Harm Incident have a responsibility to request support if they feel it's required.

6.12 **Standing Members of Review Meetings**

6.12.1 The Head of Governance and the Head of Patient Safety and Risk will be standing alternate members of each Serious Incident Review Meeting. The Patient Experience Manager, or nominated deputy, will have a standing invitation to any Serious Incident Review that originated from a Patient Experience contact.

6.12.2 A standing invitation to all Serious Incident Review meetings will be extended to the Communications team, the Training team and the Clinical team. Where there is a non-clinical chair of the review meeting the Clinical team **must** provide a representative to attend.

6.12.2 A standing invitation to all Serious Incident Review Meetings is also extended to the Trust Chairperson, the Non-Executive Directors and members of the relevant Clinical Commissioning Groups and the South West Commissioning Service. A weekly update of the scheduled Serious Incident Review meetings is sent to each of these groups by the Patient Safety Team.

7 Serious and Moderate Harm Incident Reporting Protocol

7.1 All adverse incidents must be recorded and reported on identification using the Trust's adverse incident procedure. In addition, any incident which is considered to be a potential Serious Incident or Never Event as defined in Section 4 should be reported to the Silver On-Call Officer at the time of the incident who should take the decision as to whether the On-Call Head of Communications should be notified. Consideration should also be given to notifying the Safeguarding Manager in their role as Designated Officer. It is the Silver On-Call Officer's responsibility to notify the Patient Safety Manager as soon as reasonably practicable following the incident occurring in order that an investigation can commence promptly.

7.2 The Patient Safety Manager will notify the Health, Safety and Security Manager should the incident be RIDDOR reportable and the Information Governance Team for Information Governance Serious Incidents Requiring Investigation (IG SIRI) (Appendix H).

7.3 Staff reporting the Serious Incident must ensure that any material evidence relating to the incident is preserved where at all possible. This may include such items as vehicles, equipment, defibrillator pads, memory cards, etc. This should then be made available to the Investigating Officer once appointed.

7.4 The Operations Managers, Operations Officers, Quality Leads or Urgent Care Service Line equivalents when reviewing incident reports should highlight any incident with the potential to meet the Serious or Moderate Harm Incident criteria to the Patient Safety team for review.

7.5 Once the Patient Safety Manager is made aware of a potential Serious or Moderate Harm Incident they will consider the details of the incident, together with any supporting evidence [such as the patient clinical record; call audit, sequence of events, IG SIRI checklist (Appendix I)] prior to circulation.

7.6 If the Patient Safety Manager considers the incident to meet the Serious or Moderate Harm Incident criteria they will circulate the details of the incident with associated evidence to the Serious and Moderate Harm Decision Making Group who will make the decision over whether the incident should be confirmed as a Serious Incident.

7.7 Incidents that clearly meet the Serious Incident criteria (Barn Door incidents) will be raised by the Patient Safety Manager immediately to the Executive Director of Nursing and Governance (or in their absence Chief Executive or Executive Medical Director). These cases will be assessed and either confirmed immediately or referred to the Serious and Moderate Harm Decision Making Group.

7.8 Incidents that are recognised as being a Never Event, against the Never Events list available on the NHS England website, will be raised by the Patient Safety Manager immediately to the Executive Director of Nursing and Governance (or in their absence Chief Executive or Executive Medical Director). These cases will be assessed and confirmed immediately

7.9 The Patient Safety Manager will arrange weekly teleconference on a predetermined day and time with the Serious and Moderate Harm Decision Making Group in order to discuss and gain a decision on any outstanding potential Serious or Moderate Harm Incidents.

7.10 If the decision is that a potential Serious Incident does not meet the Serious Incident criteria, the Patient Safety Manager will ask the Serious and Moderate Harm Decision Making Group to consider the case as a Moderate Harm incident.

7.11 If no agreement is reached between the decision making group the Patient Safety Manager will forward the case to the Executive Director of Nursing and Governance for a final decision.

7.12 In the absence of any of the Executive Director of Nursing and Governance , the Chief Executive, or Executive Medical Director will be involved in the decision making process.

7.13 Once the incident is confirmed as a Serious or Moderate Harm Incident or Never Event, an investigating officer will be appointed by the relevant Director or Head of Department.

7.14 The Patient Safety Manager and Executive Director of Nursing and Governance will meet on a monthly basis to moderate the decision making process and review the Serious Incident Action Plan for assurance. This will be reported on to the Trust Board of Directors and Trust Chairperson.

8. Confirmed Serious Incidents (and Never Events)

8.1 All Serious Incidents and Never Events should be reported to the Trust's South West Commissioning Support Unit or Lead Clinical Commissioning Group, as appropriate (ref 999, UCS, 111 etc) via the Strategic Executive Information System (STEIS) within 2 working days of confirmation and uploaded to the National Reporting Learning System (NRLS). For clarity Never Events should be highlighted as such on both STEIS and NRLS. For Information Governance SIRIS level 2 or above, the expectation is details of initial findings should be inputted onto the Information Governance Incident Reporting Tool within 24 hours of becoming aware of the incident in addition to reporting on STEIS.

8.2 The Patient Safety Manager will assess the level of the Serious Incident when it is confirmed and entered onto the STEIS system which will be confirmed by the South West Commissioning Support Unit or Lead Clinical Commissioning Group in order to determine the type of investigation required – Comprehensive or concise. All Never Events will be investigated with a comprehensive Root Cause Analysis. Appendix I provides a guide for grading information governance serious incidents requiring investigation (IG SIRI).

8.3 It should be noted that failure to report a Never Event is likely to constitute a breach of CQC requirements and the NHS Standard contract. Where there is evidence to prove that an organisation had opportunities to report a Never Event Commissioners could consider using the full range of powers as afford within the NHS Standard Contract.

8.4 Where a Never Event has occurred learning is the main requirement as a result of its confirmation. That said the NHS considers that it will not pay for care that is substandard and so will look to recover costs and so Commissioners will seek to withhold or recover payment for the episode of the cost of the care and any subsequent costs. Further information relating to Never Events can be found in on the Trust intranet.

8.5 In addition, a brief report will be sent to the relevant group by the Patient Safety Manager within 72 hours of confirmation of the Serious Incident. This will include:

- Date and location of incident and STEIS identification number;
- Initials, gender and date of birth of patient (if known);
- Incident type; e.g. ambulance delay / never event;
- Brief details leading up to the incident to include care and treatment;
- Immediate actions taken (including actions to mitigate any further risk);
- Chronology of contacts.

8.6 Media relations will be the responsibility of the Head of Communications and Engagement and, where it is deemed that the public should be made aware of a Serious Incident, this will also be the responsibility of the Head of Communications.

8.7 The Head of Communications will alert the Director of Communications and Corporate Services or on call communications lead at the NHS England Local Area Team to the media handling strategy. The NHS England Local Area Team will be responsible for briefing the Department of Health Media Centre, as appropriate.

8.8 For incidents for which multiple enquiries are likely to be received, the Trust will set up an incident hotline ensuring that:-

- extra phone lines are available;
- phone lines are appropriately staffed;
- the staff are appropriately briefed to manage incoming calls;
- there is sufficient capacity to manage calls;
- records are made of all calls and advice provided.

8.9 The nominated Investigating Officer will be sent all information pertinent to the incident, including relevant deadlines, by the Patient Safety Team.

8.10 A weekly meeting to discuss confirmed Serious Incidents and reporting requirements will be held in order to determine notification to regulators and other agencies such as Monitor and the CQC. This is outlined in more detail in section 16.

8.11 The nominated Investigating Officer should ensure that their investigation is carried out in line with the Trust's Investigation Guide. The draft investigation report should be completed within 35 working days of confirmation of the Serious Incident.

8.12 The nominated Investigating Officer is required, where appropriate, to make verbal contact with the patient or their next of kin within 10 working days of the incident being confirmed as Moderate Harm.

8.13 Where verbal contact cannot be made within 10 working days due to lack of contact information, such as a telephone number, the Patient Safety team will send an initial letter to be sent to the patient or next of kin if appropriate outlining the details of the incident and Trust's Moderate Harm investigation process.

8.14 A method of feedback with the outcome of the investigation should be agreed between those affected and the Investigating Officer.

8.15 Records of any contact with staff, patients, relatives, the public or the media should be documented and maintained securely by the Investigating Officer.

8.16 The Investigating Officer will present their draft report to the relevant Head of Department and Patient Safety Manager prior to the Serious Incident Review Meeting in order that the Head of Department has oversight of the investigation and recommendations and can provide Quality Assurance. Appendix F provides a format for Quality Assurance to guide the Head of Departments.

8.17 The Investigating Officer will present their report, findings and recommendations to a Serious Incident Review Meeting. The Serious Incident Review Meeting will generate a final Investigation Outcome Report and Action Plan which will be reviewed by the Trust's Directors' Group and monitored by Patient Safety Team. Any issues will be escalated to the Executive Director of Nursing and Governance. Any changes made to the investigation report during the Review Meeting will be recorded along with the rationale for the change. This record will be kept in the relevant folder with the amended report.

8.18 The Trust will provide the South West Commissioning Support Unit or Lead Clinical Commissioning Group as appropriate with a copy of the final investigation report and action plan once it has been agreed by the Chair of the Serious Incident Review Meeting and will update STEIS accordingly.

8.19 The Patient Safety Manager will provide reports on Serious Incidents confirmed and investigated to Directors Group, The Trust Board of Directors and the Quality Committee.

9 Moderate Harm Process

9.1 When an incident has been confirmed as Moderate Harm by the nominated Trust Directors, the appropriate Head of Function will be asked to nominate a dedicated Investigating Officer. The Investigating Officer will be issued, by the Patient Safety team, with the Moderate Harm investigation template along with all supporting documents to assist in their investigation.

9.2 The Investigating Officer is required, where appropriate, to make verbal contact with the patient or their next of kin within 10 working days of the incident being confirmed as Moderate Harm.

9.3 Where verbal contact cannot be made within 10 working days due to lack of contact information, such as a telephone number, the Patient Safety team will send an initial letter to be sent to the patient or next of kin if appropriate outlining the details of the incident and Trust's Moderate Harm investigation process.

9.4 A method of feedback with the outcome of the investigation should be agreed between those affected and the Investigating Officer.

9.5 The Investigating Officer's timeframe for completion of the investigation report is 25 working days. The report must be sent on the Moderate Harm template to the Patient Safety team for review within the agreed timeframe.

9.6 A quality assurance process will be managed by the Patient Safety Manager.

9.7 In certain circumstances the patient or next of kin may request that no further contact is made and feedback is not required from the Trust. In such cases the investigation will be completed in the standard way without any further contact being made. A note will be added to the record for this incident.

9.8 The investigation must be closed within 35 working days of the date that the incident has been confirmed as being Moderate Harm.

9.9 Following completion of the investigation, it is the Investigating Officer's responsibility to follow up recommendations made within their report and to ensure these are completed in a timely manner. These actions will be monitored on the Moderate Harm action plan by the Patient Safety team.

9.10 All documentation relating to the investigation will be held centrally by the Patient Safety team. The Investigating Officer is responsible for providing the Patient Safety team with all information relevant to the investigation.

9.11 Investigations conducted through the Moderate Harm process will be included within the Trust's Patient Experience report provided to the Quality Committee.

9.12 Further detail surrounding the Moderate Harm process can be found in Appendix B.

10 Duty of Candour

10.1 The Trust has a statutory obligation to be open in cases of suspected or actual patient safety incidents that are deemed moderate or serious in nature. This is set out in the 2015/16 NHS Standard Contract Service Conditions and by the statutory legislation.

10.2 When 'being open' the Trust should acknowledge the incident occurred, apologise to the patient or next of kin, and explain why the incident occurred and what actions will be put in place to tray and prevent a reoccurrence.

10.3 The statutory Duty of Candour requires that the Trust makes contact with the patients or their next of kin within at most 10 working days of identification of a Serious or Moderate Harm patient safety incident on a locally reportable system. Where individuals cannot be contacted/traced, the Trust will maintain a comprehensive

record of all attempts to make contact. These will be reviewed with South West Commissioning Support Unit Quality team at monthly meetings. Where sufficient effort has been made but contact has not been achieved, this will not constitute a breach (in line with guidance within the Duty of Candour Statutory Instrument).

10.4 The initial notification must be verbal (face to face where possible) unless the patient cannot be contacted in person or declines notification. The verbal notification must be accompanied by an offer of written notification.

10.5 Any incident investigation report must be shared within 10 working days of being signed off as complete by the Trust and Lead Commissioner.

10.6 The Patient Safety Officer will record and monitor the Trust's compliance with its Duty of Candour process for management of Serious and Moderate Harm patient safety incidents, including open communication with the affected individual(s) or their next of kin. A risk assessment on making contact will be undertaken by the Trust for any incident where the patient or their next of kin may be considered 'vulnerable' (whether this is due to their general psychological or physiological state; or due to the circumstances surrounding or following the incident), .

10.7 Breaches in the contractual Duty of Candour may result in a number of actions being taken by the Commissioners as set out within the NHS standard contract.

10.8 Further detail surrounding the Duty of Candour procedure can be found in Appendix C.

11 Investigations

11.1 The relevant Director or Head of Department is responsible for identifying and nominating a suitably experienced Investigating Officer who, wherever practicable, should be external to the area or function being investigated. In most cases the Investigating Officer will be the Quality Lead or Quality Improvement Manager.

11.2 Investigations should be conducted and reported in line with the Trust's Investigation Guide and will follow the principles of Root Cause Analysis.

11.3 The Investigating Officer should declare whether there may be potential for a conflict of interest. Such cases would include the Investigating Officer being related to a person involved in the incident. Other examples are set out in the Trust's Conflict of Interest Policy.

11.4 The Investigating Officer will be responsible for the 'being open' contact with the patient or next of kin as outlined section 10 and Appendix C.

11.5 Terms of Reference and Investigation Scope

11.5.1 The scope of the investigation will be set by the Executive Director of Nursing and Governance and the Patient Safety Manager and will be confirmed to the Investigating Officer.

11.5.2 The terms of reference for the Investigating Officer and Review Meeting may be specified in writing but will always include the requirement to:-

a) To establish the sequence of events leading up to the incident or to map the control system in place designed to prevent the incident occurrence;

b) To investigate 'what' happened against the Trust's policies / procedures / standards and guidelines;

c) Where significant gaps are identified between what happened and what should happen that:

- Are considered as having a causal link to the incident
- Pose a significant threat to safety but had a negative impact in this case

To find out how and why the gaps occurred including identifying any gaps in the policies and procedures;

d) To clarify for each 'gap' the most important significant factors (root causes);

e) To develop recommendations to address the root causes that are:
- Specific
- Measurable
- Actionable
- Realistic
- Timely;

f) To provide a report that sets out clearly:
- What happened
- Where standards were delivered
- Where standards lapsed
- Contributory factors analysis of each lapse (including root causes)
- Recommendations.

11.6 The investigation report should be thorough, impartial and the findings based on the available evidence. It is important to remember that such investigations may be

disclosable in the case of litigation, may be requested by the patient or their family or under Freedom of Information Act 2000.

11.7 The investigation report should therefore be written in plain English, avoid jargon and with the requirements of the various potential audiences in mind. All reports should contain anonymised information. The report should contain conclusion based on evidence and fact. Any opinion within the report should be stated as that, for instance.

11.8 The content of any reports released to Commissioners including any appendices relating to Serious or Moderate Harm Incidents should not contain the names of practitioners or patients or information which could lead to their identification.

11.9 The required content of an investigation report is at Appendix J.

11.10 Draft Serious Incident investigations should be completed within 35 working days of the incident being confirmed as a Serious Incident. Serious Incident investigations should be quality assured by the Head of Department prior to the investigation being provided to the Patient Safety Team using the template in Appendix F. The investigation should be provided to the Patient Safety Team for review 10 working days prior to the date of the Serious Incident Review Meeting. The Patient Safety Manager will be responsible for the final quality assurance of the report.

11.11 Only in exceptional circumstances, and with the permission of the Patient Safety Manager, will an extension be appropriate. Applications for further extensions will be considered by the Executive Director of Nursing (or in their absence, the Chief Executive or Executive Medical Director). If agreed the Patient Safety Manager will apply to South West Commissioning Support Unit or the Lead Clinical Commissioning Group for an extension, there is however no guarantee that an extension will be granted.

11.12 Independent Investigations

11.12.1 Where a Serious Incident or Never Event requires an independent investigation, this will be commissioned by the South West Commissioning Support Unit, Lead Clinical Commissioning Group and/or the NHS England Local Area Team and will follow the structure set out within the NHS England's Serious Incident framework 2015 on Independent Investigations. Following initial reporting within 2 working days, independent investigators should be commissioned to complete an investigation within 6 months.

11.12.2 Where an independent investigation is confirmed as being required Lead Clinical Commissioning group will be approached for assistance in nominating an Independent Investigator.

11.13 External Serious Incidents

11.13.1 On occasion other agencies may report an incident on STEIS that may also involve our organisation. Alternately the Trust may report an incident on STEIS that involves external agencies and / or is referred to NHS England or the CCG for co-ordination. When this occurs the Patient Safety team will assess the level of input that is being requested by the outside agency and if a full investigation is required by SWASFT they will request a meeting with the reporting agency and all other agencies involved. If the investigation is being led by the Trust the Patient Safety team will co-ordinate a multi-agency meeting. This is further highlighted in section 16.

11.13.2 The initial meeting between agencies will look to agree the investigation scope, timescales, Terms of Reference, Duty of Candour and areas such as family liaison, setting out responsibilities for each organisation. This assists with overall clarity of what is required and by whom and is in line with the Memorandum of Agreement (SD&T, Kernow, NEW Devon CCG and NHS England South 2015.

11.13.4 Any external investigation being led by NHS England need to be referred for notification to Monitor and CQC, as outlined in section 16.

11.13.5 An internal review meeting will be held in order to assure the Trusts internal report in addition the Executive Director of Nursing and Governance should sign off the final internal report prior to sharing it with external agencies. Any recommendations for the Trust will be placed on the serious incident action plan in order that the Trust can proactively implement improvements and learning.

11.13.6 External Serious Incident will be reported to the Trust Board of Directors and Quality Committee as per internal Serious Incidents.

12 De-escalating serious incidents

12.1 The Investigating Officer should highlight any incident that no longer meets the Serious Incident Criteria through investigation to the Patient Safety Manager.

12.2 The Patient Safety Manager will review the evidence that has been presented and will make a decision on whether to continue with a full Serious Incident or start a de-escalation process.

12.3 If an incident requires de-escalation the Patient Safety Manager will present the case for de-escalation to the Executive Director of Nursing and Governance, or in their absence the Chief Executive or Executive Medical Director, for final decision to deescalate and what level of investigation is required (Moderate Harm or Adverse incident).

12.4 The Patient Safety Manager will notify South West Commissioning Support Unit or Lead Clinical Commissioning Group and will request that the incident be considered for downgrade supplying a rationale. The STEIS record for the incident will be updated accordingly.

12.5 The Investigating Officer will continue with the investigation and complete the appropriate template, as advised by the Patient Safety Manager.

12.6 The completed investigation will be forwarded to South West Commissioning Unit or the Lead Clinical Commissioning Group for consideration and removal from STEIS.

12.7 The Investigating Officer will maintain communication with the patient or next of kin updating them as to the investigations progression and will feedback, as per the Duty of Candour, when the report is completed.

12.8 The Investigating Officer will feedback appropriately to all staff involved in the incident.

13 Serious Incident (And Never Event) Review Meeting

13.1 The findings of the investigation will be formally presented by the Investigating Officer to a Serious Incident Review Meeting chaired by an Executive Director or Deputy Director and consisting of relevant Trust managers including a member of the Governance team and the Patient Safety Manager (or a nominated deputy). In the case of clinical incidents, where the Review Meeting chair is not from the Medical Directorate, a Clinical Development Manager or other nominated clinical manager from the Medical Directorate must also attend. Other standing members will be invited as highlighted in section 6.12

13.2 All staff involved in the incident will be invited to attend in order that they can contribute towards the learning of lessons and development of recommendations. Their line manager will also be notified by the Patient Safety team in order to help facilitate their attendance through the rearrangement of working patterns.

13.3 All staff invited to the Serious Incident Review Meeting will be provided with an electronic copy of the Investigation Report prior to the Review Meeting.

13.4 Depending on the implications of the investigation's outcome the Executive Director of Nursing and Governance (or Deputy Chief Executive Officer/Executive Director of Finance in the case of regulatory bodies) may authorise notification of the outcome to other bodies, as set out in paragraph 15.

13.5 Staff and other individuals involved in the investigation of a Serious Incident will be informed of the outcome of the investigation and its associated recommendations by the Investigating Officer. The Patient Safety Manager will ensure that a copy of the Investigation Outcome Report is also issued to those concerned.

13.6 In accordance with the Duty of Candour where a patient or relatives are involved, they will be advised of the outcome of the investigation by the Investigating Officer and will be given the opportunity to discuss the findings. In certain circumstances the chair of the Serious Incident review meeting will be involved with this contact. This will be discussed and agreed at the meeting.

13.7 After the Serious Incident Review Meeting has taken place a draft copy of the Investigation Outcome Report and Action Plan will be circulated to attendees at the Review Meeting; any staff members to whom an action has been assigned; the Standing Members of the Review Meeting; and the relevant Directors that have been assigned actions, for comment.

13.8 A draft copy of the Investigation Outcome Report and Action Plan is also sent to the South West Commissioning Support Unit or the Lead Clinical Commissioning Group by the Patient Safety Manager.

13.9 Following a 5 day circulation for comment period to the meeting attendees and relevant Directors, a copy of the final report will be sent to the South West Commissioning Support Unit or Lead Clinical Commissioning Group or confirmation sent that the report has been signed off unchanged since the version previously sent.

13.10 A summary of the Serious Incidents and their outcomes will be provided to the Trust Board of Directors. at every board meeting.

14 Recommendations from Serious Incident Reviews

14.1 The recommended actions determined in the investigation and agreed within the review meeting will be added to the Serious Incident Action plan. The Lead Director will be responsible for nominating a lead for each action and a realistic timescale for delivery. The Outcome Report and recommended actions will be circulated to all Directors for comment and agreement for a period of 5 days. After this period the actions will be finalised and entered on to the Trust Serious Incident action plan.

14.2 Actions resulting from External Serious Incident investigations will also be added to the action plan in order for them to be actioned and monitored.

14.3 The Serious Incident Action Plan is reported on and monitored by the Patient Safety Manager. The Patient Safety Manager will meet with the Lead Directors in order to discuss progress against the actions listed on the Serious Incident Action Plan.

14.4 The Patient Safety Manager is required to report on progress against the actions listed on the Serious Incident Action Plan to the South West Commissioning Support Unit and Lead Commissioner on a monthly basis

14.5 The Patient Safety Manager will meet with the Executive Director of Nursing and Governance on a monthly basis to review the full action plan and highlight any pertinent issues or emerging trends for escalation.

14.6 The Directors Group will receive a bi-monthly up-date on progress against the outstanding actions on the Serious Incident Action Plan.

15 Support For Staff

15.1 A key principle of this policy, rather than apportioning blame, is to ensure that learning takes place. However it is recognised that some staff may find the process difficult and line managers should therefore ensure that they are appropriately supported.

15.2 The Investigating Officer is responsible with the Line Manager of the staff involved for offering and nominating an appropriate Welfare Officer.

15.3 During the investigation the Investigating Officer, together with the Line Manager and Welfare Officer, is responsible for maintaining a contact log for staff involved in the incident.

15.4 Consideration should be given by the Investigating Officer, in conjunction with the Line Manager, to instigating support for staff involved in the incident such as TRiM, Signposting to the Trust's Staying Well service or Occupational Health.

15.5 In addition, staff have the right to be accompanied during the process by a Trade Union representative, friend or other representative, not acting in a legal capacity.

16 Reporting to Other Bodies

16.1 **South West Commissioning Support Unit, Lead Clinical Commissioning Group and NHS England Local Area Team**

16.1.1 Once an incident is confirmed as a Serious Incident, South West Commissioning Support Unit or the Lead Clinical Commissioning Group will be notified by the Patient Safety Manager (or in their absence by the Head of Patient Safety and Risk

via the STEIS system within 2 working days of the Serious Incident being confirmed. In addition, the Trust will take into account the requirements of any guidance published by its' Lead Clinical Commissioning Group regarding the reporting of Serious Incidents.

16.1.2 If an incident warrants reporting out of hours, this should be reported to the Clinical Commissioning Group and NHS England's Local Area Team duty Communications leads by the Head of Communications. Such incidents include:-

- incidents which necessitate activation of the NHS Trust or Primary Care Trust Major Incident Plan, where the NHS England Local Area Team needs to take action.
- incidents which will give rise to significant media interest or will be of significance to other agencies such as the police or other external agencies;
- incidents which will be of significant public concern.

16.1.3 In addition to notifying the Lead Clinical Commissioning Group, the Patient Safety Manager is responsible for advising the Clinical Commissioning Group responsible for the area that the incident occurred in, via STEIS.

16.1.4 The STEIS report must be updated by the Patient Safety Manager once the Trust's Investigation Report has been agreed.

16.2 **Care Quality Commission and Monitor**

16.2.1 Any Serious Incidents that the Trust are involved in which have the potential to attract media interest and or should be considered for reporting to the regulatory bodies are reviewed on a weekly basis by a senior Governance Manager, Trust Business Planning Manager and members from the Patient Safety, Patient Experience, Communications and Claims teams. The Group will meet in order to establish if the Care Quality Commission and Monitor should be provided with a full report. The final decision regarding reporting to those bodies should be made by the Head of Governance, or their designated representative. However, each 72 hour report for an SI is provided to the Trust's CQC Relationship Manager, who can then also request additional information.

16.3 **Multi-agency Serious Incidents**

16.3.1 Where more than one organisation is involved in a Serious Incident, the organisation which has identified the incident will make the initial report to the relevant Lead Clinical Commissioning Group. A meeting should then be arranged

to include all key stakeholders. A lead manager will be identified to manage, lead and coordinate the Serious Incident procedure and investigation. A Memorandum of Agreement is in place within SD&T, Kernow, NEW Devon and NHS England South in order to improve joint working.

16.3.2 Where it is identified that the Serious Incident has an impact on other organisations the Patient Safety Manager will implement a notification plan in liaison with the Head of Patient Safety and Risk.

16.3.3 Potential stakeholders for notification other than those outlined in paragraphs 16.1 and 16.2 may include:-

- Health and Safety Executive;
- Fire and Rescue Service
- Department of Health;
- Medicines and Healthcare Regulatory Agency;
- Environmental Agency;
- Police;
- Social Services;
- NHS Litigation Authority;
- Coroner;
- NHS Protect;
- Information Commissioner;
- Public Health England;
- Trust legal advisors;
- Staff representatives.

This list is not exhaustive.

16.4 If a Serious Incident occurs involving unexpected death or serious harm which requires investigation by the police or Health and Safety Executive the Memorandum of Understanding: Investigating Patient Safety Incidents Including Unexpected Death or Serious Untoward Harm (Appendix D) should be followed.

17 Monitoring

17.1 The effectiveness of this policy will be monitored by the Trust Board of Directors who will receive a Serious Incident report at each Board meeting.

17.2 Action plans arising from Serious Incident Review Meetings will be monitored by the Trust's Directors Group.

17.3 A bi-monthly summary of Serious Incidents and the learnings from those investigations will be provided to the Lead Clinical Commissioning Group, the Trust's Directors' Group and the Quality Committee as part of the Patient Safety Report.

17.5 The Patient Safety Manager will carry out regular reviews of the changes made as a consequence of learning from Serious Incidents to ensure that the changes are embedded sustained and effective.

17.6 The Patient Safety Manager will attend a monthly review with the Executive Director of Nursing and Governance in order to moderate Serious and Moderate harm decisions and in addition the Serious Incident action plan.

17.6 An annual summary report on the number of Serious Incidents reported including the identification of trends and themes of incidents will be provided to the Quality Committee and shared with the Trust's Lead Clinical Commissioning Group.

17.7 The Patient Safety Manager will have regular meetings with South West Commissioning Support Unit in order to monitor action plans and reports produced by the Trust for assurance.

18 References

18.1 The following references informed the development of this policy:-

- Serious Incident Framework, NHS England, March 2015.
- South West Commissioning Support, Serious Incidents Requiring Investigation, Supporting Guidance for the Management of Serious Incidents January 2014.
- Memorandum of Understanding: Investigating patient safety incidents involving unexpected death or serious untoward harm, Department of Health, 2006
- National Patient Safety Agency Guidance on Root Cause Analysis Investigation Report Template Guidance.
- Checklist Guidance for Reporting, Managing and Investigating Information Governance Serious Incidents Requiring Investigation, Health and Social Care Information Centre, June 2013.
- Statutory Duty of Candour, Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.
- National Standard Contract 2016/17.
- Memorandum of Agreement for Multi-Agency Serious Incidents Requiring Investigation (SD&T, Kernow, NEW Devon and NHS England 2015)
- Revised Never Events Policy and Framework, NHS England, March 2015

19 Associated Documentation

19.1 This guidance links to:-

- Governance Strategy
- Investigation Guide
- Incident Reporting Policy
- Duty of Candour Procedure
- Safeguarding Policy
- Capability Policy including Restriction of Practice
- Information Governance policies and associated guidelines
- Major Incident Plan
- Claims and Inquests Policy
- Complaints Policy
- Conflict of Interest Policy
- Employment Policies
- Trust Health and Safety Policies

APPENDIX A

EXAMPLES OF SERIOUS INCIDENTS (SIs)

The 2015 national Serious Incident Framework does not include examples of serious incidents, therefore the Trust is using the following examples taken from the previous National Framework for Reporting and Learning From Serious Incidents Requiring Investigation as a guide. It is not an exhaustive list and is intended as a guide only. However, in deciding whether the incident is a Serious Incident the Trust should consider whether it meets the definition set out within Section 4 of this policy and the possible impact the incident could have, including what lessons may be learnt from it. If the initial judgement is that the issue is/was unavoidable or had no adverse impact, it is important that public perception is considered. If the incident could be damaging to an organisation or the wider NHS, the incident should be reported as a SI.

Supplementary terms

1. **Incident** – an event or circumstance which could have resulted, or did result in unnecessary damage, loss or harm such as physical or mental injury to a patient, staff, visitors or members of the public.
2. **NHS-funded services and care** – healthcare that is partially or fully funded by the NHS, regardless of the location.
3. **Unexpected death** – where natural causes are not suspected. Local organisations should investigate these to determine if the incident contributed to the unexpected death.
4. **Permanent harm** – directly related to the incident and not related to the natural course of the patient's illness or underlying conditions, defined as permanent lessening of bodily functions; including sensory, motor, physiological or intellectual.
5. **Prolonged pain and/or prolonged psychological harm** – pain or harm that a service user has experienced, or is likely to experience, for a continuous period of 28 days.
6. **Severe harm** – a patient safety incident that appears to have resulted in permanent harm to one or more persons receiving NHS-funded care.
7. **Major surgery** – a surgical operation within or upon the contents of the abdominal or pelvic, cranial or thoracic cavities or a procedure which, given the locality, condition of patient, level of difficulty, or length of time to perform, constitutes a hazard to life or function of an organ, or tissue (if an extensive orthopaedic procedure is involved, the surgery is considered 'major').
8. **Abuse** – a violation of an individual's human and civil rights by any other person or persons. Abuse may consist of single or repeated acts. It may be physical, verbal or psychological, it may be an act of neglect or an omission to act, or it may occur

when a vulnerable person is persuaded to enter into a financial or sexual transaction to which he or she has not consented, or cannot consent.

Examples of Categories and Incidents that Should be Reported as Serious Incidents

Serious incident category ***(in alphabetical order)***	**Further Description**
ABUSE OF ADULTS	▪ The abuse of an adult described in "*No Secrets*". This includes:- – death or injury to a vulnerable adult where abuse or neglect is suspected to be a factor – where a vulnerable adult has suffered harm as a result of staff failing to follow agreed procedures or acceptable practice – when a vulnerable adult has suffered significant injuries suspected to be as a result of abuse
CHILDREN	▪ Significant harm to a child where reported under the local child protection procedures. This could be defined as:- – a child death where abuse or neglect is suspected to be a factor in the death – when a child has suffered significant injuries suspected to be as a result of child abuse – where a child has suffered further harm as a result of a health care worker failing to follow procedures – unexplained child death in a health care setting – unexplained death of more than one sibling – when a serious case review is to be undertaken – children and adults with complex health needs failing to obtain their assessed and agreed packages of health care, thus putting their health at serious risk ▪ Multiple attendances at A&E for a single child or more than one sibling; – death of child on child protection register
EMERGENCY PLAN INVOKED	▪ Adverse incident that would invoke an emergency plan (affecting business continuity including multiple ward closure due to infection, serious damage to occupied NHS property through fire, flood or criminal damage, IT failure (for terrorist activity – see

Serious incident category *(in alphabetical order)*	Further Description
	separate section). ▪ Wilful damage to property, destruction and vandalism.
HEALTH PROTECTION	Major outbreaks, serious incidents of communicable disease or exposure to environmental hazards caused by healthcare failures or other NHS system failures that have put patients/staff at harm/risk of harm or restrict service delivery e.g. - outbreaks of infection that involve presumed transmission **within** healthcare settings (acute, community) e.g. norovirus, Clostridium difficile, Panton-valentine leukociden (PVL) positive, Methicillin – resistant staphylococcus aureus (MRSA) etc - case of blood borne virus (hepatitis B, C, HIV), TB etc. infection in a healthcare worker that necessitates consideration of a look-back exercise - case of infection in a patient to whom others have been exposed that necessitates consideration of a look-back exercise - failed vaccination cold chain - a confirmed death of a patient due to hospital acquired infection including MRSA and C. difficile - exposure to chemical agents or radiation caused by failures in healthcare settings - an outbreak/health protection incident that is poorly managed**,** resulting in harm
INFORMATION GOVERNANCE	▪ Major breaches of confidentiality such as the loss or theft of personal identifiable records or information (including missing notes). ▪ An incident involving the actual or potential loss of personal information that could lead to identity fraud or have other significant impact on individuals should be considered as serious. See appendix I for further information
INFORMATION TECHNOLOGY	▪ Systems failure leading to serious outcomes. ▪ Data loss resulting in severe breach of confidentiality.
MAJOR	▪ Any circumstance that necessitates the activation of an NHS

Serious incident category *(in alphabetical order)*	Further Description
INCIDENTS	Trust, Primary Care Trust or wider community Emergency Plan.
MEDIA ISSUES	▪ Matters likely to attract interest from local, regional or national newspapers, TV or radio. ▪ All incidents reported to or involving the police that are considered serious or may have adverse media interest. ▪ Any Health and Safety Improvement Notices or convictions being served upon an NHS or Primary Care Trust. ▪ Matters involving any patients likely to attract media interest. ▪ Any other sudden unexpected incidents: including apparently trivial incidents that lead to something more serious including those which could attract media attention. ▪ Serious fraud or security-related media matters (to be reported to NHS SMS).
MEDICAL DEVICES	▪ Any serious harm to staff or patients involving medical equipment whether due to human error or due to equipment found to be or suspected of being faulty or to have failed e.g. hoist collapsing, defibrillator failing. ▪ Any medical device-related incident that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of device users (including patients) or other persons.
MEDICINES AND SERIOUS ADVERSE DRUG REACTIONS	▪ Suspected or actual serious side effects or adverse drug reactions from a medicine, be it:- – prescription medicines – herbal remedies – over-the-counter (OTC) medicines – counterfeit medicines causing harm or potential harm
MEDICO-LEGAL INCIDENTS/LITIGATION	▪ Suspicion of large scale theft or any incident that might give rise to serious criminal charges. ▪ Potential legal claims against the hospital regarding a serious incident. ▪ Potential legal claims against the hospital or Department of Health that may affect national policy.

Serious incident category *(in alphabetical order)*	Further Description
	▪ Impending court hearing or out of court settlement in cases of large scale litigation, including negligence claims (as defined by the NHS Litigation Authority [NHSLA], large scale claims are considered to be those over £250,000).
MENTAL HEALTH, SUBSTANCE MISUSE AND INCIDENTS INVOLVING LEARNING DISIBILITIES **MENTAL HEALTH , SUBSTANCE MISUSE AND LEARNING DISABILITIES (staff related**	▪ A serious offence including homicide committed by an individual in receipt of mental health and/or learning disability services. ▪ The criteria set out below will at times duplicate the criteria already stated but they are included to remind those delivering mental health services of the need to report them:- – all deaths of persons who are subject to the Mental Health Act 1983 or equivalent legal restriction who has or is receiving care and treatment from the mental health services:- - any serious criminal acts involving patients - an episode of restraint that does not comply with national or local trust policy ▪ A serious offence involves an assault of staff by patients, causing: - serious harm or injury to staff or - places life of staff members in jeopardy - death or serious injury to staff occurs - a member of staff is a victim of abuse - a security issue
MORTALITY/ MORBIDITY/ CARE INCIDENTS	▪ Clusters of unexpected or unexplained deaths. ▪ Where the death results in adverse comments from a coroner. ▪ Maternity: maternal deaths, neonatal deaths and unexpected stillbirths. ▪ The suicide of any person currently in receipt of NHS services on or off NHS premises, or who has been discharged within the last twelve months. ▪ Death or injury where foul play is suspected. ▪ Situations when a patient requires additional intervention(s) as a result of failures in the assessment or diagnosis process. ▪ The accidental death of, or serious harm to, a patient, a member of staff, or visitor on NHS or primary care premises, or involving

Serious incident category *(in alphabetical order)*	Further Description
	NHS or primary care staff or equipment. ▪ Out of county critical care transfers or any other transfer that could have resulted in a serious untoward incident. ▪ Abuse that has been perpetrated within the remit of the organisation; this may be abuse by a member of staff, visitor or member of the public.
NEVER EVENTS	▪ Never Events are serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented.
PREMISES/ EQUIPMENT INCIDENTS	▪ Serious damage that occurs on the premises of NHS, primary care, or independent sector premises providing NHS work, serious damage to property belonging to NHS or primary care, or any incident that results in serious injury to any individual or serious disruption to services (such as evacuation of patients due to fire). ▪ Failure of equipment so serious as to endanger life, whether or not injury results. ▪ Suspicion of malicious activity, such as tampering with equipment. ▪ Circumstances that lead to the provider organisation no longer being able to provide an element of service and not reportable through situation reports (SITREP) (such as closure of caseloads to new referrals).
PROFESSIONAL MISCONDUCT	▪ Allegations of serious professional misconduct.
STAFF-RELATED INCIDENTS	▪ Serious complaints about a member of staff or primary care contractor or any incident relating to a staff member where adverse media interest could occur. ▪ Any serious criminal acts involving patients or staff. ▪ Suspicion of a serious error or errors by a member of staff, primary care contractor or other healthcare contractor. ▪ Where a member of staff is suspected of harming patients. ▪ A serious drug error, such as mal-administered spinal injections.

Serious incident category *(in alphabetical order)*	Further Description
	▪ Where professional competence is in question (see NPSA Incident Decision Tree). ▪ A serious breach of confidentiality. ▪ Where a member of staff is suspected of committing serious fraud. ▪ The exclusion of employed doctors or dentists under the NHS Trust disciplinary procedures that refer to 'High Professional Standards in the Modern NHS: a framework for the initial handling of concerns about doctors and dentists in the NHS' (HSC 2003/12). ▪ Significant disciplinary matters of other staff. ▪ Serious verbal and/or physical aggression. ▪ Where a member of staff shows gross disrespect for the dignity of a patient/deceased patient.
TERRORISM AND CHEMICAL, BIOLOGICAL, RADIOLOGICAL OR NUCLEAR (CBRN) INCIDENTS	▪ Any act of terrorism is normally covered under the Major Incident Policy and will therefore have a comprehensive list of definitions. Generally, the following incidents must be reported:- – terrorist threats/incidents which include incendiary devices or the use of other weapons including chemical, biological, radiological or nuclear agents (CBRN) – potential or confirmed chemical, biological, radiological or nuclear agents (CBRN) incident
UNEXPECTED DEATH, SERIOUS HARM OR INJURY	▪ Patients, individuals or groups of individuals suffering serious or catastrophic harm or unexpected death whilst in receipt of health services, including screening and immunisation/radiation errors and equipment failures. ▪ Serious injury or unexpected death of any individual to whom the organisation owes a duty of care including staff, visitor, contractor or any other person
VIOLENCE TOWARDS HEALTH CARE	▪ Counter Fraud and Security Management Service (CFSMS) in the case of fraud and violence to staff. In such circumstances this serious incident framework should be followed in conjunction with the national guidance.

Serious incident category ***(in alphabetical order)***	**Further Description**
STAFF	▪ Serious violence/death of healthcare worker.

APPENDIX B

MODERATE HARM PROCESS

1.0 Introduction

1.1 The Moderate Harm Procedure has been implemented in the Trust to meet the Duty of Candour contractual requirement from 1st April 2013. The Moderate Harm process is managed by the Patient Safety team. The aim of this procedure is to provide information on what is expected of Investigating Officers in relation to Moderate Harm incidents.

1.2 The contractual duty's primary concern is to ensure that patients/their families are advised of patient safety incidents that affect them, that they receive appropriate apologies, are kept informed of investigations, and are supported through any bereavement. This duty applies to patient safety incidents that occur during care provided under the NHS Standard Contract and that result in moderate harm, severe harm or death (using National Patient Safety Agency (NPSA) definitions), that are reported via local risk management systems. To avoid excessive burden on the NHS it does not apply to low/negligible harm incidents, however these incidents should still be shared with the patient or their family if appropriate.

1.3 Moderate Harm patient safety incidents have been defined with the Duty of Candour consultation document as:-

- a moderate increase in treatment as a result of the incident;
- a scenario that causes significant but not permanent harm;
- prolonged psychological harm.

The Trust have further clarified this as:

- An increase in treatment as a result of the incident
- A scenario that causes significant but not permanent harm
- A scenario that has resulted in a delay in the care pathway:

For example;

Arrival of an ambulance outside of disposition which resulted in prolonged and avoidable pain or deterioration.

Inappropriate handovers which have resulted in a delay in the arrival of a patient to hospital and a detrimental impact on their outcome.

Resourcing issues which have resulted in the above.

Inappropriate non-conveyance.
Missed fracture due to lack of assessment.
Incorrect disposition assigned to incident which resulted in prolonged and avoidable pain or deterioration.

- A scenario that causes harm to patient whilst in our care:

For example:
Patient injuries caused by Trust staff, equipment or vehicles such as falls from carry chairs / trolley beds; injured by or in our vehicles; trauma caused by pulling catheters; skin tears.
Deviation from our clinical protocols which results in deterioration of the patient.

1.4 The Duty of Candour guidance applies to all Moderate Harm and Serious Incidents. This duty forms part of the Trust's contract agreement with Commissioners and therefore is a mandatory process.

2.0 Moderate Harm Incident Process

2.1 When an incident has been confirmed as Moderate Harm by the nominated Trust Directors, the appropriate Head of Function will be asked to nominate a dedicated Investigating Officer. The Investigating Officer will be issued, by the Patient Safety team, with the Moderate Harm investigation template along with all supporting documents to assist in their investigation.

2.2 The Investigating Officer is required, where appropriate, to make verbal contact with the patient or their next of kin within 10 working days of the incident being confirmed as Moderate Harm.

2.3 Where verbal contact cannot be made within 10 working days due to lack of contact information, such as a telephone number, the Investigating Officer will send an initial letter to the patient or next of kin if appropriate outlining the details of the incident and Trust's Moderate Harm investigation process.

2.4 A method of feedback with the outcome of the investigation should be agreed between those affected and the Investigating Officer.

2.5 The Investigating Officer's timeframe for completion of the investigation report is 25 working days. The report must be sent on the Moderate Harm template to the Patient Safety team for review within the agreed timeframe.

2.6 A quality assurance process will be managed by the Patient Safety Manager.

2.7 In certain circumstances the patient or next of kin may request that no further contact is made and feedback is not required from the Trust. In such cases the investigation will be completed in the standard way without any further contact being made. A note will be added to the record for this incident.

2.8 The investigation must be closed within 35 working days of the date that the incident has been confirmed as being Moderate. This includes:

- completion of the investigation report
- patient/family provided with the investigation outcome via verbal contact
- evidence of any remedial action taken
- recommendations for further action agreed, and if requested, a follow up letter to the patient/family with the investigation outcome completed

2.9 Following completion of the investigation, it is the Investigating Officer's responsibility to follow up recommendations made within their report and to ensure these are completed in a timely manner. These actions will be monitored on the Moderate Harm action plan by the Patient Safety team.

2.10 All documentation relating to the investigation will be held centrally by the Patient Safety team. The Investigating Officer is responsible for providing the Patient Safety team with all information relevant to the investigation.

2.11 Investigations conducted through the Moderate Harm process will be included within the Trust's Patient Experience report provided to the Quality and Governance Committee.

3.0 Support and Guidance

3.1 Further guidance and support on the Moderate Harm process can be sought from a member of the Patient Safety team at patientsafety@swast.nhs.uk.

3.2 In the absence of the Patient Safety Manager, the point of contact for Moderate Harm incidents is the Patient Safety Officer who oversees the Moderate and Serious Incident processes.

Confirmed as Moderate Harm Incident

Investigating Officer appointed and issued with Moderate Incident investigation template and all relevant documents sourced

Moderate Incident decision recorded on Master Incident Log and relevant Lead Commissioner notified

Reasonable steps taken to make contact with the patient or next of kin (NoK) or guardian within 10 working days (If unsuccessful this must be evidenced and the Patient Safety Team made aware prior to the deadline)

Relevant documents sourced, interviews set up etc, and further contact made with (or support provided for) patient/NoK/guardian as appropriate

Investigating Officer to return completed report to include interviews, PCRs etc, within **25** working days from confirmed date

Assurance process

Report outcome of investigation fed back to patient, NoK or guardian including details of actions (within 10 working days of investigation report completion)

Recommendations to be input onto the Moderate Incidents Action Plan and monitored by the Patient Safety Team

Lessons learnt to be shared through internal reporting systems

APPENDIX C

DUTY OF CANDOUR PROCEDURE

1. Introduction

1.1 The introduction of a statutory Duty of Candour is a major step towards implementing a key recommendation from the Mid Staffordshire NHS Foundation Trust Public Inquiry (the Francis Inquiry). The Duty of Candour will place a requirement on providers of health and adult social care to be open with patients when things go wrong. Providers should establish the duty throughout their organisations, ensuring that honesty and transparency are the norm in every organisation registered by the CQC.

1.2 The Duty of Candour is defined as a duty to be open with our patients, informing them of any moderate or serious patient safety incident in which they have been involved. When 'being open', the Trust should acknowledge the incident occurred, apologise to the patient or next of kin, and explain why the incident occurred and what actions will be put in place to try and prevent a recurrence. Where individuals cannot be contacted/traced, the Trust will maintain a comprehensive record of all attempts to make contact and will apply the process outlined in paragraph 3.10.

1.3 The Duty of Candour guidance applies to all Moderate Harm and Serious Incidents.

1.4 The Trust currently has a contractual obligation to be open in cases of suspected or actual patient safety incidents that are deemed moderate or serious in nature. This is set out within the NHS Standard Contract Service Conditions.

1.5 The Duty of Candour is part of the CQC registration requirements.

2.0 Definitions

2.1 Definitions of serious and moderate harm incidents are set out within section 4 of this policy.

3.0 Process

3.1 When a Patient Safety incident is identified as Serious or Moderate Harm the Duty of Candour process must be followed as part of the investigation process.

3.2 The contractual Duty of Candour requires that the Trust make contact with the patients or their next of kin within at most 10 working days of identification of a Serious or Moderate Harm patient safety incident on a locally reportable system.

3.3 It is the responsibility of the nominated Investigating Officer to instigate contact with the Patient or Next of Kin (Relevant Person).

3.4 When making contact the Investigating Officer must act in an open and transparent way with relevant persons in relation to the Patient's care and treatment.

3.5 The initial notification must be verbal (face to face where possible) unless the patient cannot be contacted in person or declines notification. The verbal notification must be accompanied by an offer of written notification. All telephone contact should be completed on a recorded telephone line.

3.6 The Investigating Officer will:

- provide the relevant person with all information directly relating to the incident;
- provide reasonable support to the relevant person in relation to the incident;
- provide a truthful account of all the facts the service provider knows about the incident as at the date of the notification;
- advise and, if possible, agree with the relevant person what further enquiries into the incident are appropriate;
- include an apology.

3.7 Following the Investigation the Investigating Officer must arrange for the incident investigation report must be shared within 10 working days of being signed off as complete by the Trust and Lead Commissioner.

3.8 The Patient Safety Officer will record and monitor the Trust's compliance with its Duty of Candour process for management of Serious and Moderate Harm patient safety incidents, including open communication with the affected individual(s) or their next of kin.

3.9 Where individuals cannot be contacted/traced, the Trust will maintain a comprehensive record of all attempts to make contact.

3.10 These will be reviewed with the Commissioning Support Unit Quality team.. Where sufficient effort has been made but contact has not been achieved, this will not constitute a breach (in line with guidance within the Duty of Candour Statutory Instrument). A risk assessment on making contact will be undertaken by the Trust for any incident where the patient or their next of kin

may be considered 'vulnerable' (whether this is due to their general psychological or physiological state; or due to the circumstances surrounding or following the incident).

3.11 Breaches in the contractual Duty of Candour may result in a number of actions being taken by the Commissioners as set out within the NHS standard contract.

4.0 Support and Guidance

4.1 Further guidance and support on the Duty of Candour can be sought from a member of the Patient Safety team at patientsafety@swast.nhs.uk.

5.0 Associated Documentation

5.1 This guidance links to:-

- Serious and Moderate Harm Policy
- Investigation Guide
- Incident Reporting Policy
  Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20: Duty of Candour.

APPENDIX D

MEMORANDUM OF UNDERSTANDING: INVESTIGATING PATIENT SAFETY INCIDENTS INCLUDING UNEXPECTED DEATH OR SERIOUS UNTOWARD HARM

In November 2006 the Department of Health produced 'Guidelines for the NHS: In support of the Memorandum of Understanding: Investigating patient safety incidents involving unexpected death or serious harm'. These guidelines provide practical advice to NHS organisations about what to do when faced with a patient safety incident that may require investigation by the police and/or Health and Safety Executive (HSE).

A 'Memorandum of Understanding: Investigating Patient Safety Incidents Involving Unexpected Death or Serious Untoward Harm' was published by the Department of Health in February 2006 and sets out a protocol for liaison and effective communication between the NHS, Association of Chief Police Officers (ACPO) and the Health and Safety Executive (HSE).

The purpose of the protocol is to promote effective working relationships between the three organisations, setting out the general principles for the NHS, Police and HSE to observe when liaising with each other. The protocol applies to those patient safety incidents involving unexpected death or serious harm requiring investigation by the police or by the police and HSE jointly.

It will sometimes be immediately obvious that the police and/or the HSE should be contacted, however there may be cases that the need does not come to light until the Trust, Coroner, or other body such as the Medicines and Healthcare products Regulatory Agency (MHRA) has carried out its own investigations. The decision to report an incident to the police should be made at a senior level, e.g. the Chief Executive or another executive director.

Once such a decision has been taken representatives of the Trust, police and, where appropriate the HSE, should arrange an initial meeting. The meeting of this 'Incident Coordination Group' should be called as soon as practicable following the referral and, in any case, the group should meet within 5 working days of the referral. All 3 organisations are entitled to call an Incident Coordination Group meeting, but responsibility for organising the meeting rests with the NHS Trust.

The police and/or the HSE may also call an Incident Coordination Group meeting in response to a complaint, referral from a Coroner or in response to other concerns.

Until the first meeting of the Incident Coordination Group, the Trust should continue to deal with concerns about patient safety but not undertake any activity that may compromise any subsequent investigations conducted by the police and/or the HSE. If in doubt about this matter, the Trust should seek legal advice and consult the police, HSE or where appropriate, other investigating bodies.

It is also critical that any relevant physical, scientific and documentary evidence is secured and preserved.

Some patient safety incidents may result in the police or HSE investigating possible offences by individual NHS employees and/or the NHS employer. Investigation of the NHS employer will normally involve the HSE because health and safety legislation places the primary responsibility on the employer. In such cases, it may not be appropriate for those who may be investigated or could be defendants in a criminal case to be members of the Incident Coordination Group. When this issue arises, it should normally be discussed at the outset by the agencies involved and, if necessary, the strategic health authority should take on the role of liaising with the police and HSE on behalf of the Trust.

APPENDIX E

72 HOUR REPORT

Serious Incident Requiring Investigation (SIRI) 72 Hour Report

SIRI Reference Number:	
STEIS Identification Number: 2016/ (Our Ref – W)	
Report completed by:	
Designation:	
Date / Time report completed:	
Date/Time/Place of Incident:	
Incident Type:	
Description of Incident:	
Details of any police or media involvement/interest	
Immediate Actions Taken including actions to mitigate any further risk:	
Details of other organisations/individuals notified;	
Commissioning Group	

APPENDIX F

QUALITY ASSURANCE DOCUMENT

Quality Review of a Root Cause Analysis Investigation Report

Serious Incident Investigation Review Template and Contributory Factor Grid

The aim of this template and contributory factor grid is to provide guidance and support towards a structured approach of the review of Serious Incident Investigation reports as defined in the National Framework for the Reporting and Learning from Serious Incidents Requiring Investigation, NPSA May 2010 and the NHS South of England Process. Application of a root cause analysis approach is recognised as a robust methodology, this template aligns with that methodology. It may be useful as an internal checklist by quality leads in Provider organisations and by commissioners. For ease of complete the responses are primarily designed as Yes No. The last section of the template is set aside for the reviewer to use as an aide memoire of the review but may also be used to provide feedback or request for additional information or improvement. To support wider identification of key themes and trends the key contributory factors may be captured in the Contributory Factors theme grid.

Reviewed by:		Date:
Designation:		

SECTION 1

Details

Reporting Organisation:			
Lead Commissioner:			
Organisation Type:			
Speciality:		Incident Date:	
Incident Type:		Grade:	
STEIS Number:		Actual Effect on Patient:	
Never Event:		Coroner's Inquest Pending:	

SECTION 2 – Further detail may be provided in the summary at the end of the report

1. Background and Content *Is there a clear overarching description of the events leading up to the incident with detail of the type of care or treatment provided?*

Yes ☐

No ☐

Comments:

2. Details of Investigator/Investigative Team *Is the membership of the team appropriate to the incident? This is particularly relevant in the case of Grade 2 incidents and incidents where specialist advice should be provided e.g. drug incidents?*

Yes ☐

No ☐

Comments:

3. Does the scope of and level of the investigation seem appropriate?

The report should make clear the point (date) in the patient pathway from which information to support the investigation has been gathered. This should include a review of all relevant contacts. The level (Grade) of investigation should follow the National Framework and local Strategic Health Authority Process.

Yes ☐

No ☐

Comments:

4. Is there evidence that all relevant information has been gathered to support full exploration of problems?

This should align with 3 above. Such information gathering should include relevant patient records, staff rotas, interview transcriptions or statements, referral and discharge letters, diagnosis, police or other external agency information as appropriate to the level of complexity of the incident. Policies, procedures and guidance both national and local.

Yes ☐

No ☐

Comments:

5. Is there evidence of appropriate support and communication for patients and relatives?

This should reflect the principals of 'Being Open', Duty of Candour and (as appropriate) include details of how the findings will be shared.

Yes ☐

No ☐

Comments:

6. Support for staff *Is there evidence that appropriate support for staff is in place including where appropriate the application of the incident Decision Tree, training and development?*

Yes ☐

No ☐
Comments:

7. Chronology/timeline *Has a detailed chronology or timeline been included with the report? Any gaps in the chronology or timeline should have been satisfied.*

Yes ☐

No ☐
Comments:

8. Does the report identify good practice? *It is helpful to reflect where things went well as well as those where problems existed. The learning from good practice should not be lost.*

Yes ☐ Comments:

No ☐

9. Problem identification? *Any problems identified in the early stages of the analysis should be clearly listed and noted at the point at which they occurred within the chronology or timeline, some may have little or no impact but will help inform overall learning.*

Yes ☐

No ☐
Comments:

10. Analysis of problems leading to contributory factors? *Identification of contributory (or causal) factors is achieved through further in-depth analysis of problems identified (asking and answering 'WHY'). Is there evidence of clear and in depth analysis of problems leading to the identification of contributory factors? (see attached contributory factor grid)*

Yes ☐

No ☐
Comments:

11. Key contributory (causal) factors – Root Cause/s? *The investigation should seek to identify the key contributory (causal) factors, root causes that had the most significant* impact *on the outcome – these should be clearly stated and can be tracked back to the original incident*

Yes ☐

No ☐

Comments:

12. Recommendations *Do the recommendations address the key contributory (causal) factors, root causes as identified?*

Yes ☐

No ☐

Comments:

13. Action plan *Is there a clear time framed action plan that includes named individuals or departments responsible for implementation and review?*

Yes ☐

No ☐

Comments:

14. Lessons learned *Has the investigation identified learning and stated how this investigation will be shared internally and more widely if appropriate?*

Yes ☐

No ☐

Comments:

Section 3 – Reviewer Comments

This section should be used to provide supportive information for the decisions made above together with any further information required or other relevant details in relation to the incident; e.g. referred to independent investigation etc.

Is the reviewer satisfied that the investigation is robust, with in depth analysis, thorough identification of any contributory or causal factors root causes and a time framed action plan: **Yes** ☐ **No** ☐ **Comments:**	
Give brief details to support decision (it may be helpful to refer to the relevant section in the report)	
How will the action plan be monitored and reviewed?	
Has a contributory factor grid been completed and attached to the review?	**Yes** ☐ **No** ☐
Has the contributory factor grid identified any recurring themes from other similar incidents? *If yes, state what action will be taken.*	**Yes** ☐ **No** ☐
Has this review identified the need for further information or action?	**Yes** ☐ **No** ☐
State Section and item number and brief details.	

Contributory (Causal) Factors (Root Causes) Identification Grid

Findings from analysis within report		Description
Contributory/causal Factors/Root causes	Patient Factors	
	Task Factors	
	Individual Staff	
	Team and Social/Leadership/supervision/	
	Education and training	
	Equipment/Resources	
	Communication	
	Working Conditions/Environment	
	Organisational/strategic	

The above taxonomy has been taken from the National Patient Safety Agency Root Cause Analysis Taxonomy. The chart should be completed describing the contributory or causal factor where applicable in each of the taxonomy headings above. Some investigation reports may have applied this approach in their analysis in which case these could be cut and pasted to this review. All factors may not be present in all investigations. Those with the most significant impact are generally considered to be key, leading to Root Cause/s where if eradicated or significantly reduced would or may have prevented the outcome. It is these factors that require the most robust actions (solutions) to remove or mitigate any similar incident from occurring. Over time capturing these factors in a structured way should lead to identification of any key themes reoccurring and subsequently to the building of an organisational memory.

APPENDIX G

INVESTIGATION LOG

Investigation Log	
Investigator:	**Designation:**
Trust Ref:	**STEIS Ref:**

Date	Information / Event

APPENDIX H

INFORMATION GOVERNANCE SERIOUS INCIDENTS REQUIRING INVESTIGATION (IG SIRI)

In June 2013, the Health and Social Care Information Centre (HSCIC) published 'Checklist Guidance for Reporting, Managing and Investigating Information Governance Serious Incidents Requiring Investigation'. The HSCIC document is independent of the 2010 National Framework for Reporting and Learning from Serious Incidents Requiring Investigation.

The HSCIC document states that there is no simple definition of a serious incident but as a guide offers the following:

- Any incident which involves actual or potential failure to meet the requirements of the Data Protection Act 1998 and/or the Common Law 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.
- Such 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.

The method of reporting these incidents should follow this policy. For potential IG SIRIs the checklist below should be completed to determine the score and submitted as part of the supporting evidence to Directors *(Paragraph 6.3)*. A separate copy of the checklist can be found on the intranet.

Any incidents scoring 2 or more should be classified as a serious incident as defined within this policy. The Information Governance team should then be notified as soon as possible so that the incident can be reported on the IG Incident Reporting Tool (hosted by the IG Toolkit website). The incident will still also need to be reported on STEIS. The Patient Safety Manager and IG team will liaise with each other to ensure there is consistency of reporting on the two systems.

Incidents reported on the IG Incident Reporting Tool scored 2 or more will trigger an automated notification email to the Department of Health, HSCIC and the Information Commissioner's Office in the first instance and to other regulators as appropriate. Updates on the investigation and final outcomes should also be input onto the system. Reports on closed IG SIRIs will be published on the IG Toolkit website quarterly. Quarterly reports

APPENDIX I

Assessing the severity of an Information Governance Serious Incident Requiring Investigation (IG SIRI)

Datix reference number:	
Brief description of incident:	

Step 1: Establish the scale of the incident. If this is not known it will be necessary to estimate the maximum potential scale point.

Baseline Scale		No People	Score
0	Information about less than 10 individuals		
1	Information about 11-50 individuals		
1	Information about 51-100 individuals		
2	Information about 101-300 individuals		
2	Information about 301 – 500 individuals		
2	Information about 501 – 1,000 individuals		
3	Information about 1,001 – 5,000 individuals		
3	Information about 5,001 – 10,000 individuals		
3	Information about 10,001 – 100,000 individuals		
3	Information about 100,001 + individuals		

Step 2: Identify which sensitivity characteristics may apply and the baseline scale point will adjust accordingly**.**

Low: For each of the following factors reduce the baseline score by 1		Score
-1 for each	No clinical data at risk	
	Limited demographic data at risk e.g. address not included, name not included	
	Security controls/difficulty to access data partially mitigates risk	
Medium: The following factors have no effect on baseline score		
0	Basic demographic data at risk e.g. equivalent to telephone directory	
	Limited clinical information at risk e.g. clinic attendance, ward handover sheet	

Continued….

High: For each of the following factors increase the baseline score by 1		Score
+1 for each	Detailed clinical information at risk e.g. case notes	
	Particularly sensitive information at risk e.g. HIV, STD, Mental Health, Children	
	One or more previous incidents of a similar type in past 12 months	
	Failure to securely encrypt mobile technology or other obvious security failing	
	Celebrity involved or other newsworthy aspects or media interest	
	A complaint has been made to the Information Commissioner	
	Individuals affected are likely to suffer significant distress or embarrassment	
	Individuals affected have been placed at risk of physical harm	
	Individuals affected may suffer significant detriment e.g. financial loss	
	Incident has incurred or risked incurring a clinical untoward incident	
Final Score:		

Any incidents scoring 2 or more should be classified as a serious incident and reported on the IG Incident Reporting Tool.

Further information, including examples of how incidents have been scored, can be found in the 'Checklist Guidance for Reporting, Managing and Investigating Information Governance Serious Incidents Requiring Investigation'

APPENDIX J

SERIOUS INCIDENT INVESTIGATION REPORT

The outcome of any Serious Incident investigation will be a written report and should follow the headings below. A full template is available from the Patient Safety team and the Trust intranet:

Cover Page

Summary of Version Control data

Contents Page

Introduction

Incident Description

Terms of Reference

Scope

List of Information

List of contributors

Communication, Monitoring and Evaluation

Involvement and Support of Family

Root Cause Analysis

Background and Summary

Findings

Problem Identification and Contributory Factors

These may include:

Patient factors	Factors unique to the patient concerned, e.g. mobility, underlying conditions.
Individual factors	Factors that the individual(s) involved in the event bring that are unique to them, e.g. fatigue, stress, experience.

Task factors	Those that support and aid in the safe and effective delivery of the process, e.g. procedures, guidelines and protocols.
Communication factors	Considers whether any aspect of verbal, non-verbal or written communication contribute to poor performance or the occurrence.
Team and social factors	Predominantly involve team communication issues and leadership.
Education and training factors	The availability and quality of training programmes to support competence.
Equipment and resource factors	Those that relate to the safety and operation of medical and non-medical equipment.
Working condition factors	Those that affect an individual's ability to function at optimum levels in the workplace.
Organisational and management factors	These are factors that are either inherent or embedded within the organisation. Often these factors are latent and only come to light when an incident occurs.

Conclusions

Recommendations

Action Plan

Appendices

Additional Reportable Information should be recorded within Appendix 1. This includes:

- **FOI Statement**
- **Service Line**
- **NRLS Severity Rating**

- **Theme/Trend**
- **Pre-investigation Risk Assessment**
- **Post-recommendation Risk Assessment**
- **Involvement and Support of Staff**
- **Serious Incident Review Meeting Attendees**

When compiling the report, the following guidance should be followed in relation to documents used as part of the investigation:

- Witness statements, relevant Trust policies, procedures, systems, instructions, risk assessments, health and safety inspections, clinical audit reports, photographs, etc, should be considered. Such information may also include work rosters, time sheets, patient clinical records, clinical and medical records, voice and data records from the Clinical Hub, transcripts, status reports, etc. This should be recorded in a logical order and the following standards achieved:-

  (i) when collecting documentary evidence regarding Trust policies, procedures, systems, instructions, etc., ensure the documents collected are those that were in use at the time of the incident;

  (ii) ensure that all relevant copies are preserved within the investigation file;

  (iii) reference all documentary evidence collected (including any photographs) and include reference numbers;

  (iv) ensure records are relevant to the investigation and that any patient identifiable information is deleted;

  (v) record details such as serial number of any equipment involved in the incident. Any equipment believed to have precipitated or caused harm should be impounded with any disposables such as pads retained;

  (vi) ensure training and competency assessments for those involved in the incident have been included, including training assessment instruments and learner outcome plans;

  (vii) ensure all documentation relating to the incident is classified as highly sensitive and is subject to the standards for security and transit defined in the Information Governance Policy and guidelines set out within 'Private and Confidential' available on the Trust's intranet;

(viii) store information in a ring binder with a numbered or lettered index system. This will lead to easy access and less likelihood of any documents being accidentally destroyed.

Contributory factors and Root Causes.

APPENDIX K

Version Control Sheet

Version	Date	Author	Summary of Changes
2	April 2016	K Silvester-Eccles	Reworking of the policy to reflect the revised framework and new process, with key changes relating to the addition of Never Events, the Quality Development Forum, the Decision Making Group, and new audit template of change to SI Outcome Reports
1	27/06/2014	K. Silvester-Eccles	New policy to incorporate moderate harm and duty of candour and to reflect local and national NHS organisational and process changes. This replaces the previous Serious Incident and the Being Open policies.