The Reporting and Investigation of Adverse Events (including Being Open and Duty of Candour)

Document Control Sheet

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<tr>
<th>Q Pulse Reference Number</th>
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This policy supersedes all previous issues.
**Version Control - Table of Revisions**

All changes to the document must be recorded within the ‘Table of Revisions’.

<table>
<thead>
<tr>
<th>Version number</th>
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<tr>
<td>001</td>
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<td>New Policy – combining Reporting and Investigation of Adverse Events (POL-CCPS-RM-4 and Being Open and Duty of Candour Policy POL-CCPS-Comp-3) CCPS-RM-4 policy number shall remain</td>
<td>Risk Manager</td>
<td>15 May 2017</td>
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1. Introduction

The Trust aims to provide high quality and safe care to all service users, ensuring that our staff are safe whilst at work. Unfortunately due to the nature of our services Adverse Events can occur. The timely reporting and investigation of Adverse Events is an essential part of an open and honest culture, which in turn improves staff and patient safety. Through the identification of actual or potential (near miss) Adverse Events, the subsequent investigation to identify what, how and why it happened and the implementation of learning should reduce or prevent the recurrence of similar Adverse Events.

Themes and trends of the most reported Adverse Events can be utilised as wider learning for the Trust in order to prioritise required developments.

The North East Ambulance Service NHS Foundation Trust (the Trust) is committed to proactively encouraging staff to raise concerns through appropriate channels.

The Trust has systems and processes for reporting of Adverse Events. Staff will also be advised of the Freedom to Speak Up; Raising Issues of Concern (Whistle blowing) Policy (EXT-CE-DOC-1) although the Trust would expect this would only be required in exceptional circumstances.

In terms of Patient Safety Incidents, the Trust recognises the effects of harming a patient can be widespread (emotional and physical) and can be distressing for the professionals involved. The Trust recognises the importance of Being Open and compliance with the legal Duty of Candour, sharing information about what happened and the importance of discussing patient safety Adverse Events promptly, fully and compassionately and how this can help patients and professionals to cope better with the after effects.

2. Purpose

This Policy provides staff with the necessary detail to ensure that Adverse Events are reported in a timely manner and appropriately managed, investigated and practice-change implemented Trust wide in order to improve safety for patients, staff, visitors and contractors.

This policy also provides a best practice framework to create an environment where patients, families, carers, healthcare professionals and managers all feel supported when things go wrong and have the confidence to act appropriately. The policy also offers advice on how to communicate with patients, their families and carers under the guiding principles of ‘Being Open’.
3. Scope
The Policy will apply to all Adverse Events that:

- occur in/on any Trust premises;
- occur off Trust premises but involve persons employed by the Trust whilst on Trust business;
- affect the delivery of, or the business continuity of, services;
- affect an individual to whom the organisation owes a duty of care including: patients, visitors, the public and Trust employees, including those seconded, people on work experience or training placements and any subcontractors;
- that are engaged by the Trust i.e. working as third party providers.

4. Duties - Roles & Responsibilities

4.1 Trust Board of Directors
The Trust Board are committed to ensuring the delivery of safe high quality care and are responsible for ensuring that learning from, trends and themes when things go wrong are acted upon and managed effectively so that services are improved as a result.

Reports, risks and assurances relating to Adverse Events and application of the 'Being Open' principles and Duty of Candour are presented to the Board of Directors via the risk management committees/groups (see 4.3)

4.2 Chief Executive
The Chief Executive has overall responsibility for risk management and any related policies and procedures to ensure the safety of patients and staff. These duties are delegated onto the Director of Quality and Safety.

4.3 Committees and Groups
The following Committees/Groups are involved in the monitoring and review of investigations arising from Adverse Events and associated Being open and Duty of Candour processes;

- Quality Committee
- Quality Governance Group
- Patient Safety Group
- Strategic Health and Safety Committee
- Vehicle Risk Management Group
- Experience Complaints Litigation and PALS Group (ECLIPS)
- Executive Risk Management Group
- Serious Incident Review Group
The Quality Committee has overall responsibility for gaining assurances that Adverse Events are being managed in a timely and effective manner, that lessons learned are disseminated effectively throughout the Trust and for monitoring compliance with the Duty of Candour process.

4.4 **Director of Quality and Safety**

The Director of Quality and Safety has delegated responsibility to ensure;

- Adverse Events are pro-actively actioned;
- an Adverse Event trend analysis is undertaken;
- monitoring of agreed investigation action plans to gain assurances;
- a review of the effectiveness of actions taken to reduce the likelihood of a recurrence of Adverse Events;
- Compliance with the Being open and Duty of Candour process.

4.5 **Executive Directors**

All Executive Directors will ensure within their service areas that;

- this Policy is implemented;
- all Adverse Events are investigated and application of the Duty of Candour where relevant are carried out within the agreed timescales unless an extension is agreed;
- all associated action plans within their service area are progressed to completion.

4.6 **Heads of Services**

Heads of Services will ensure that:

- staff are encouraged to report Adverse Events;
- they are reported within the required timeframe;
- Adverse Events are appropriately investigated and investigation leads are provided with appropriate training, resource and time;
- ‘Duty of Candour requirements are implemented through to completion;
- investigation reports and feedback are used to improve the quality of service.

4.7 **Senior Managers and Operational Managers**

Senior Managers are responsible for;

- the investigation of all Adverse Events which have an actual impact of moderate harm, severe harm or death within the respective statutory and agreed timescales;
- meeting the requirements of the Duty of Candour for those patient safety incidents where severe harm or death have occurred.
4.8 Managers, Emergency Care Clinical Managers, PTS Team Managers

Manager, Emergency Care Clinical Managers and PTS Team Managers are responsible for

- the investigation of all Adverse Events which have an actual impact of low harm, no harm and near miss within the respective statutory and agreed timescales;
- meeting the requirements of the Duty of Candour for those patient safety incidents where moderate harm has occurred.

4.9 Irrespective of level all Investigating Officers (IOs) will ensure that;

- the Risk & Regulatory Services team is notified of any unavoidable delays in their investigation as soon as possible;
- for moderate harm cases and above, a comprehensive report is produced, supported with recommendations and action plan including any corrective actions that have already taken place;
- all local actions are implemented as soon as possible;
- all learning points are communicated to the relevant parties;
- consider support that may be required for individuals during the investigation i.e. for staff the offer of Counselling and Occupational Health Services.

4.10 Risk Manager

The Risk Manager will oversee the management of Adverse Events and Duty of Candour within the incident module of Trust’s integrated Risk Management system (Ulysses Safeguard) and ensure;

- the appropriate investigating officers are automatically notified;
- summary reports of Adverse Events and Duty of Candour are sent to the Trust Service Lines and appropriate groups/committees as required;
- action plans are monitored effectively;
- support/advice in connection with this Policy is provided to managers and staff;
- this Policy is reviewed and maintained.

4.11 Patient Safety Manager

The Patient Safety Manager will oversee the management of Serious Incidents and Duty of Candour (for Serious Incidents) within the Incident Module of Trust’s integrated Risk Management system (Ulysses Safeguard) and ensure;

- action plans are monitored effectively;
- for Serious Incidents, Family Liaison Officers are identified and appointed to fulfil the Duty of Candour requirements,
• provide support/advice in connection with this Policy is provided to managers and staff;

4.12 Serious Incidents Officer

The Serious Incidents Officer will fulfil the day to day management duties of Serious Incidents and Duty of Candour (for Serious Incidents) within the Incident Module of Trust’s integrated Risk Management system (Ulysses Safeguard) and ensure;

• action plans are monitored effectively;
• for Serious Incidents, Family Liaison Officers are identified and appointed to fulfil the Duty of Candour requirements,
• provide support/advice in connection with this Policy is provided to managers and staff;

4.13 Family Liaison Officers

For Serious Incidents an appropriately trained and resourced member of Trust staff, a Family Liaison Officer (FLO) will be the point of contact throughout an investigation between the patient and family and the Trust. The FLO will be appointed by the Quality and Safety Directorate.

4.14 All Staff

All Staff will:

- report all Adverse Events within the agreed timeframe
- ensure information is factual and consideration given to data quality i.e. no Personal Identifiable Information (PII) is used in the body of the report
- co-operate fully with any investigation conducted on behalf of the Trust and provide all factual information that may assist in the investigation.
- ensure all learning points communicated to them are implemented
- take corrective action immediately to prevent a reoccurrence
- demonstrate the principles of ‘Being Open’ and Duty of Candour when a patient safety incident occurs

It is the responsibility of all NEAS employees to adhere to this Policy.
### 5. Glossary of Terms

This following terms are either used in the Policy or are of particular reference

<table>
<thead>
<tr>
<th>Term</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>Adverse Event</strong></td>
<td>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. Adverse Events encompasses incidents and accidents as well as those defined as Serious Incidents</td>
</tr>
<tr>
<td><strong>Accident (HSE Definition)</strong></td>
<td>“any unplanned event that resulted in injury or ill health of people, or damage or loss to property, plant, materials or the environment or a loss of business opportunity”</td>
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</table>
| **Incident (HSE Definition)** | A single distinct event, including;  
  ✓ a near miss incident under slightly different circumstances may have resulted in injury or ill health of people, or damage or loss to property, plant, materials or the environment or a loss of business opportunity”  
  ✓ other incidents i.e. threatening behaviour  
  ✓ Dangerous Occurrence |
| **Near Miss**                 | An unplanned event that did not result in injury, illness or damage – but had the potential to do so and could therefore happen again                                                                               |
| **Patient Safety Incident (PSI)** | Any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS care                                                                                       |
| **Serious Incident**          | “An incident or near miss occurring on health service premises or in relation to health services provided, resulting in death, serious injury or harm to patients, staff or the public, significant loss or damage to property or the environment, or otherwise likely to be significant public concern”. |
| **Never Event**               | A ‘serious, largely preventable patient safety incident that should not occur if the available preventative measures have been implemented by healthcare providers                                                   |
| **Death**                     | Any patient safety incident that directly resulted in the death of one or more patients receiving NHS-funded care. Any other Adverse Event resulting in a fatality of a staff member, member of the public, escort, visitor, contractor, third party provider engaged by the Trust. |
| **Severe Harm**               | Any patient safety incident that appears to have resulted in permanent harm to one or more patients receiving NHS-funded care. Also;  
  ✓ serious injury or harm to a staff member, member of the public, escort, visitor, contractor, third party provider engaged by the Trust.  
  ✓ a road traffic collision involving a NEAS vehicle resulting in any vehicle involved becoming unroadworthy (recovered from scene rather than being driven) and deemed a total loss or requiring significant repair and/or substantial ‘downtime’.  
  ✓ Loss or misuse of controlled drugs  
  ✓ Loss or misuse of airwaves radio equipment |
| **Moderate Harm** | Any PSI that resulted in a moderate increase in treatment and that caused significant but not permanent harm to one or more patients receiving NHS funded care. Moderate harm means harm that requires a moderate increase in treatment, and significant, but not permanent, harm, for example a “moderate increase in treatment” means an unplanned return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another treatment area. Also

- an Adverse Event resulting in a moderate injury or harm to a staff member, member of the public, escort, visitor, contractor, third party provider engaged by the Trust.
- a road traffic collision involving a NEAS vehicle resulting in any vehicle involved becoming unroadworthy (recovered from scene rather than being driven) and requiring repair / ‘downtime’ as a result.
- 'Loss or misuse of non-controlled drugs |

| **Low Harm** | Any PSI that required extra observation or minor treatment* and caused minimal harm to one or more patients receiving NHS-funded care. Also

- Any adverse event that required extra observation or minor treatment and caused minimal harm to a staff member, member of the public, escort, visitor, contractor, third party provider engaged by the Trust. |

| **No Harm** | Adverse event prevented – any adverse event / PSI that had the potential to cause harm but was prevented, and no harm was caused to patients receiving NHS-funded care or staff member, member of the public, escort, visitor, contractor, third party provider engaged by the Trust. Adverse event not prevented – any adverse event / PSI that occurred but no harm was caused |

| **Investigation** | The act or process of investigating – a detailed enquiry or systematic examination |

| **Root Cause Analysis** | A systematic process whereby the factors that contributed to an Adverse Event are identified as part of an investigation technique which looks beyond the individual concerned and seeks to understand the underlying causes and environmental context in which an Adverse Event happened |

| **Accident at Work (DWP Definition)** | “An ‘accident’…means any unintended happening or Adverse Event at work that has arisen out of and in the course of employment, and has resulted in a personal injury” “Generally an accident which happens when you are at work is accepted as having happened as a result of your work, unless there is some evidence that this is not so”. |
| Reporting of Injuries, Diseases and Dangerous Occurrence (RIDDOR) | The Trust is legally required under the RIDDOR Regulations of 1995, to report all accidents and Adverse Events defined in the regulations to the Health and Safety Executive within 15 days of the accident/Adverse Event occurring. This includes any Adverse Event involving a member of staff that results in any of the following:
- Death;
- Major injury;
- Hospital admission over 24 hours;
- More than 7 days absence from work.
The Trust also has a legal obligation to record any incidences of an employee being absent from work for longer than 3 days as a result of an injury incurred in the course of duties performed for the Trust. |
| Being Open | Open communication of PSIs that result in harm or the death of a patient while receiving healthcare |
| Duty of Candour (NHSLA Definition) | A legal duty on NHS Trusts to inform and apologise to patients if there have been mistakes in their care that have led to significant harm. Duty of Candour aims to help patients receive accurate and truthful information from health providers. |
| Apology | A sincere expression of regret offered for harm sustained or service delivery failure. |
| Patient's carers. Family and friends | The patient has consented to their being informed of their confidential information and to their involvement in any decisions about their care. |
| Complaint | An expression of dissatisfaction by one or more members of the public about the Trust's action or lack of action, or about the standard of a service, whether the action was taken by the Trust itself or by somebody acting on behalf of the Trust. |
| Liability | Legal responsibility for an action or event |
| Litigation Claim | An action brought in court to enforce a particular right. The act or process of bringing a lawsuit in and of itself; a judicial contest |
6. Policy Content

6.1 Reporting Adverse Events

Adverse Events must be reported using Ulysses Safeguard system, except in the event of a technical failure whereby Adverse Events should be reported manually using the paper form (FM-CCPS-RM-1).

All Adverse Events resulting in moderate harm, severe harm or death must to be reported before the end of the shift by the staff member involved in the Adverse Event. If this is not possible then they should be reported by another member of staff on their behalf such as a line manager or on call officer.

All Adverse Events resulting in a near miss, no harm or low harm should also be reported by the staff member involved in the Adverse Event or another member of staff on their behalf by end of the shift, but within 3 days at the latest.

For online Adverse Event reporting guidance staff can refer to the Ulysses Safeguard – Incident Module WEB System (QSSD-CCPS-RM-2)

The Trust has obligations under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) 1995 to report all injuries to employees as a result of an accident at work that led to incapacitation of the employee for more than seven days to the Health & Safety Executive (HSE) within 15 days of the Adverse Event that caused the incapacitation. For guidance staff can refer to Adverse Events Requiring Immediate Notification to the Health and Safety Executive (SOP-CCPS-HS-4).

Any Adverse Event report forms received more than 3 days after an Adverse Event cannot be accepted, unless the employee can provide legitimate reasons for the delay in submitting the report. The employee will be required to explain in writing any extenuating circumstances behind the delay, and it shall be a matter for the line manager as to whether the Adverse Event should be investigated.

For those incidents reported late where there are legal requirements under (RIDDOR), this may influence the decision as to whether a line manager may accept the Adverse Event for investigation. However each case will be considered on its own merit. Equally any Patient Safety Incident should be accepted if reported late, due to the National reporting requirements laid out by NHS England.

6.2 The Investigation of Adverse Events

6.2.1 Identifying which Adverse Events need to be investigated

It is not possible for the Trust to conduct detailed investigations into each and every Adverse Event. Adverse events are therefore notified to the appropriate line manager based on the level of harm, who would then be expected to review/investigate and take appropriate action and then close this.
6.2.2 Adverse Events Resulting in Moderate Harm, Severe Harm or Death

These will require review and investigation by the notified manager as soon as possible, but no later than 24 hours after notification. They must also endeavour to contact the staff involved within 60 minutes to offer advice, guidance and support.

In the event of an Operational (Emergency Care or PTS), Adverse Event resulting in moderate harm, severe harm or death a member of the crew must notify the respective Operations Centre immediately.

In the event of a staff physical assault, the relevant Emergency Operations Centre Duty Manager must be notified who must then comply with the Management of Violence and Physical Assaults – Control Guidelines (SOP-CCPS-SM-7).

If a Road Traffic Collision (RTC) renders the Trust vehicle un-roadworthy the crew must remain at the scene until an IO, and/or a backup crew, arrive, unless they themselves require transporting to hospital.

Where death, injury or serious damage occurs, the on call Executive Director must be informed as soon as practicable.

Upon being made aware of the Adverse Event, the recipient (likely to be the Operations Centre Duty Manager) must:

- If 'in hours', contact the nearest available relevant Manager/
- If 'out of hours' contact the nearest on-call Officer.

The nominated Manager/on-call Officer must assume responsibility for conducting the initial enquiries.

The investigation of the Adverse Event will then be transferred to the relevant line manager as soon as practically possible.

For all other (non-operational) staff, the person concerned must notify their Line Manager as soon as possible.

For such Adverse Events that occur between the hours of 0800 and 1700 Monday to Friday, the Investigating Officer/Line Manager must notify the Risk & Regulatory Services Department immediately. If the Adverse Event has occurred outside of these hours, then the Risk & Regulatory Services Department must be notified at the beginning of the next working day.

If the Adverse Event requires immediate notification to the HSE (SOP-CCPS-HS-4) then the IO/Line Manager will do this in conjunction with the Risk & Regulatory Services Department.
Road Traffic Collisions (RTCs)

When the Investigating Officer/Line Manager arrives on-scene and liaises with the crew/injured party they must, after an appropriate interval, conduct an interview. An online Adverse Event report form must be completed for each person injured. In addition for RTCs or vehicle theft a NEAS 03 form must be completed by the person responsible for the vehicle, this will usually be the driver at the time of the incident, even if the vehicle was stationary at the time. Statements must be taken from each witness as far as is reasonably practicable.

If treatment has been administered, capture fullest details where possible; if equipment/vehicle is involved, take photographic evidence, a note of serial number(s) and set equipment aside for further investigation/inspection, which may be done independently.

The staff member/IO/Line Manager must take appropriate action at the time to prevent a recurrence of the accident (i.e. either remove the hazard, or remove the injured party away for treatment/rest).

The Investigating Officer/Line Manager will collate all documents (including memos written, line manager’s comments etc.) and write an investigation report and will make recommendations for risk control measures where appropriate.

This report, together with all documentation must then be uploaded to Ulysses Safeguard.

Further investigations may be deemed necessary and could result in independent investigators being appointed by i.e. the Trust’s Motor Insurers or the NHSLA.

Liaison with the North of England Commissioning Support (NECS) / Clinical Commissioning Groups (CCGs) may also take place in respect of potential or actual Serious Incidents.

The investigation is to be completed within 28 days unless an extension of time is required and agreed with the Risk and Regulatory Services Department and staff involved or the investigation has a prescribed time frame i.e. Serious Incidents.

6.2.3 Near Miss, No Harm or Low Harm Adverse Events

All Adverse Events resulting in a near miss, no harm and/or low harm require investigation by the notified line manager.

The investigation is to be completed within 28 days unless an extension of time is required and agreed with the Risk and Regulatory Services Department and staff involved.

The IO must review all evidence, causes, and will make recommendations for risk control measures where appropriate.

Upon completion of the investigation, the investigating officer will complete their response onto Ulysses Safeguard which will automatically provide feedback directly to the staff involved.
6.2.4 Accidents at Work

Where an employee triggers 3 separate occasions of absence as a result of accidents at work within a 12 month period, a panel consisting of representation from Risk & Regulatory Services, HR and the individual’s Line Manager will meet to discuss the cases in detail and agree a way forward. The root cause of these accidents at work must be identified and discussed. The outcome of the panel may include further training for the employee, further analysis into either equipment failure or role/task investigation and if safe practices are applied. If it is determined that the injury was due to the individuals own negligence and/or acts and omissions then further investigations and discussions may be undertaken.

6.3 The Investigation Process

This Trust’s investigation process seeks to answer when, where, who, what, why and how questions? The Trust’s preferred choice of investigation method is Root Cause Analysis for those cases where moderate harm and above has been confirmed. By repeatedly asking the question ‘why?’ (Using five why’s a rule of thumb), the Investigator/RCA Review Panel can peel away the layers of an issue, which can lead to the root cause of a problem. The reason for a problem can often lead into another question and the investigator/RCA Review Panel may need to ask the question fewer or more than five times before they get to the origin of a problem. The real key for the investigator/RCA Review Panel is to avoid assumptions and logic traps and encourage them to keep drilling down to the real root cause.

6.3.1 Root Cause Analysis (RCA)

Unless the fundamental, or root causes of adverse events are properly understood, lessons will not be learned and suitable improvements will not be made to reduce the risk. Adverse Events rarely arise from a single cause. There are usually underlying failures in management systems, which have helped to create the circumstances leading to the Adverse Event.

The purpose of root cause analysis is to identify the immediate, contributory and root causes of the Adverse Event and recommend remedial actions through an improvement strategy/action plan. The Trust convenes a RCA meeting when required, whilst membership will vary depending on the nature of the adverse event itself. Typically the attendees will include senior Trust representation from the following areas:

- Quality and Safety Directorate (Clinical and/or Risk)
- Service Lines (i.e. Emergency Operations Centre, Emergency Care and PTS)
- Training
- IO
- Experts from specific fields
- FLO (if appointed)
In all but exceptional cases, staff involved in the Adverse Event, as well as any identified external stakeholders, are routinely invited to the RCA meeting.

### 6.3.2 Involving External Agencies

From time to time the Trust will need to involve external agencies in its investigation and learning processes. For certain types of Adverse Event the decision to involve an external body in the investigation process is an immediate one and/or a statutory duty. The table below sets out guidance on which agencies may be involved, who is responsible for alerting them and time scales. Where the requirement is immediate the on call Executive Director must be notified and or involved in the decision. Notwithstanding the above, time should not be lost in making the initial contact.

The table below is not an exhaustive list. Further clarification can be obtained from the Risk and Regulatory Services Department if required.

<table>
<thead>
<tr>
<th>Responsible Person(s)</th>
<th>Timescale</th>
<th>External Agency</th>
<th>Type of Adverse Event</th>
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<tbody>
<tr>
<td>Duty Control Manager</td>
<td>Immediate</td>
<td>Police, Fire &amp; Rescue Service</td>
<td>Serious RTC involving a Trust vehicle, crime, industrial accident resulting in serious injury or death, Fire on Trust premises.</td>
</tr>
<tr>
<td>Director of Finance and Resources and/or the Head of Risk or Risk Manager</td>
<td>As soon as is reasonably practicable</td>
<td>Police and Health and Safety Executive</td>
<td>Security related Adverse Events i.e. assaults, theft, criminal damage etc.</td>
</tr>
<tr>
<td>Director of Quality and Safety and/or the Head of Risk</td>
<td>As soon as is reasonably practicable or as statute requires</td>
<td>MHRA Health &amp; Safety Executive Other NHS organisations Police Social Services</td>
<td>Serious medical equipment failures/faults Breaches of H&amp;S Legislation, i.e. COSHH, RIDDOR Allegations against staff</td>
</tr>
<tr>
<td>Head of Risk</td>
<td>Immediate</td>
<td>Care Quality Commission (via NHS England / NRLS)</td>
<td>Notification of a death of a person who uses services / death of member of staff whilst on duty</td>
</tr>
<tr>
<td>Safer Care Manager</td>
<td>As soon as is reasonably practicable</td>
<td>NHS England / NRLS</td>
<td>Patient Safety Incidents</td>
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6.3.3 Gathering Information

It is extremely important to gather as much factual information as soon as possible and should aim to provide the answer to the following questions;

- Who was involved?
- What happened?
- Where did it happen?
- Why did it happen?
- When did it happen?
- How did it happen?

6.3.4 Mapping the Events

The Trust uses timelines as a tool for mapping a chronological chain of events. They are useful to identify any information gaps, critical problems that arise, points of inefficiency and possible opportunities for improvement.

6.3.5 Analysing the Information

Once information has been gathered the IO can start to piece together the sequence of events and to start understanding why the Adverse Event occurred. Where appropriate, i.e. Serious Incidents or Adverse Events where there are significant learning opportunities, the Trust will, analyse the information further using a RCA Panel and various RCA tools, i.e. the fishbone, barrier analysis etc.

6.3.6 Developing Solutions and an Action Plan for Implementation

It is important that the Trust learns from the investigation of Adverse Events.

Following the investigation an agreed action plan will be drawn up by the Trust’s IO and/or Root Cause Analysis Review Panel that sets out how each recommendation from the investigation will be implemented. This action plan (which will be in the Trust’s standard format) will include a named responsible person/job role department and agreed timescales. The following subjects should be considered during the process of creating an action plan (this list is not exhaustive and is for reference only);

- Whether training and/or capability gaps are identified;
- Mechanisms to ensure appropriate actions are taken where referral of a health professional to his/her professional body is indicated;
- Arrangements for ensuring that improvements in practice are implemented and evaluated;
- Arrangements for the dissemination of learning within the organisation and, where appropriate, across the wider NHS.

Changes need to be realistic, sustainable and cost effective and incorporated into the way staff work at all levels of the organisation.
6.3.7 Completing a Report

The RCA meeting will review an investigation following conclusion of the report. The relevant department will monitor the subsequent Action Plans relating to their specialist area. The Risk and Regulatory Department will have oversight to ensure action plans are closed once completed.

6.3.8 Challenging a Report's Findings

Where the reporter objects to the findings of an Investigation Report, they must set out their objections in writing to the Line Manager of the Investigating Officer.

The appropriate Line Manager should consider the submissions made by complainant and provide a response in writing, either making changes to the Investigation Report where appropriate or explaining to the complainant why their concerns have not been upheld.

If the complainant remains dissatisfied following a response to their complaint, the complainant has the right to ask the Root Cause Analysis Panel to consider their concerns. The complainant should make such a request in writing.

The RCA Panel shall then review the Investigation Report, the objections of the complainant and the explanation provided by the relevant Line Manager. The RCA Panel can make changes to an Investigation Report if it is thought necessary. The Root Cause Analysis Panel should explain their final decision in writing to the complainant, the IO and the appropriate Line Manager. The decision of the RCA meeting is final.

6.4 Being Open and the Duty of Candour

The effects of harming a patient can be widespread. Patient safety incidents can have devastating emotional and physical consequences for patients, their families and carers and can be distressing for the professionals involved.

‘Being Open’ about what happened and discussing patient safety incidents promptly, fully and compassionately can help patients and professionals to cope better with the after effects. Openness and honesty can also help to prevent such events becoming formal complaints and litigation claims.

A number of the benefits to Being Open for patients, their family and carers, healthcare staff and healthcare organisations are shown in Figure 1.
The Duty of Candour sets out some specific requirements that providers must follow when things go wrong with care and treatment (moderate, severe harm or death incidents). The Duty of Candour is a legislative requirement (came into force 27 November 2014) Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 and also a requirement per the NHS standard contract (since 2013) and a CQC registration requirement (Regulation 20).

6.4.1 What does ‘Being Open’ mean?

‘Being Open’ about what happened and discussing events promptly, fully, openly, honestly and compassionately can help patients, families, carers and professionals cope better with the after effects. The guiding principles are;

- Acknowledging, apologising and explaining when things go wrong
- Conducting a thorough investigation into the adverse events and reassuring patients, their families and carers that lessons learned will help the event from recurring
- Providing support for those involved, patients, families, carers and/or staff to cope with the physical and psychological consequences of what happened.

---

**Figure 1 – Benefits of Being Open**

<table>
<thead>
<tr>
<th>Healthcare organisations and teams</th>
<th>Healthcare professionals</th>
<th>Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>• A reputation of respect and trust for the organisation and/or team;</td>
<td>• Confident in how to communicate effectively when things go wrong;</td>
<td>• Receive a meaningful apology and explanation when things go wrong;</td>
</tr>
<tr>
<td>• Reinforces a culture of openness;</td>
<td>• Feel supported in apologising and explaining to patients, their families and carers;</td>
<td>• Feel their concerns and distress have been acknowledged;</td>
</tr>
<tr>
<td>• Potentially reduces the costs of litigation;</td>
<td>• Feel satisfied that communication has been handled in the most appropriate way;</td>
<td>• Reassured that the organisation will learn lessons to prevent harm happening to someone else;</td>
</tr>
<tr>
<td>• Improves the patient experience and satisfaction with the organisation;</td>
<td>• Improved understanding of incidents from the perspective of the patient, their family and carers;</td>
<td>• Reduce the trauma felt when things go wrong;</td>
</tr>
<tr>
<td>• A reputation for supporting staff when things go wrong;</td>
<td>• Know that lessons learned from incidents will help prevent them happening again;</td>
<td>• Have greater respect and trust for the organisation.</td>
</tr>
<tr>
<td>• Embodies the NHS Constitution for England pledge to patients around <em>Being open</em>;</td>
<td>• Gain a good reputation for handling a difficult situation well.</td>
<td>• Reassured that they will continue to be treated according to their clinical needs.</td>
</tr>
<tr>
<td>• Embodies the work of the ‘Putting Things Right’ project in Wales;</td>
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<td></td>
</tr>
<tr>
<td>• Greater opportunity to learn when things go wrong.</td>
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<td></td>
</tr>
</tbody>
</table>
The Trust follows the 10 principles laid out within the national framework to create and embed a culture of 'Being Open' prescribed within the national framework:

- Acknowledgement
- Truthfulness, timeliness and clarity of communication
- Apology
- Recognising patient and carer expectations
- Professional support
- Risk management and systems improvement
- Multidisciplinary responsibility
- Clinical governance
- Confidentiality
- Continuity of care

6.5 Being Open and Duty of Candour Process

The 'Being Open' process begins with the recognition that a patient has suffered harm or has died as a result of an unexpected event in the course of their care. As soon as an event is detected the top priorities are prompt and appropriate clinical care and prevention of further harm.

If the staff involved are aware of the adverse event at the time of treatment/attendance they should ensure that a verbal apology is afforded wherever possible. This must then be followed up by formally reporting the adverse event.

If the incident is considered to have caused moderate or severe harm or caused the death of a patient then it will be subject to Duty of Candour requirements.

6.5.1 Choosing the individual to communicate with patients, their families or carers

Ultimately for all cases requiring Duty of Candour, the Head of Service/Department Manager is accountable for compliance. They may delegate the formal duty however they must be assured this has taken place and the case updated using the Ulysses Safeguard system.

The individual appointed to enact the Duty of Candour will be dependent on the severity of the issue.

Ordinarily for moderate harm cases the Head of Service/Department Manager will delegate responsibility to the appointed investigating officer for enacting Duty of Candour and updating the case using the Ulysses Safeguard system.

For Serious Incidents (severe harm or death) a suitably trained Family Liaison Officer (FLO) is responsible for enacting Duty of Candour. FLO’s will be appointed by the Serious Incidents Officer and managed by the appointed Senior Investigating Officer. The ultimate accountability for ensuring
compliance with Duty of Candour remains with the Head of Service/Department Manager.

Those enacting the Duty of Candour must;

- have a good grasp of the facts relevant to the event;
- be senior enough or have sufficient experience and expertise in relation to the type of event to be credible to the patient, their family or carer;
- have excellent interpersonal skills, including being able to communicate in a way that can be easily understood and avoids excessive use of medical jargon;
- be willing and able to offer a meaningful apology, reassurance and feedback;
- be able to maintain a medium to long-term professional relationship with the patient, their family or carer, if required.

6.5.2 Application of ‘Being Open’ and Duty of Candour

The patient or their family/carer must be informed that a suspected patient safety incident has occurred within 28 days of the incident being reported to local systems, and sooner where possible, other than in exceptional circumstances i.e. a case where there is an ongoing criminal investigation.

The initial notification must be verbal and face to face where possible and will be followed by a letter from the appropriate manager. An apology must be provided, a sincere expression of sorrow or regret for any suspected harm caused must be provided verbally and in writing.

The nominated person or FLO must;

- liaise with the IO to establish the facts and agree/understand the aims of the meeting to be held with the patient and/or relatives and others;
- use this opportunity to identify the needs of the patient and/or relatives;
- confirm the date, time and venue in writing (including email).
- provide factual feedback to the patient or representatives at the earliest opportunity and be kept up to date on progress;
- Ensure no communication errors arise by giving unsubstantiated facts as this can create anxiety;
- record meetings (for SIs use a FLO Log) and ensure details are then entered into/attached to the case in the Ulysses Safeguard risk management system within 24 hours of the meeting.

The patient and/or the relatives and others should be given the opportunity to choose:

- Whom they would prefer to meet with;
- Where and when the meeting will be held (it is usually for the patient/relative to decide and for the Trust to accommodate);
- Whether they would like to bring a friend to the meeting;
6.5.3 Involving Trust staff, after the event, who have made mistakes

Some events will have resulted from errors made by Trust staff without their immediate knowledge at the time. In these circumstances the member(s) of staff may or may not wish to participate in the ‘Being Open’ discussion with the patient or their family/carers. Such cases need to be considered individually, balancing the needs of the patient, their family and carers. In cases where they choose to attend to apologise personally, they should feel supported by their colleagues. In cases where the member(s) of staff feel unable to attend, then consideration should be given to them providing a written apology to be given to the patient and/or carer during the initial discussion.

6.5.4 The Initial ‘Being Open’ Discussion

The initial Being Open discussion with the patient, their family or carer is the first part of an ongoing communication process and should occur as soon as possible after recognition of the event. Where moderate or severe harm is deemed to have occurred this should be verbal or face to face where possible but must take place within 28 days of the incident being declared, to satisfy conditions relating to Duty of Candour requirements.

Factors to consider when timing this discussion include the clinical condition of the patient, the patient preference (when and where the meeting takes place), privacy and comfort for the patient, availability of the patient’s family or carer, availability of key staff involved and availability of support staff (i.e. a translator or advocate etc).

6.5.5 First Meeting

The discussion should cover the following:

- An expression of genuine sympathy, regret and a meaningful apology for the harm that occurred;
- The facts that are known at that time, as discussed/agreed with the IO.
- That an investigation is being carried out and more information will become available as it progresses including time frames;
- The patient’s understanding of what happened is noted, as well as any questions they may have (these must be fed to the IO) so that an informed response can be given;
- Give the patient and/or relatives an opportunity to ask as to why they thought it went wrong and an error occurred;
- An offer of practical and emotional support. For example from charities and voluntary organisations. Information about such groups can be obtained from the Patient Advice and Liaison Service (PALS) or from Patient UK on www.patient.co.uk
• Inform the patient and/or relative(s) and others what steps are being/will be taken to prevent the incident recurring;
• Agree with the patient and/or relatives and others any future meetings as appropriate;

It is essential that the following does not occur:

• Speculation
• Attribution of blame
• Denial of responsibility
  ▪ Provision of conflicting information from different individuals

There may be reasonable adjustments required relating to individual circumstances to consider prior to a meeting i.e.

• Children present
• Patients with mental health issues
• Patients with cognitive impairment
• Patients with learning disabilities
• Patients who do not agree with the information provided
• Patients with a different language or cultural considerations
• Patients with different communication needs

More information can be found within the National Reporting and Learning Service – Communicating with Patients, their Families and Carers guide – p28
www.nrls.npsa.nhs.uk/EasySiteWeb/GatewayLink.aspx?alId=65172

6.5.6 Follow-up Discussion

Depending on the event a follow up discussion or discussions with the patient, their family or carer may be required and in these circumstances providing updates on known facts and responding to any queries is an important step in the ‘Being Open’ process. It should be agreed at the initial ‘Being Open’ meeting how this will be relayed, a point of contact and the frequency of communication.

6.5.7 Process Completion

For patient safety incidents involving Severe Harm or Death, a letter of apology signed by the Chief Executive or Director of Quality and Safety or nominated deputy will be sent, explaining how and, if possible, why the error occurred. This letter will also clarify the information previously provided; reiterate key points, and record action points and future deadlines

The communication should include:

• The chronology of clinical and other relevant facts;
• Details of the patient’s and/or their carers concerns;
• A repeated apology for the harm suffered and any shortcomings in the delivery of care that led to the event;
• A summary of the factors that contributed to the event; and
• Information on what has been and will be done to avoid recurrence of the event and how these improvements will be monitored.

It is expected that in most cases there will be a complete discussion of the findings of the investigation and analysis. In some cases information may be withheld or restricted. For example, in rare cases, where communicating information will adversely affect the health of the patient; where investigations are pending; or where specific legal requirements preclude disclosure for specific purposes.

6.5.8 Documentation

Throughout the ‘Being Open’ process it is important to record and retain discussions with the patient, their family or carer. The amount of documentation that will be required will be dependent on the specifics of the issue. For more serious issues, particularly when a full investigation has taken place, a full written record of the ‘Being Open’ discussions should be made. For these cases the detail should be recorded in a Family Liaison Log (FM-CCPS-RM-13).

All records must be uploaded to Ulysses Safeguard by the nominated person or FLO. The following shall require evidencing:

• The record of an open and honest apology;
• Sharing any facts that are known and agreed with the patient/carers;
• An invitation to the patient/carers to participate in the investigation and to agree how they will be kept informed of the progress and results of that investigation; An explanation of any likely short and long-term effects of the incident; A clear response to questions the patient/carer may have;
• An offer of appropriate practical and emotional support to the patient/carer;

6.6 Performance Management

6.6.1 Quantitative and Reports

Quantitative and qualitative reports will be presented to the Trust groups and committees (see 4.3).

Ulysses Safeguard will allow quantitative and qualitative information together with exception reports relating to adverse events to be collated and presented in reports. Information may include a breakdown of adverse events by number, type, area, the top 5 reported, actual impact and details of compliance with the investigation timeframe, application of the Duty of Candour, investigation recommendations and actions (list not exhaustive).

Representatives of the committee/group will be charged with the responsibility of disseminating relevant information to appropriate groups through a variety of methods such as Patient Care Updates, Health and Safety Bulletins, annual reports,
staff training/conferences/meetings and the Trust’s media sources (The Pulse magazine, Weekly Summary and Intranet).

6.6.2 Learning from Experience

Internally

The Trust is committed to sharing trends, themes and lessons learnt post investigation throughout the organisation at all levels. The Trust collates statistics and trends relating to adverse events, feedback from the application of the Duty of Candour and risks on the Ulysses Safeguard.

Trends and themes are analysed on this information to help inform associated risk registers.

The Trust ensures lessons learnt from analysis result in change in organisational culture and practice by:

- Reflection and learning
- Incident debrief
- e-mail correspondence;
- Internet and Intranet sites;
- SharePoint sites i.e. Operations Centre ‘The Lamp’
- Weekly Summary (Trust wide) with specific Risk Department topics
- Patient Care Updates, Bulletins / Alerts (i.e. safety, security)
- NEAS staff magazine (The Pulse)
- Information shared by various Committees and Groups
- Statutory and Mandatory Training
- Training including specific training Events, Podcasts and DVDs
- Rapid Performance Improvement Workshops
- Document Development (i.e. Policies, Procedures, SOPs, guidance)
- Meetings (staff / public)
- Monitoring of Action Plans by the internal Trust Committee/Groups

This list is not exhaustive

Evidence of lessons learnt and actions taken as a result of adverse events will be retained in Ulysses’ Safeguard i.e. Investigation RCA Panel Minutes. Other repositories will include for example;

- Committee/Group minutes and associated Actions Registers
- National Benchmarking data
- Claims/NHSLA Solicitors Risk Management Reports

Externally
The Trust is also committed to sharing this information, where appropriate, with the wider health community, including:

- Participation in other organisation RCA Panel reviews
- Clinical Commissioning Groups (CCG’s) for Serious Incidents;
- Her Majesty’s Coroners where evidence at an Inquest gives rise to a concern that circumstances creating a risk of other deaths will occur or continue to exist in the future.

The Coroner has powers to take action by publicising their concerns in order to try to prevent similar events from occurring in the future. This action is known as a 'report under regulation 28' or a Preventing Future Deaths report.

The Chief Executive or nominated deputy attends the national Ambulance Directors Risk, Safety and Governance meetings where risk management approaches are shared. The Head of Risk and the Head of Patient Safety attend regional and national Patient Safety and Clinical Governance Forums and participate in national benchmarking workstreams.

7. Training Required

7.1 Staff Training

In accordance with the Education, Learning and Development Policy (POL-WOD-TD-1) and reflected in the annual Risk Management Training Needs Analysis all new staff will receive risk management/Adverse Event reporting training as part of their induction programme. Refresher training will also be provided via the Statutory and Mandatory Training program or specifically introduced training courses.

Additional training will be provided, where appropriate, to Managers and any other nominated staff member conducting investigations for Adverse Events and fulfilling the role of Family Liaison Officer for Serious Incidents. This training may be provided in combination with an external provider i.e. Trust’s Solicitors, the Police etc. and may include the following:

- Statement taking
- Investigation Techniques
- Root Cause Analysis
- Report Writing
- Family Liaison

8. Equality and Diversity

The Trust is committed to ensuring that, as far as is reasonably practicable, the way we provide services to the public and the way we treat our staff reflects their
individual needs and does not discriminate against individuals or groups on the
grounds of any protected characteristic ( Equality Act 2010). An equality analysis has
been undertaken for this policy, in accordance with the Equality Act (2010).

An equality analysis has been undertaken for this policy, in accordance with the
internal Equality Policy and the Equality Act (2010); Appendix A.

Details of this assessment are stored within the central register for Equality Analysis
Assessments maintained within the Equality and Diversity team within the
Communications and Engagement department.

9. Monitoring Compliance with and Effectiveness of
this Policy

9.1 Compliance and Effectiveness Monitoring

Arrangements for the monitoring of compliance with this policy and of the
effectiveness of the policy are detailed below. The reporting and investigation of
Adverse Events is monitored by reports to various Trust groups and Committees
(1.2.1), which then feed into the Trust Board.
### 9.2 Compliance and Effectiveness Monitoring Table for this policy

<table>
<thead>
<tr>
<th>Process in the policy</th>
<th>Key Performance Indicators (KPI)/ Criteria</th>
<th>Method</th>
<th>Who By</th>
<th>Committee / Group</th>
<th>Frequency</th>
<th>Learning / Action Plan</th>
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</thead>
<tbody>
<tr>
<td><strong>Overall Adverse Event reporting levels</strong></td>
<td>Appropriate reporting of adverse events increases</td>
<td>Integrated Governance Report</td>
<td>Risk &amp; Regulatory Services Department</td>
<td>Trust Board</td>
<td>Monthly</td>
<td>Reporting levels are reported to monitor compliance and implement any changes to improve the position.</td>
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<td>Integrated ECLIPS Report</td>
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<td>Quality Review Group</td>
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<td>ECLIPS Group</td>
<td>Monthly</td>
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<tr>
<td><strong>Provision of reports showing reporting and management of adverse events</strong></td>
<td>Directorates/Departments/Groups/Committees receive regular reports relating to reporting/management of adverse events</td>
<td>Integrated Governance Report</td>
<td>Risk &amp; Regulatory Services Department</td>
<td>Trust Board</td>
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<td>Health and Safety Reports</td>
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<td>Patient Safety Group</td>
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<td>Patient Safety Report</td>
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<td>Serious Incident Review Group</td>
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<td>Serious Incident Reports</td>
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<td>Monthly</td>
<td>Trends/themes are reported to monitor compliance and implement any changes to improve the position.</td>
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<tr>
<td><strong>Compliance with investigation/closure of adverse events</strong></td>
<td>Directorates/Departments/Groups/Committees receive regular reports relating to reporting/management of adverse events, specifically the investigation/closure within policy timescales.</td>
<td>Integrated Governance Report</td>
<td>Risk &amp; Regulatory Services Department</td>
<td>Trust Board</td>
<td>Monthly</td>
<td>Closure/investigation timescales is reported to monitor compliance and implement any changes to improve the position.</td>
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<td>Integrated ECLIPS Report</td>
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<td>Quality Review Group</td>
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<td>Process in the policy</td>
<td>Key Performance Indicators (KPI)/ Criteria</td>
<td>Monitoring and audit</td>
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<tr>
<td><strong>Duty of Candour</strong></td>
<td>Directorates/Departments/Groups/Committees receive regular reports relating to the reporting/management of Duty of Candour within policy timescales.</td>
<td><strong>Integrated Governance Report</strong>&lt;br&gt;Integrated ECLIPs Report</td>
<td><strong>Risk &amp; Regulatory Services Department</strong>&lt;br&gt;Trust Board Quality Review Group Quality Committee Quality Governance Group ECLIPs Group</td>
<td><strong>Committee / Group</strong>&lt;br&gt;<strong>Frequency</strong></td>
<td><strong>Learning / Action Plan</strong>&lt;br&gt;Enactment of the Duty of Candour is reported to monitor compliance and implement any changes to improve the position.</td>
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<tr>
<td><strong>Compliance with mandatory external reporting</strong></td>
<td>Directorates/Departments/Groups/Committees receive regular reports relating to the reporting/management of adverse events reported to external agencies, i.e. RIDDOR, NRLS.</td>
<td><strong>Integrated Governance Report</strong>&lt;br&gt;Integrated ECLIPs Report Health and Safety Reports Integrated ECLIPs Report Patient Safety Report Serious Incident Reports</td>
<td><strong>Risk &amp; Regulatory Services Department</strong>&lt;br&gt;Trust Board Quality Review Group Quality Committee Quality Governance Group Strategic Health and Safety Committee ECLIPs Group Patient Safety Group Serious Incident Review Group</td>
<td><strong>Committee / Group</strong>&lt;br&gt;<strong>Frequency</strong>&lt;br&gt;Monthly Monthly Quarterly Bi-monthly Monthly</td>
<td><strong>Learning / Action Plan</strong>&lt;br&gt;Reporting levels are reported to monitor compliance and implement any changes to improve the position.</td>
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<tr>
<td><strong>Provision of reports showing themes and trends of adverse events</strong></td>
<td>Directorates/Departments/Groups/Committees receive regular reports relating to themes/trends of adverse events</td>
<td><strong>Integrated Governance Report</strong>&lt;br&gt;Integrated ECLIPs Report Integrated ECLIPs Report Health and Safety Reports</td>
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<td><strong>Committee / Group</strong>&lt;br&gt;<strong>Frequency</strong>&lt;br&gt;Monthly Monthly Quarterly Bi-monthly Quarterly Monthly Monthly Monthly</td>
<td><strong>Learning / Action Plan</strong>&lt;br&gt;Trends/themes are reported to monitor compliance and implement any changes to improve the position.</td>
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</table>
| Lessons learned from Adverse Events| Directorates/Departments/Groups/Committees receive regular reports relating to learning gained from adverse events | Method: Quarterly Learning Bulletin  
- Integrated Governance Report  
- Health and Safety Reports  
- Integrated ECLIPs Report  
- Patient Safety Report  
- Serious Incident Reports  
Who By: Clinical and Patient Safety Directorate  
Committee / Group: Intranet/Pulse/Summary Trust Board  
- Quality Committee  
- Quality Governance Group  
- Strategic Health and Safety Committee  
- ECLIPs Group  
- Patient Safety Group  
- Serious Incident Review Group  
Frequency: Quarterly  
- Monthly  
- Bi-monthly  
- Monthly  | Lessons learned from Adverse Events                                                                          |
| Data Quality (quality of data input into Ulysses Safeguard) | Not applicable                                                                                           | Method: Routine daily and weekly audit conducted on reported adverse events  
Who By: Risk & Regulatory Services Department  
Committee / Group: Not applicable  
Frequency: Daily  
- Weekly  | Feedback to individual and/or line manager where applicable                                                  |
10. Consultation and Review of this Policy

This policy has been reviewed in consultation with the members of the Trust’s ECLIPs group and Quality Committee and with the Senior Managers within the Clinical Care and Patient Safety Directorate.

11. Implementation of this Policy

This policy will be available to staff via the Trust’s Quality system on the intranet (QPulse).

12. References

This document refers to the following guidance, including national and international standards:


Care Quality Commission – Regulation 20 – Duty of Candour [http://www.cqc.org.uk/content/regulation-20-duty-candour](http://www.cqc.org.uk/content/regulation-20-duty-candour)

13. Associated Documentation

This following Trust documents are particularly relevant or referenced in the Policy

<table>
<thead>
<tr>
<th>Term</th>
<th>Description</th>
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<tbody>
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<td>POL-CCPS-RM-8</td>
<td>Risk Management Policy</td>
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<tr>
<td>STR 11</td>
<td>Security Management Strategy</td>
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<tr>
<td>POL-CCPS-RM-3</td>
<td>Reporting and Investigation of Serious Incidents</td>
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<tr>
<td>FM-CCPS-RM-13</td>
<td>Family Liaison Log</td>
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<td>QSSD-CCPS-RM-2</td>
<td>Ulysses Safeguard – Incident Module WEB System</td>
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<td>SOP-CCPS-HS-4</td>
<td>Adverse Event requiring immediate notification of H.S.E.</td>
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<tr>
<td>FM-CCPS-RM-2</td>
<td>Root Cause Investigate File</td>
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<td>FM-CCPS-RM-1</td>
<td>Adverse Event Report Form</td>
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<tr>
<td>EXT-CE-DOC-1</td>
<td>Freedom to Speak Up; Raising Issues of Concern (Whistle blowing) Policy</td>
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