

Incident Reporting and Management Policy Including Serious Incidents

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Partners in Care

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Document Information

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Amendment History

Issue	Status	Date	Reason for Change	Authorised
V1.0	Final	July 2013	To include recommendations from the Francis report and Duty of Candour.	24 July 2013
V2	Final	February 2015	Amendments to contents: <ul style="list-style-type: none"> • NPSA no longer exists - altered to NRLS • Links amended • Never event list updated • Incident Reporting SOP's updated and are now stand-alone documents. • Contact details (section 13) updated and correct. 	5 February 2015

			<ul style="list-style-type: none"> • H&S RIDDOR information amended to new legislation 	
V3	Final	May 2015	<ul style="list-style-type: none"> • New NHS Incident reporting framework SIRI incident grades. • Investigation timescales for the completion of STEIS reported SIRI's. • New Never Events 2015-2016. • 'Care Quality and Safety Team' name changed to 'Quality and Experience Team'. • Roles of MDSO and MSO added . • "Personal Relationships at Work Policy" included in list of overlapping policies. 	

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1 Introduction

- 1.1 This policy covers the reporting and investigation processes for all clinical and non-clinical incidents including Serious Incidents Requiring Investigation (SIRI's), near misses and hazards and applies to incidents involving service users, patients, visitors or carers, the public, employees or business of the Trust.
- 1.2 Torbay and Southern Devon Health and Care Trust (TSDHCT, referred to as "the Trust") recognises that although serious incidents in health and social care are relatively uncommon, from time to time things can and do go wrong. When adverse incidents do occur the Trust has a responsibility to ensure that there are systematic measures in place for safeguarding people, property, Trust resources and reputation. This includes responsibility to learn from these incidents in order to minimise the risk of them happening again.
- 1.3 The reporting and management of incidents is a critical tool in assisting the organisation to effectively manage risk. The reporting of incidents and near misses provides valuable data which can help improve safety, prevent the recurrence of incidents and facilitate wider organisational and cross-organisational learning.
- 1.4 This policy is supported by the Learning from Experience Policy: Analysis and Improvement following Incidents, Complaints and Claims Policy which helps the organisation to understand why things went wrong, how we can prevent or minimise similar incidents and how we can share that learning across the organisation and externally.
- 1.5 This policy for all staff includes the principles of "Being Open" and "Duty of Candour". Where incidents occur we need to evidence openness, honesty and transparency so that early warning systems can work. Expectations of the Duty of Candour following the Francis Report (2013) include ensuring that any patient/service user harmed by the provision of a healthcare service is informed of the fact and an appropriate remedy offered, regardless of whether a complaint has been made or a question asked about it. The Duty of Candour became a contractual obligation in April 2013 and a CQC registration requirement in October 2014.
- 1.6 The Trust recognises that incidents may occur because of problems with systems, processes or by individuals. It is the policy of the Trust to promote a positive approach to incident reporting throughout the organisation. Staff are encouraged and will be supported to be open and honest about events and issues that have or could cause damage to people, property or the organisation. The Trust operates an open and fair blame culture and will accept vicarious liability for the actions of staff as long as they were carrying out their duties in accordance with Trust policy, their professional standards, information, instruction, training and supervision they had received.

2 Aims and Objectives

- 2.1** The aim of this policy is to ensure that the organisation is compliant with all relevant regulations and guidelines and to support staff in reporting, investigating and managing incidents. This policy follows the Department of Health guidance on national reporting arrangements to NHS England, National Reporting and Learning System (NRLS), Medicines, Healthcare Products Regulatory Agency (MHRA), Health and Safety Executive (HSE), NHS Litigation Authority (NHSLA) and the Counter Fraud and Security Management Service (CFSMS).
- 2.2** The purpose of this policy is to set out the Trusts process for the reporting, reviewing and learning from all types of incidents. It provides a robust framework to ensure a consistent approach across the whole organisation and is to be implemented throughout all the services provided.
- 2.3** The Trust expects all employees to be open and honest and that those who admit to being involved in accidents and incidents, to making mistakes or near misses will be supported and treated fairly.
- 2.4** The objectives of the policy are to ensure that the NRLS guidance on the Seven Steps to Patient Safety (2009) are followed by:
- Promoting a culture of learning through review and reflection of incidents and near misses,
 - Ensuring a consistent approach across the organisation in the reporting and management of incidents,
 - Enabling the effective reporting and provision of information on incident trends to ensure that lessons can be learnt and improvements made reducing re-occurrence of similar incidents,
 - Improving the safety of service users, staff and visitors,
 - Minimising the human, organisational and financial impacts of incidents through effective management,
 - Enabling the identification and correction/ improvement of weaknesses in practices, systems or equipment,
 - Ensuring the onward reporting of serious hazards and incidents to relevant stakeholders including the NRLS.

3 Explanation of Terms

3.1 Incident – An event or circumstance that could have or did lead to unintended or unexpected harm, loss or damage. This relates to any physical or mental injury to a patient, employee, visitors or members of the public or damage to organisational reputation.

3.2 Harm/Severity terms used for patient safety related incidents.

No Harm' – no injuries or obvious harm. No loss of property. No significant likelihood of service issues arising from incident.

‘Near Miss’ – potential harm - an unexpected or unintended occurrence or incident that did not lead to harm, loss or damage, but had serious potential to do so and was prevented either by intervention or luck.

‘Low harm’ – any incident that required extra observation or minor treatment and caused minimal harm, to one or more persons receiving NHS funded care.

‘Moderate harm’ – any incident that resulted in a moderate increase in treatment and which caused significant but not permanent harm, to one or more persons receiving NHS funded care.

‘Severe harm’ – any incident that appears to have resulted in permanent harm to one or more persons receiving NHS funded care – related directly to the incident and not to the natural course of the patient’s illness or underlying condition.

‘Catastrophic or Death’ – any incident that directly resulted in the death of one or more persons receiving NHS funded care. Death must be related to the incident rather than the underlying condition or illness.

3.3 Hazard - A hazard may be defined as;

“Something with the potential to cause harm, or a situation/factor that may cause an incident or make it more likely to happen.”

3.4 RIDDOR - The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR) require a range of incidents to be reported to the Health & Safety Executive (HSE), including any injury where an employee is unable to carry out their normal duties for more than 7 days after the injury. Reportable incidents include service users as well as employees e.g. if the incident results in an increased patient stay of more than 3 days, or staff absence for more than 7 days.

3.5 Medicines and Healthcare products Regulatory Agency (MHRA) - All incidents related to medicines and healthcare devices should be reported on Datix and then reported in accordance with the Medical Devices Management to the MHRA via their website at <http://www.mhra.gov.uk/> accessed (8th June 2015). The MHRA may look into incidents including the regulation of medicines and medical devices and equipment used in healthcare and the investigation of harmful incidents. The MHRA also is responsible for incidents relating to blood and blood products, working with UK blood services, healthcare providers, and other relevant organisations to improve blood quality and safety.

3.6 Serious Incident Requiring Investigation (SIRI)

Serious Incidents in the NHS include:

- Acts and/or omissions occurring as part of NHS-funded healthcare (including in the community) that result in:
 - Unexpected or avoidable death of one or more people. This includes
 - suicide/self-inflicted death; and
 - homicide by a person in receipt of mental health care within the recent past.
 - Unexpected or avoidable injury to one or more people that has resulted in serious harm;
 - Unexpected or avoidable injury to one or more people that requires further treatment by a healthcare professional in order to prevent:—
 - the death of the service user; or
 - serious harm;
 - Actual or alleged abuse; sexual abuse, physical or psychological ill-treatment, or acts of omission which constitute neglect, exploitation, financial or material abuse, discriminative and organisational abuse, self-neglect, domestic abuse, human trafficking and modern day slavery where:
 - healthcare did not take appropriate action/intervention to safeguard against such abuse occurring; or
 - where abuse occurred during the provision of NHS-funded care.

This includes abuse that resulted in (or was identified through) a Serious Case Review (SCR), Safeguarding Adult Review (SAR), Safeguarding Adult Enquiry or other externally-led investigation, where delivery of NHS funded care caused/contributed towards the incident.

- A Never Event - all Never Events are defined as serious incidents although not all Never Events necessarily result in serious harm or death. See Never Events Policy and Framework for the national definition and further information;
- An incident (or series of incidents) that prevents, or threatens to prevent, an organisation's ability to continue to deliver an acceptable quality of healthcare services, including (but not limited to) the following:
 - Failures in the security, integrity, accuracy or availability of information often described as data loss and/or information governance related issues.
 - Property damage;
 - Security breach/concern;

- Incidents in population-wide healthcare activities like screening¹³ and immunisation programmes where the potential for harm may extend to a large population;
 - Inappropriate enforcement/care under the Mental Health Act (1983) and the Mental Capacity Act (2005) including Mental Capacity Act, Deprivation of Liberty Safeguards (MCA DOLS);
 - Systematic failure to provide an acceptable standard of safe care (this may include incidents, or series of incidents, which necessitate ward/unit closure or suspension of services); or
 - Activation of Major Incident Plan (by provider, commissioner or relevant agency)
- Major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare or an organisation.

The following additional incident categories have also been agreed as Level 2 SIRIs by NHS South of England.

- A domestic homicide (a decision to report onto the Strategic Executive Information System (STEIS) should be made by the Commissioner in conjunction with NHS South of England).
- A safeguarding incident (following initial review)
- Significant media interest (related to patient safety).
- Serious failure of screening services that has caused or is likely to cause long term harm or reduced life expectancy. In these cases please refer to the United Kingdom National Screening Committee guidance on managing serious incidents in the English NHS National Screening Programmes.

3.7 Never Events

'Never Events' are serious incidents that are wholly preventable as guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers.

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 as a 'Never Event'. Incidents are considered to be never events if:

- The incident either resulted in severe harm or death or had the potential to cause severe harm or death.
- There is evidence that the never event has occurred in the past and is a known source of risk (for example through reports to the

National Reporting and Learning System or other serious incident reporting system).

- There are existing national guidance or safety recommendations, which if followed, would have prevented the incident from occurring.
- Occurrence of the never event can be easily identified, defined and measured on an on-going basis.

The 'Never Event List' for 2014/15 is attached (appendix 2).

3.8 Safeguarding Incidents (Adults and Children)

Safeguarding the vulnerable from abuse and harm is everyone's business and an important part of everyday healthcare practice.

Reporters should always consider safeguarding if they have any concerns that the incident has resulted from abuse or neglect and as well as reporting the incident they must also raise their Safeguarding Concern to the relevant contact, see Section 13 for contact details.

Any incident which has resulted in a safeguarding referral must also be reported as an incident.

3.9 Abuse

A violation of an individual's human or 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. Abuse can occur in any relationship and may result in significant harm, or exploitation, of the person subjected to it. This is defined in No secrets: Guidance on developing and implementing multi-agency policies and procedures to protect vulnerable adults from abuse (DH 2000), and Working Together to Safeguard Children: A guide to inter-agency working states that abuse and neglect are forms of maltreatment of a child. Somebody may abuse or neglect a child by 'inflicting harm' or by failing to act to prevent harm (DCSF 2006, p37).

3.10 Duty of Candour

An obligation to disclose errors that may not be immediately obvious to the patient/service user. Exercising candour narrows the gap between what the healthcare professional and the patient/service user know about an incident (Francis 2013).

Any patient harmed by the provision of a healthcare service is informed of the fact and an appropriate remedy offered, regardless of whether a complaint has been made or a question asked about it (Francis 2013).

3.11 STEIS

The Strategic Executive Information System (STEIS) where SIRI's are reported and monitored. It is NHS England's web-based serious incident management system.

4 Roles and Responsibilities

4.1 Chief Executive – Has overall responsibility for risk management and shall ensure systems are in place to maintain effective systems for incident management. The Chief Executive is responsible for:

- Ensuring that this policy is implemented by all directly employed staff, contractors and volunteers
- Ensuring that systems are in place to minimise risk, identify issues early and manage promptly.
- Leading the development of a culture where openness is encouraged and employees feel able to report incidents and near misses.
- Ensuring that wherever care is commissioned, the provider has robust arrangements in place for the recording, reporting, investigating and learning from incidents.

4.2 Executive Directors - All Directors have a responsibility to ensure that the teams within their sphere of responsibility report and investigate all incidents and near misses according to this policy.

4.3 Director of Nursing and Professional Practice – The Director of Professional Practice has corporate responsibility for the safety of service users and for the risks associated with incident reporting and subsequent management. It is their responsibility to ensure implementation of this policy and monitoring its effectiveness within the Trust.

4.4 Medical Director - The Medical Director is also the Caldicott Guardian and has responsibility for ensuring personal identifiable data is safe and secure. Any incident which involves breaches of confidentiality will be investigated with appropriate reference to the Trust Caldicott Guardian, Senior Information Risk Officer (SIRO) and Head of Information Governance.

4.5 Director of Estates and Facilities Management (EFM) – The Director of EFM has corporate responsibility for the safety of staff and for the risks associated with the working environment, non-clinical incident reporting and subsequent management. It is their responsibility to ensure implementation of this policy and monitoring its effectiveness within the Trust for non-clinical incidents.

4.6 Assistant Director of Nursing and Professional Practice – is responsible for:

- Promoting the critical exploration of the underlying and contributory factors during investigations;
- Ensuring that remedial action and organisational learning occurs;
- Ensuring systems are in place to monitor organisation wide compliance with this policy;

- Initiating the investigations of serious incidents, identifying the investigator, agreeing terms of reference and ensuring delivery within the agreed timescales;
- Review the standards and quality of SIRI reports.

4.7 Quality and Experience Lead – Leads the Quality and Experience Team and is responsible for:

- Managing Care, Quality, Safety and Clinical Risk Systems.
- Ensuring procedures for managing incidents and SIRI's are consistent with national guidance
- Monitoring the timeliness and progress of investigations
- Timely reporting of SIRIs via the Strategic Executive Information System (STEIS).
- Developing and overseeing systems for the reporting and management of incidents and providing regular reports to the Care Quality & Safety Group, the Quality, Safety and Clinical Risk Committee and the Integrated Governance Committee.
- Ensuring onward timely reporting of serious hazards and incidents to relevant stakeholders, providers and external agencies in line with statutory and mandatory requirements.
- Providing reports on medical device related incidents.

4.8 Quality and Experience Team - are responsible for:

- Reviewing all reported incidents (on Datix) daily, excluding weekends.
- Weekly uploading of incidents to the National Reporting and Learning System (NRLS).
- In collaboration with the Trust Education Team providing support, training and advice on the principles of incident and SIRI reporting, investigation and management to staff
- Supporting staff, investigators and managers by providing feedback, advice and training on incident reporting and management.
- Promoting a culture of incident reporting across the Trust.
- Instigating investigations and supporting departments, zones and teams to take appropriate remedial action
- Support management in the production of reports and trends analysis, including reports on progress of action plans.

4.9 Head of Information Governance - The Head of Information Governance will oversee the reporting of information governance incidents, agree the terms of reference and lead the management, investigation and closure of all Information Governance SIRI's. They will also be responsible for involving the Caldicott Guardian and Senior Information Risk Officer (SIRO) where appropriate.

4.10 Health & Safety Manager - The Health and Safety Manager is responsible for the monthly reporting of non-clinical incidents to the Capital and Infrastructure Steering Group and the Health and Safety Committee and for investigating health and safety incidents if they fall under the requirements of the Reporting of Incidents, Diseases and Dangerous Occurrences Regulations (RIDDOR) and informing the Health & Safety Executive (HSE) (see Trust RIDDOR Policy).

4.11 Trust Security Manager/Local Security Management Specialist

Any incident that has implications for the security e.g. violence and aggression against a member of staff or loss of identity must be reported to the Trust Security Manager, contact details of which can be found on iCare.

4.12 Accountable Officer for Controlled Drugs

All Controlled Drug related incidents are reported to the Accountable Officer for Controlled Drugs who, with the Medicines Management team and other professionals, will investigate incidents and report to NHS England in a quarterly Occurrence Report.

4.13 Medical Devices Safety Officer (MDSO)

The MDSO will support local medical device incident reporting and learning, act as the main contact for NHS England and the MHRA and medical device manufacturers and be a member of the new National Medical Devices Safety Network; and, identify an existing or new multi-professional group to regularly review medical device incident reports, improve reporting and learning and take local action to improve the safety of medical devices

4.14 Medicines Safety Officer (MSO)

The role of the MSO is to regularly review information from the NRLS (NPSA's National Reporting and Learning System) and the MHRA (Medicines and Healthcare Products Regulatory Agency) to support improvements in reporting and learning around medication incidents and to take local action to improve medication safety. This is facilitated through the Trust's Multi-Disciplinary Medicines Governance Group.

4.15 All Managers - Are responsible for the safety of all service users within their Zones /Community Hospitals/ Departments and for directly employed staff and others including visitors, volunteers and contractors, who may be affected by the actions of the team or individuals within the sphere of their responsibility. They are responsible for ensuring that staff read, understand and comply with this policy at a local level. They are also responsible for ensuring that:

- Incidents are reported and managed in accordance with this policy;
- All staff are familiar with this policy and the procedure for incident reporting and investigation;
- The individual patient/service user involved in an incident is informed of the event and subsequent actions as soon as possible after the event (Being Open Policy/Duty of Candour)
- Support is offered to staff reporting or involved in an incident (See Supporting Staff Policy);

- At the request of the Quality and Experience Lead, incidents are investigated using the agreed report template and appropriate action plans are produced;
- All actions are completed within agreed timescales;
- Any learning identified from the investigation is shared with staff and the Care Quality and Safety Group to facilitate wider learning;
- Patients (or their representative) and staff are offered feedback following the completion of an incident investigation;
- Where appropriate risk assessments are carried out to assess the potential of the incident re-occurring and the local risk register is updated accordingly;
- A culture of openness and fairness culture is encouraged and supported.
- Feedback is provided to staff for all incidents (including those that do not require a formal investigation) that are reported within their areas.

4.16 Investigator

An investigator may be appointed who is not a manager or supervisor. Anyone appointed as an investigator must have completed the appropriate training. This RCA investigator training is provided at the Trust Horizon training centre as a course or can also be provided to an investigator on a 1:1 basis if necessary. An investigator is responsible for carrying out an investigation into an incident while adhering to this policy and the Investigation Policy. They will ensure that a comprehensive report and recommendations are provided to the appropriate individuals and committees.

4.17 Role of all employees

All employees (including temporary staff, placement students, sub-contractors, and people on honorary contracts or volunteers) are responsible for reading and adhering to this policy. Staff must report incidents, including near-misses in accordance with this policy and fully co-operate with any investigations. They must ensure the patient/service user involved is aware of the incident consequences and actions taken.

Staff reporting the incidents should include their name as reporter and the area in which they work. However, there is scope to report incidents and concerns anonymously although this may make it more challenging to investigate. Staff should consult the Whistle Blowing Policy or contact HR for advice if they feel it is necessary to retain their anonymity.

4.18 The Trust Board - has a statutory responsibility to effectively manage risks relating to actual or potential incidents, to ensure the most effective use of public money and to monitor the Trust's compliance with legislation such as the Health and Safety at Work Act 1974. This includes responsibility for:

- Monitoring procedures to ensure that incident investigations meet the Trusts objectives and that any required follow up action is instigated (including in social care commissioned providers where SIRI's occur).

- 4.19 Integrated Governance Committee** - has overall responsibility for monitoring the incident management system and providing assurance to the Trust Board. It receives regular reports from the Care Quality & Safety Group and Clinical Advisory Group
- 4.20 Quality, Safety and Clinical Risk Committee-** receive reports of incident trends and number of SIRIs and learning from SIRIs. They also receive reports from Care, Quality and Safety Group to provide assurance that action plans are being followed up and learning is being shared across the organisation.
- 4.21 Care, Quality and Safety Group** – will receive reports of incident data, trends, number of SIRIs and learning from SIRIs. They are responsible for ensuring that recommendations and action plans are followed up and learning is shared and implemented across the organisation.
- 4.22 Management of Information Group** - The group will receive regular reports on incidents relating to information security/ governance. They are responsible for ensuring that recommendations and action plans from information governance/ security related incidents are followed up and learning is shared and implemented across the organisation.
- 4.23 Health and Safety Committee** - receive regular reports on incidents relating to Health and Safety. They are responsible for ensuring that recommendations and action plans from Health and Safety related incidents are followed up and learning is shared and implemented across the organisation.
- 4.24 Medicines Governance Group** - Medicines incidents that related to controlled drugs or drugs of diversion are referred to the Controlled Drugs Medicines Incident Group, who will consider the investigation outcomes and recommendations to enable shared learning. This group reports to the Medicines Governance Group who are responsible for analysing trends, monitoring action plans and sharing learning from all types of medicines related incidents that require investigation.
- 4.25 Medical Devices Operational Group** - All incidents relating to medical devices and equipment will usually be investigated in the locality, however reports and recommendations will be made to this group who will monitor action plans and ensuring learning is shared across the organisation. All Medical Devices involved in the incident should be removed from use and sent to the relevant technical support department for inspection.

5 Response, Communication and Notification

5.1 Immediate response by organisation

- 5.1.1 In all instances, the first priority for the Trust is to ensure the needs of individuals affected by the incident are attended to, including any urgent clinical care which may reduce the harmful impact.

- 5.1.2 A safe environment should be re-established, all equipment or medication retained and isolated, and all relevant documentation copied and secured to preserve evidence to facilitate the investigation and learning. If there is a suggestion that a criminal offence has been committed, the police should be contacted.
- 5.1.3 Demonstrate a “Duty of candour “ by informing the patient or their family/carer of the incident and support given see section 5.4
- 5.1.4 The ‘Being Open Policy’ should also be referred to regarding communication with patients, family or carers.
- 5.1.5 The needs and involvement of staff in the incident should also be considered. The Trusts Policy for Supporting Staff can assist here.
- 5.1.6 Incidents suspected of being either a Safeguarding Adult or a Safeguarding Children’s alert must be reported to the appropriate multiagency team and named child protection professional as soon as possible (See Section 13 contact details)

5.2 Reporting the Incident

- 5.2.1 Once the safety of the service user/patient/staff member/ has been established then the incident should be reported by any member of staff who has been witness to it. It is important not to assume someone else will report the incident. Therefore if you witness, or are involved in an incident you should report it. This process is detailed within the ‘Incident Reporting Procedure’ SOP and summarised in the flow chart (appendix 1)
- 5.2.2 If there are any concerns regarding the impact of the incident then the staff member should inform the person in charge/manager immediately and the Quality and Experience Team. During Out of Hours the staff member should contact the on call manager.
- 5.2.3 Incidents are reported electronically using the Datix system. This can be accessed by all employees; a password is not required to report an incident. Datix can be found on the Trust intranet, click [here](#) or type in the following address: <http://10.181.81.31/Datix/live/index.php>
- 5.2.4 The following Standard Operating Procedures (SOPs) support staff regarding reporting and reviewing incidents and can be found on iCare-
 - SOP for reporting an incident through Datix
 - SOP to review an incident
 - SOP for Medicines Incident Reporting

Each incident needs to be graded using the risk matrix (appendix 4).

- 5.2.5 Where the incident involves a patient or service user the details of the incident along with the ‘INC’ number should also be recorded in the medical/ care

records. This should include the date, brief summary of the incident, who treated the patient/service user, the outcome and whether the patient/service user/family have been informed of incident in line with the 'Being Open Policy' and Duty of Candour.

5.2.6 Depending on the severity of the incident the following actions should be performed by the Investigator or Manager (unless otherwise stated). The Quality and Experience Team will monitor, review and follow up these actions with appropriate management and Director level support. This is in line with the South of England Process for reporting and learning from serious incidents requiring investigation.

- If there is a suggestion that a criminal offence has been committed, the police should be contacted.
- If a SIRI requires reporting to the Police or the Health and Safety Executive (HSE) an Incident Coordination meeting will need to be held as per the Memorandum of Understanding between the NHS, Police and HSE.
- Where an incident occurs which could result in a significant impact on the Trust including legal, media or other interest, it is important to ensure that the situation is managed appropriately to safeguard service users, staff and the organisation. This means that any person affected by the incident should, where possible, be notified prior to the media being informed. See Sections 6 and 7.
- The Chief Executive, Chief Operating Officer, Medical Director, Director of Professional Practice and the Trust Communications team must be informed of all incidents that may involve or attract the attention of the media; this would usually be done via the Director on Call.

5.2.7 All patient safety incidents are reported a minimum of monthly to the National Reporting and Learning System. The Care Quality and Safety team upload the incidents direct to the NRLS using Datix. Reports are then produced 6 monthly by the NRLS and published.

5.2.8 SIRI's must be reported to the STEIS system within 48 hours of identifying that the incident is a SIRI.

5.2.9 The Quality and Experience Team will request a chronology report (to be completed in 2 working days if possible) where a SIRI is suspected. The chronology must be reviewed by the Quality and Experience Lead, the Assistant Director of Professional Practice or other appropriate persons delegated this task. If the chronology identifies the incident as a SIRI, it is input into the STEIS system and submitted under the appropriate incident grade. Once an incident is input on to STEIS the Commissioners, CQC and NHS England are automatically notified through the STEIS system. The SIRI incident details will be uploaded from Datix to the NRLS once reported onto STEIS. The Trust Development Authority (TDA) must also be notified of any 'Never Event' and any SIRI Level 2 or 3. The Quality and Experience team

lead and/or the Director/Assistant Director or Nursing and professional practice will ensure that all the required external bodies have been notified.

5.2.10 'Never events' are classed as SIRI's and must be reported on STEIS. The Trust ensures compliance with reporting and liaison requirements with agencies such as Monitor, the Trust Development Authority, the Care Quality Commission (CQC), Public Health England, the Health and Safety Executive, and coroners. Never Events are clearly defined as serious incidents and therefore, must be reported to the CQC. (See **appendix 3**)

5.2.11 "What should happen when a never event is suspected". The CQC may use information on never events to inform its regulatory processes in conjunction with other indicators. Following a never event, the CQC may take any enforcement action it deems appropriate.

5.2.12 Where further clarity regarding grading is required, guidance will be sought by the Quality and Experience Team from commissioners or NHS England on a case by case basis with advice from specialist sources where appropriate.

5.2.13 With the exception of STEIS reporting (described in 5.2.6) the reporting to other external agencies should be done by the relevant lead (where required/appropriate) as described in the table below:

Type of Incident	External Agency	Trust Lead / Manager
Incident involving a medical device	MHRA	Medical Electronics Manager
Any breach of confidential personal identifiable information	Information Commissioner Office (ICO), Strategic Health Authority (SHA)	Head of Information Governance
RIDDOR incident	Health & Safety Executive (HSE)	Health and Safety Manager
Incidents likely to result in litigation against the Trust	NHS Litigation Authority	Company Secretary
Drug incident	Medicines Control Agency	Head of Medicines Management
Security Incidents	SIRS	Local Security Management Specialist (LSMS)
Infection Control Incidents	Health Protection Authority (HPA)	Lead Infection Control and Decontamination Nurse
Substances hazardous to health including Asbestos	Health & Safety Executive (HSE)	Head of Estates
Fire	Fire Service	Fire Advisor
Food Hygiene	Environmental Health	Head of Facilities
Fuel leak	Environment Agency	Head of Estates

5.3 Reporting Timescales

5.3.1 The timescales for completion of incidents reported on Datix is dependent on the severity rating:

- Low harm/no harm/near miss incidents – 1 month from reported date
- Moderate/severe/Death incidents – 3 months from reported date which allows for appropriate investigations to take place.

This means the time from first reporting the incident to when it is 'Finally Approved'.

5.3.2 The timescale for completion of investigations for SIRI's will be dependent on the grade of the serious incident as reported on STEIS. The following timescales will apply which are in line with the current 2015 serious incident investigation framework :

STEIS SIRI Level	Application	Product/ outcome	Owner	Timescale for completion
Level 1 Concise internal investigation	Suited to less complex incidents which can be managed by individuals or a small group at a local level	Concise/ compact investigation report which includes the essentials of a credible investigation	Provider organisation (Trust Chief Executive/relevant deputy) in which the incident occurred, providing principles for objectivity are upheld	Internal investigations, whether concise or comprehensive must be completed within 60 working days of the incident being reported to the relevant commissioner All internal investigation should be supported by a clear investigation management plan
Level 2 Comprehensive internal investigation (this includes those with an independent element or full independent investigations commissioned by the provider)	Suited to complex issues which should be managed by a multidisciplinary team involving experts and/or specialist investigators where applicable	Comprehensive investigation report including all elements of a credible investigation	Provider organisation (Trust Chief Executive/relevant deputy) in which the incident occurred, providing principles for objectivity are upheld. Providers may wish to commission an independent investigation or involve independent members as part of the investigation team to add a level of external scrutiny/objectivity	

<p>Level 3 Independent investigation</p>	<p>Required where the integrity of the investigation is likely to be challenged or where it will be difficult for an organisation to conduct an objective investigation internally due to the size of organisation or the capacity/ capability of the available individuals and/or number of organisations involved.</p>	<p>Comprehensive investigation report including all elements of a credible investigation</p>	<p>The investigator and all members of the investigation team must be independent of the provider. To fulfil independency the investigation must be commissioned and undertaken entirely independently of the organisation whose actions and processes are being investigated.</p>	<p>6 months from the date the investigation is commissioned</p>
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5.3.3 On rare occasions, extensions to the above timescales can be agreed. Extensions must be agreed with the Lead Commissioner. The reason for the extension must be included in the ‘further information’ section of the Strategic Executive Information System (STEIS) incident form.

5.4 Duty of Candour

In compliance with the NHS Constitution for Duty of Candour and the Trusts Being Open Policy all patient safety incidents that occur during care provided by the Trusts services that result in moderate or severe harm or death (using NRLS definitions) the following actions to inform patients, families or carers must take place. (Contractually this does not apply to low/no harm incidents however best practice is that these should be reported to the patient). Full details of the Trust’s “Being Open” policy is available on the Trust’s public web site.

5.4.1 The patient or their family / carer must be informed that a suspected or actual patient safety incident has occurred within at most 10 working days of the incident being reported to local systems and sooner where possible.

5.4.2 The initial notification must be verbal (face to face where possible) unless the patient cannot be contacted in person or declines notification. Providers must take into account any circumstances that will affect ease of communication with the patient (language barriers, communication difficulties, relevant disability). The verbal notification must be accompanied by an offer of a written notification. The notification must be recorded by the reporter on the Datix system.

5.4.3 It may initially be unclear whether a patient safety incident has occurred, or what degree of harm was caused. This is not a reason to avoid disclosure.

Patients or their carers / families must be told if there is a suspected patient safety incident within 10 working days of the incident being reported. They should be given all the facts that are known at the time, and be kept updated throughout the process of investigation.

- 5.4.4 An apology must be provided – a sincere expression of sorrow or regret for the harm caused must be provided verbally and in writing. This does not require fault to have been demonstrated (Being Open Policy) Expressing regret for harm caused is not the same as admitting liability and the risk of litigation should not prevent an apology.
- 5.4.5 A step by step explanation of what happened, in plain English, based on the facts, must be offered as soon as is practicable. This may constitute an initial view, pending an investigation, but patients and families must be kept informed of progress.
- 5.4.6 Full written documentation of any meetings must be maintained, according to the principles of Being Open guidance. If the patient or their family / carer explicitly decline any offers of meetings, this must be clearly recorded and open to audit.
- 5.4.7 Information that emerges during an investigation or subsequent to the initial explanation will be offered to patients and their carers / families as soon as is practical. Regular updates will be provided to affected individuals should they wish to be informed. Any incident investigation reports should be shared with the affected individuals within 10 working days of being signed off as complete if they so wish.
- 5.4.8 All SIRI investigations which are submitted to the Commissioners contain clarification as to whether the Duty of Candour has been applied. Copies of the documentation and information given to the patient and their family / carer will be available on request, observing compliance with contractual requirements, data protection and Caldicott principles.
- 5.4.9 There may be circumstances where a patient safety incident is not reported on Datix, but the Trust becomes aware from a third party, (e.g. commissioners, CQC) via an MP letter for example. These incidents (if resulting in moderate or severe harm or death) are also subject to the contractual duty of candour and, in addition, may represent further failures in reporting. Incidents that have not been reported are, by their nature, harder to detect and verify. Where a relevant patient safety incident is found to have occurred and not been reported on Datix and to the patient, this should be treated extremely seriously.
- 5.4.10 For incidents assessed as a SIRI, a senior clinician will be identified as the key point of contact with the service user / relatives/ family or to undertake this discussion and ensure that the service user is kept informed. Where appropriate, follow-up counselling should be offered and a referral made to the appropriate service. During and following an investigation, contact must be maintained with the service user and key people as above (should they so

wish), ensuring they are kept informed of progress at all times and that the outcome is discussed with them. They should be informed of the Trust's Complaints Procedure.

5.5 Internal Communication

The table in 5.2.13 details who should be informed when particular types of incidents occur. In addition to this, Datix will notify the lead/manager or matron to whom the incident has been allocated to as the reviewer by the incident reporter. Datix will also automatically notify specialist teams depending on the incident category and sub-category (for example, the PUP team lead is notified of Pressure Ulcers Grades 3 and 4). When necessary, the Quality and Experience Team will manually notify Zone Managers, Matrons, department managers and/or specialist leads or teams of any internal RCA Investigations or externally reported SIRI's, as well the Director/Assistant Director of Nursing and Professional Practice if required.

5.6 External Stakeholder Notification

Reporting Responsibilities

NHS organisations, including providers of community services, are accountable to commissioning bodies through contracting and commissioning arrangements. NHS organisations are also regulated by the CQC. Section 5.2.9 details which organisations should be notified and who is responsible for notifying them. These notifications should be monitored by the relevant Committee or Group.

6 Communication with Staff

6.1 Communication with staff following an incident

Communication with staff may need to be both pre and post investigation. Staff personally involved in the incident itself and other staff within the organisation may need to be involved in discussions. The Investigator is responsible for communication linked to the investigation, however may involve the line manager and/or HR if they feel would be beneficial. Communications and discussions/ interviews should all be documented within the investigation report. More information is available in the Supporting Staff Involved in an Incident, Complaint or Claim Policy.

7 Media Involvement

7.1 Communications are a vital element of supporting and delivering effective management of serious incidents. The Trust ensures robust communications and media management arrangements are in place for both internal and external communication, through the Communications Strategy.

7.2 In many cases serious incidents can lead to a high level of media attention and not only in the immediate aftermath. The management, investigation and learning from incidents can be triggers for media coverage for an extended

period after the incident itself. The Communications Team should be informed of any incident that may draw media attention.

- 7.3** The Communications Team will work closely with NHS England communications professionals to agree appropriate media handling strategies, working alongside the relevant colleagues responsible for the wider management of the incident. Responsibility for briefing the Department of Health Ministerial Briefing Unit or Media Centre rests with NHS England; therefore they need to be briefed in a timely manner.
- 7.4** In forensic/criminal cases, the police lead all communications with the media and liaise with the relevant agencies where they have involvement in the incident.
- 7.5** The Communications Team and the Lead Investigator will detail how the problem will be understood and how steps being taken to put it right in order to provide reassurance that the risks of the same thing happening again have been minimised. This is the key principle that should inform all public and media contact. The Investigator, Communications Team and Director of Professional Practice / Director on Call will use their judgement in deciding when help lines and counselling are necessary; if, when and how patients are contacted and when to hold press briefings on and off the record, as well as press conferences. Decisions will be taken between the communications professional at the SHA in consultation with the serious incident team and the organisation.
- 7.6** Generally there are three communication categories which will determine how a serious incident may be handled:
- the media is unaware of a serious incident;
 - the media is unaware of a serious incident but should be informed so it can help with the handling of the incident by notifying the general public and/or section of the public of, for example, the need to come forward for re-testing following a screening programme incident; or
 - the media is aware of an incident first and in this case the SHA/commissioning body/provider organisation may have only learned of a problem because it has been publicised by the media or the handling of an on-going serious incident has 'leaked' into the public domain.

Media Unaware of Serious Incident

- 7.7** It is essential that a holding statement for the media is prepared as soon as possible so that the organisation is prepared. This will require revision depending upon how well a subsequent media inquiry is informed.
- 7.8** Some types of incident such as those involving screening programmes can involve contacting patients for recall or reassurance. Where this is the case all attempts should be made to contact patients before the media is alerted (where

the media is unaware of the serious incident or where you have to seek the media's assistance), as long as it does not compromise patient safety in any way. However, contacting patients hugely increases the chances of the serious incident reaching the public domain and the media ahead of planned management. Prior to making contact with patients there should ideally be a reactive media handling strategy in place. However, any delay in such circumstances should not place patients at any increased risk of harm.

- 7.9** Another source of information reaching the public domain is from health care staff. Such instances may be accidental or deliberate. For example, if staff believe managers are not taking seriously their concerns about a serious incident or if they do not seem to be acting on their warnings then there is a high likelihood of the story 'leaking' to the media. See the Supporting Staff Policy for more details.

Media Unaware but Proactive Media Handling Necessary

- 7.10** A proactive media approach should be followed where time and wider public health concerns can only be addressed through this route, for example, after the loss of personal data records where the only way a large number of patients can be contacted is by public appeal.
- 7.11** The Communications Team will work in line with the Communications Strategy to ensure the media is handled in a timely and robust way.

Media Aware of Serious Incident

- 7.12** Those directly involved in the incident, including the investigation team and head of communications, need time, space and support and it is the role of communication leads to provide this space whilst keeping journalists informed. This includes planning for the next stage, posing solutions and recommended handling to help support investigation and use the team most effectively. Under these circumstances the need to rapidly establish the facts and fully understand the extent of the problem and its cause is even more essential.
- 7.13** It is important to keep the public and media informed and share communications with partner agencies in advance of public information release, whilst balancing the needs of the affected people, staff and patients. The Communications Strategy and the Major Incident Plan should be referred to for more information.

8 Hotline Arrangements

- 8.1** Where a serious incident may have implications for a number of service users or necessitate the activation of the emergency plan the Director on Call must be contacted. They will then inform NHS England and hold discussions with the Chief Executive; the Trust should then consider setting up an Incident Room with Helpline support. The on-call Director can be contacted through the Switchboard on 01803 614 567. The Major Incident Plan may need to be referred to.

9 Incident Investigation

9.1 Incident Grading and Appropriate Levels of Investigations

Adverse incidents and near misses are subject to an appropriate level of investigation and root cause analysis and where relevant an action plan for improvements prepared. Not all events need to be investigated to the same extent or depth and the investigation and analysis should be relative to the seriousness, complexity of the event and/ or whether it resulted in actual harm and the potential for learning, such as those which are high frequency but may be of low severity. Further details can be found in the Investigation Policy: For the Investigation of Incidents, Complaints and Claims Policy.

9.2 Responsibility for Investigation

The Quality and Experience Team will determine if an investigation is required and if so at what level. Once the level of investigation is determined the Quality and Experience Team will liaise with the operational management to appoint an Investigator. An individual appointed as an Investigator must have completed the appropriate training. Depending on the severity of the incident and the grading if it is a SIRI the investigator will be required to produce a Concise Investigation Report or a Comprehensive Investigation Report. Timescales for completion of the report will be agreed by the Investigator and the Quality and Experience Team at the outset of the investigation.

Where other Trusts/agencies need to be brought into the management of a serious incident the Quality and Experience Team will advise the investigator accordingly. Each organisation involved will appoint a lead, with one investigator overseeing the entire investigation.

Allegations of abuse should always be referred immediately to the Single Point of Contact and a safe guarding alert raised (see section 13 for contact details). Safeguarding investigations are coordinated by those arrangements and should not begin independently of them.

9.3 Involving Service Users and their Families in Investigations into Serious Incidents

Note: Patients and families have the right to request information held by public authorities (Freedom of Information Act 2000, Data Protection 1998). This includes access to medical records and any associated documentation (The Re-use of Public Sector Information Regulations SI 2005/1515). This should be considered when writing incident investigation reports and actions. For more information refer to Information Governance Policies and Procedures.

9.4 Involvement of Relevant Stakeholders

There may be a need to involve external agencies such as the Health and Safety Executive (HSE), the Medicines and Healthcare products Regulatory Agency (MHRA), the police or the Environmental Health Agency (EHA) etc. in an investigation. They may be needed to help investigate certain incidents

which may be outside the expertise of those within the organisation. It is the responsibility of the lead investigator to contact these agencies when they feel it is appropriate, if they are unsure they should discuss this with the Quality and Experience Team. Section 13 provides a list of external contacts.

9.5 Recommendations and Action Planning

Following an investigation the Investigator should provide recommendations to the relevant manager(s) and to the Quality and Experience Team. From these recommendations an Action Plan should be drawn up by the relevant manager. Action plans should include persons responsible and the date for completion. These should then be shared with the Quality and Experience Team and the relevant Committee (depending on the type of incident).

9.6 Monitoring of Action Plans

Action Plans are monitored by the Quality and Experience Team, the Care Quality and Safety Group and the Commissioners. The owner of the action plan will be required to report on progress to the group at agreed intervals in line with the due completion dates for the actions.

9.7 Learning and Sharing Lessons

Following an investigation and the production of an Action Plan it is important to ensure that the organisation takes risk reduction measures and that the post investigation actions have been and continue to be effective. This is covered in the Learning from Incidents, Complaints and Claims Policy.

9.8 Sharing of Lessons Learnt

The sharing of the lessons learnt post investigation is a critical part of incident management. Learning from patient safety incidents is a collaborative, decentralised and reflective process that draws on experience, knowledge and evidence from a variety of sources. The learning process is a process of change evidenced by demonstrable, measurable and sustainable change in knowledge, skills, behaviour and attitude. Learning can be demonstrated at organisational level by changes and improvements in process, policy, systems and procedures relating to patient safety within healthcare organisations. Individual learning can be demonstrated by changes and improvements in behaviour, beliefs, attitudes and knowledge of staff at the front line of healthcare delivery.

9.9 What Constitutes Learning

Learning following an incident should be linked to safety related policy, practice and process issues raised by the incident. Examples of learning are given below:

- Solutions to address incident root causes which may be relevant to other teams, services and provider organisations;
- Identification of the components of good practice which reduced the potential impact of the incident, and how they were developed and supported

- Systems and processes that allowed early detection or intervention which reduced the potential impact of the incident;
- Lessons from conducting the investigation which may improve the management of investigations in future;
- Documentation of identification of the risks, the extent to which the risks have been reduced, identified and how this is measured and monitored.

Learning points should be grouped or themed to help the reader(s) identify those points applicable to their team, service, speciality, division or wider organisation.

9.10 Identifying Issues which may be of National Significance

Investigations may identify issues of national significance or where the dissemination of national learning is appropriate. Organisations such as the NRLS, MHRA, HPA, HSE, etc. have review, response and alert mechanisms for urgent incidents. As already stated, relevant incidents should be notified to these bodies as part of the serious incident reporting process and provider organisations should subsequently share findings from investigations with these bodies where issues of potential national learning for wider sharing are identified.

9.11 Learning from Serious Case Reviews (SCR)

Executive representatives from the NHS are part of the local Safeguarding Adults Board (SAB) arrangements in each area and they are responsible for ensuring that communication between the SAB and the NHS Board is maintained. Learning lessons is the prime rationale of SCRs, and SABs are responsible for commissioning each SCR; sharing the learning across all organisations; and monitoring at agreed review periods whether the lessons have been taken on board. The SAB is responsible for ensuring that they receive regular progress reports on a commissioned SCR and to take action if the delay appears unreasonable.

10 Training

10.1 Training will be provided through the Trust's Corporate Induction Programme to ensure that all staff have a basic understanding of risk management. It is the responsibility of managers to ensure that all staff under their line management are trained to report incidents in accordance with this policy. This must be included in local induction programmes.

10.2 The Quality and Experience Team will provide training on the use of Datix for incident reporting and reviewing. Training can also be arranged for chronology writing and conducting a Root Cause Analysis investigation. This can be on an individual basis or for larger groups/teams. This will be arranged on request.

10.3 Training is provided in line with the organisations Training Needs Analysis. All managers and potential investigators must complete training to gain an in-depth understanding of risk management, be able to review incident forms, risk assess and understand the purpose of risk registers. This training

is provided by the Quality and Experience team. This should include the principles of Root Cause Analysis (RCA) and the NPSA Being Open Framework 2010. They should be supported in their continued development of knowledge and skill in incident reporting, investigator training and risk management principles.

- 10.4** Nominated Trust Senior managers/leads have a higher level of investigator training, providing the Trust with a core team of investigators with expert skills of using root cause methodologies, report writing and skills to critically review the quality of investigations.

11 Monitoring Compliance with the Document

- 11.1** The Quality and Experience Lead (or nominated deputy) will carry out a review on every completed investigation report looking at quality and compliance with this and related policies.
- 11.2** The Quality and Experience Team review all incidents twice, after they are initially reported and prior to giving final approval/ uploading to the NRLS. Data integrity reports are run monthly to ensure compliance with the NRLS reporting standards. The NRLS also provide compliance data which is presented to the Care Quality and Safety Group Monthly.
- 11.3** The Quality and Experience Team produce monthly reports detailing the breakdown of reporting across locations. This will demonstrate compliance with the policy across the organisation and/or identify areas for improvement. The reports and any associated action plans will be shared with the Care, Quality and Safety Group and the Quality, Safety and Clinical Risk Committee.

12 References

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Legislation

- Health and Safety (Consultation with Employees) Regulations 1996 SI 1996/1513
- Public Interest Disclosure Act 1998

13 Important Contact Details

- **Quality and Experience Team**
Bay House
Nicholson Road
Torquay
Tel: 01803 210 585 or 01803 210451
Email: incidentreporting.t-sd@nhs.net

- **Safeguarding Adults Team (Torbay)**
 - **Office** – 01803 218831 (not for SA alerts)

 - **Safeguarding Adult Alerts for Torbay unitary boundaries**
Single Point of Contact
3rd Floor Union House
Union Street
Torquay
TQ1 3YA
Tel: 01803 219888
Email: safeguarding.alertstct@nhs.net

- **Safeguarding Adults Team (Southern Devon – Devon County Council)**
Care Direct
Tel: 01392 382 339
Web: www.devon.gov.uk/safeguarding-adults

- **MCA/DLS**
Tel: 01803 219832
Fax: 01803 219863
Email: dolstorbay@nhs.net

- **Safeguarding Children Teams**
 - **Torbay and Southern Devon NHS Safeguarding Team**
Advice and support line Mon –Fri 9am -5pm
01803 208659
Mob-07810834583
safeguardingchildren.tct@nhs.net

 - **Children’s services Safeguarding HUB Torbay**
In hours – 01803 208100
Out of Hours – 01803 524519
torbay.safeguardinghub@torbay.gcsx.gov.uk

- **Children's services Safeguarding MASH Devon**
In hours – 0345 155 1071
Out of hours – 0845 6000 388
mashsecure@devon.gcsx.gov.uk

- **Children's Services Safeguarding HUB Plymouth**
In hours – 01752 306340
Out of Hours- 01752 346984
childprotect@plymouth.gcsx.gov.uk

- **On call Manager Torbay (Torbay Hospital switchboard)**
Tel: 01803 614567

- **Local security Management Specialist**
Tel: 07766504698

- **Medicines management Team**
Tel: 01803 217393
- Email: providermmteam.t-sd@nhs.net

- **Health and Safety Team**
- Tel: 01803 656802 or 01803 656815

- **Head of Communications**
- Direct: 01803 656720 | Internal: 56720

14 Appendix 1 Incident Reporting Process

Any member of staff witnessing an incident should ensure the service user/staff/area are safe and report the incident via Datix



If the incident is of a serious nature or gives any concerns regarding its impact, staff should inform their line manager immediately and the Quality and Experience Team. If it should occur 'out of hours' contact the on call manager



If there are any suspicious circumstances staff should contact the Local Security Management Specialist (see section 13 for contact details) ensure area safe and secure pending any police investigation



Always consider Safeguarding if you have any concerns that the incident has resulted from abuse or neglect and inform the appropriate service (see section 13 for contact details)



Complete an incident form on Datix for all incidents within 8 hours of occurrence with as much information as possible.

Log into Datix via Icare home page and select "Incident reporting"

Ensure Clinical and Care records are accurate and complete



- Once submitted the incident form is directed to the Line Manager to review, complete immediate actions and escalate as appropriate
- If it is a Serious Incident Requiring Investigation this should be ASAP and for all incidents within 2 working days.

If the incident is potentially a Serious Incident Requiring Investigation (SIRI) or if we need further information the Quality and Experience Team will request a chronology report to be completed within two working days of the incident being identified



If required, the Quality and Experience Team will appoint an investigator



Investigator completes investigation (type of investigation dependant on the incident) and an action plan with the support of the Quality and Experience Team

Please remember any written communication regarding incidents should go through the Datix 'communication and feedback' system. This gives an audit trail and keeps all relevant information within Datix (see 'Incident Reviewing Procedure SOP')

15 Appendix 2 NHS England Never Event List 2014/15

	Description
1.	Wrong site surgery <ul style="list-style-type: none"> All patients receiving NHS funded care
2.	Wrong implant/prosthesis <ul style="list-style-type: none"> All patients receiving NHS funded care
3.	Retained foreign object post-procedure <ul style="list-style-type: none"> All patients receiving NHS funded care
4.	Mis – selection of a strong potassium containing solution <ul style="list-style-type: none"> All patients receiving NHS funded care
5.	Wrong route administration of medication <ul style="list-style-type: none"> All patients receiving NHS funded care
6.	Overdose of Insulin due to abbreviations or incorrect device <ul style="list-style-type: none"> All patients receiving NHS funded care
7.	Overdose of methotrexate for non-cancer treatment <ul style="list-style-type: none"> All patients receiving NHS funded care
8.	Mis – selection of high strength midazolam during conscious sedation <ul style="list-style-type: none"> All healthcare premises.
9.	Failure to install functional collapsible shower or curtain rails <ul style="list-style-type: none"> All mental health inpatient premises.
10.	Falls from poorly restricted windows <ul style="list-style-type: none"> All patients receiving NHS funded care
11.	Chest or neck entrapment in bedrails <ul style="list-style-type: none"> All settings providing NHS funded healthcare, including NHS funded patients in care home settings, and equipment provided by the NHS for use in patients' own homes.
12.	Transfusion or transplantation of ABO-incompatible blood components or organs <ul style="list-style-type: none"> All patients receiving NHS funded care.
13.	Misplaced naso- or oro-gastric tubes <ul style="list-style-type: none"> All patients receiving NHS funded care
14.	Scalding of patients <ul style="list-style-type: none"> All patients receiving NHS funded care.

For the full NHS England document detailing Never Events please follow the following links:

[2015-2016 Never Events Policy Framework](#)

[2015-2016 Never Events List](#)

[2015-2016 Never Events Frequently Asked Questions](#)

16 Appendix 3

What should happen when a never event is suspected



Diagram reproduced from 2015-2016 Never Events Policy Framework

17 Appendix 4

Assessment of Risk

Assessment of Likelihood of Risk

	1 Rare	2 Unlikely	3 Possible	4 Likely	5 Certain
1 Minimal	1	2	3	4	5
2 Minor	2	4	6	8	10
3 Moderate	3	6	9	12	15
4 Major	4	8	12	16	20
5 Catastrophic	5	10	15	20	25
Impact	1 Minimal	2 Minor	3 Moderate	4 Major	5 Catastrophic
Clinical/Safety	No injury / prevented incident Minor cuts, bruising	Extra Observation / Treatment First Aid Major cuts, bruising Minor illness	Further treatment needed Referred to other department / hospital /A&E Additional treatment required up to 1 year RIDDOR reportable non-major injury	Major injury - RIDDOR reportable Major clinical intervention Permanent incapacity Unexpected death Death caused by the incident	Multiple deaths
Health & Safety	No physical harm or injury	First Aid Cuts / bruising No lost time	Referral to A&E Up to 7 days absence	RIDDOR reportable	Multiple deaths
Financial	£1000- £20,000	£20,000- £100,000	£100,000- £500,000	£500,000- £2.5m	Above £2.5m
Legal		Tribunal / NHSLA involvement (potential for claim)	Defensible legal action	HSE prosecution or other criminal prosecution. Civil litigation (1 person)	HSE prosecution or other criminal prosecution (major) Civil litigation (> 1 person)
Performance		Failure to meet local standards	Failure to meet national standards	Failure to meet professional standards or statutory requirements	Sustained failure to meet professional standards or statutory requirements
Reputation	Written complaints (some verbal complaints may be considered, depending upon context)	Letters in local press	Adverse articles in local press. S4BH lapse.	Adverse letters/articles in National Press. S4BH lapse	Major censure by Healthcare Commission, Ombudsman, etc. Press 'scandal'

Score	Description	Description
1	Rare	Exceptional circumstances only: e.g. less than 1 per year
2	Unlikely	Could occur at some time: e.g. quarterly
3	Possible	May occur / recur occasionally: e.g. monthly
2	Unlikely	Could occur at some time: e.g. quarterly
5	Certain	Likely to occur on many occasions, a persistent issue: e.g. daily