Trust Policy

Plymouth Hospitals NHS Trust

Incident Management Policy

Date	Version
November 2017	3

Purpose

To set out the procedure for recognising, managing, reporting and investigating incidents and the resulting action planning and implementation of changes.

Plymouth Hospitals NHS Trust expect all staff to be open and transparent with patients in relation to the care and treatment they receive and should anything go wrong, provide patients with reasonable support, truthful information and an apology.

Who should read this document?

All staff

Key messages

Plymouth Hospitals NHS Trust (PHNT) requires that all incidents or near misses involving staff, patients or others are reported, investigated and managed and that learning is identified and action is taken to prevent recurrence.

The Trust is committed to sustaining an honest and open dialogue with patients, families, carers, staff and other healthcare organisations. The aim of this document is to help all members of staff to be open and honest and apologise to patients whenever mistakes are made.

Accountabilities

Production	Risk & Incident Manager; Quality Managers (Surgery & Medicine)
Review and approval	Weekly Executive Quality Governance Meeting Quality Governance & Learning Group Meeting
Ratification	Medical Director and Director of Nursing
Dissemination	Risk & Incident Manager
Compliance	Risk & Incident Manager

Links to other policies and procedures

To be read in conjunction with;

- Serious Incident Requiring Investigation (SIRI) Procedure.
- Management of No & Minor Harm Incidents Procedure.
- Management of Moderate Harm Incidents Procedure.
- Information Governance Serious Incident Requiring Investigation Handling Standard Operating Procedure.
- Major Incident Plan.
- Risk Management Policy.
- Supporting Staff and Raising Concerns Policies.

Version History

1.0	January 2015	Revised by Risk & Incident Manager to reflect Trust's updated governance and accountability structure and NHS England's revised national Serious Incident Framework.
2.0	April 2016	Revised by Risk & Incident Manager to incorporate Duty of Candour requirements.
2.1	November 2017	Revised by Risk & Incident Manager to incorporate General Data Protection Regulation (GDPR) requirements.
3	September 2019	Extended to February 2020 by Steve Mumford

Last Approval	Due for Review
November 2017	Extended to February 2020

The Trust is committed to creating a fully inclusive and accessible service. By making equality and diversity an integral part of the business, it will enable us to enhance the services we deliver and better meet the needs of patients and staff. We will treat people with dignity and respect, promote equality and diversity and eliminate all forms of discrimination, regardless of (but not limited to) age, disability, gender reassignment, race, religion or belief, sex, sexual orientation, marriage/civil partnership and pregnancy/maternity.

An electronic version of this document is available on Trust Documents. Larger text, Braille and Audio versions can be made available upon request.

1 Introduction

Plymouth Hospitals NHS Trust (PHNT) is committed to encouraging and enabling the prompt reporting of all incidents, regardless of severity, throughout the organisation.

The Trust requires that all incidents or near misses involving staff, patients or others are reported, investigated and managed and that learning is identified and action is taken to prevent recurrence.

An increasing trend in numbers of incidents reported is considered a positive sign of a strengthening safety culture. A non-punitive approach to incident reporting is essential to strengthen and support the development of an organisational safety culture.

When Patient Safety Incidents occur, the Trust expects all staff to be open and transparent with patients in relation to the care and treatment they receive and should provide patients with reasonable support, truthful information and an apology.

2 Purpose

When Incidents in healthcare occur, everyone must make sure that there are systematic measures in place to respond to them. These measures must protect patients, staff and others and ensure that robust investigations are carried out, which result in organisations learning from incidents to minimise the risk of the incident happening again.

The purpose of the incident reporting and learning process is:

- To demonstrate assurance of robust governance.
- To facilitate the wide sharing of learning arising locally, regionally, and nationally where appropriate.
- To help prevent reoccurrence where the incident occurred and reduce the chance of a similar incident happening elsewhere.
- To support health service improvement by providing information, guidance and recommendations to support health care managers in directing resources where they are most needed to improve quality and safety.
- To record any risks associated with delayed improvement, or significant continuing incidents, on the Risk Register.

This Policy sets out the responsibilities and procedures associated with all aspects of incident management including the statutory Duty of Candour requirements.

3 Definitions

All staff have a duty to report all incidents regardless of severity to the Trust's incident reporting system, (Datix) and must, therefore, understand what an incident is.

An **Incident** is an event where a patient, a member of staff, or any other member of the public may suffer unexpected harm or injury, either on hospital premises or where health care is being provided.

A **Patient Safety Incident** refers to any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS funded care.

When an incident occurs it must be reported to all relevant bodies and in some cases external bodies also need to be informed;

- The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR) as amended 2013 require a range of incidents to be reported to the Health & Safety Executive (HSE) where an employee is absent from the workplace or unable to carry out their normal duties for more than 7 consecutive days after a workplace injury and any Trust activity or work that adversely impacts on the health and well-being of a patient or visitor to the Trust. The Trust's Health & Safety Advisor is responsible for RIDDOR reports to the Health & Safety Executive.
- Any incident involving a controlled drug should be notified to the Trust's Accountable Officer, the Director of Pharmacy.
- Information related incidents are reported by the Caldicott Guardian & Information Governance Team to the Information Commissioner.
- Radiation incidents are reported by the Radiation Protection Adviser to the appropriate body.
- Incidents that occur in the delivery of an NHS screening programme should be notified to the screening quality assurance (regional) service and the Public Health England (PHE) screening and immunisation team embedded in/associated with the commission of the service.

An incident may result in no harm, minor harm, moderate harm, severe/catastrophic harm or death caused by incident and the level of investigation required will be dependent upon the grading of the incident. Definitions of incident gradings for patient safety incidents can be found below;

Datix Severity Grading and NRLS Definitions	**Duty of Candour requirements**	**Level of Investigation required**
No harm Impact not prevented - any incident that ran to completion but no harm occurred to people receiving NHS-funded care.	Patients are not usually contacted or involved in investigations as these types of incidents are **outside** the scope of the *Duty of Candour*. Openness remains best practice but there is no requirement to follow the Duty of Candour processes.	**Local concise review, led by Service Line** Management of no & minor harm incidents procedure to be followed.
Minor harm Any incident that required extra observation or minor treatment and caused minimal harm, to one or more persons receiving NHS-funded care. Minor treatment is defined as first aid, additional therapy, or additional medication. It does not include any extra stay in hospital or any extra time as an outpatient, or continued treatment over and above the treatment already	Patients are not usually contacted or involved in investigations as these types of incidents are **outside** the scope of the *Duty of Candour*. Openness remains best practice but there is no requirement to follow the Duty of Candour processes.	**Local concise review, led by Service Line** Management of no & minor harm incidents procedure should be followed.

planned. Nor does it include a return to surgery or re-admission.		
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. Moderate increase in treatment is defined as a 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 area such as intensive care as a result of the incident.	***The Duty of Candour requirements are implemented.***	**Local concise review, led by Service Line & overseen by Care Group** Management of moderate harm incidents procedure should be followed.
Prolonged psychological harm Psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days.	***The Duty of Candour requirements are implemented.***	**Local concise review, led by Service Line & overseen by Care Group** Management of moderate harm incidents procedure should be followed.
Severe/ Catastrophic harm Any incident that appears to have resulted in permanent harm to one or more persons receiving NHS-funded care. Permanent harm directly related to the incident and not related to the natural course of the patient's illness or underlying condition is defined as permanent lessening of bodily functions, sensory, motor, physiological or intellectual, including removal of the wrong limb, organ or brain damage.	***The Duty of Candour requirements are implemented.***	**Formal RCA investigation led by Risk & Incident Team** Serious Incident Requiring Investigation (SIRI) procedure should be followed.
Death caused by Incident Any incident that directly resulted in the death of one or more persons receiving NHS-funded care. The death must be related to the incident rather than to the natural course of the patient's illness or underlying condition.	***The Duty of Candour requirements are implemented.***	**Formal RCA investigation led by Risk & Incident Team** Serious Incident Requiring Investigation (SIRI) procedure should be followed.
Near misses Impact prevented – any incident that had the potential to cause harm but was prevented, resulting in no harm to people receiving NHS-funded care.	The NHS body is not required by the regulation to inform a person using the service when a 'near miss' has occurred, and the incident has resulted in no harm to that person however openness remains best practice.	Recurring near misses should be escalated to Care Group and the Risk & Incident Team. Incidents will be reviewed by the Weekly Executive Directors Governance mtg who will confirm level of investigation required.

For investigating no harm, minor and moderate harm incidents the onus is with Service Lines to take ownership for developing the necessary infrastructure for instigating and undertaking an investigation and securely archiving associated documents and data. The investigation process for these incidents can be found on Staffnet *here*.

Those incidents where acts and/or omissions occurring as part of NHS funded healthcare have resulted in severe/catastrophic harm or death of a patient are treated as Serious Incidents Requiring Investigation (SIRI). The Risk & Incident Team are responsible for recording all Serious Incidents on the Strategic Executive Information System (STEIS - The electronic database 'hosted' by the Department of Health). The SIRI Process can be found on Staffnet *here*.

Serious Incidents are events where the potential for learning is so great, or the consequences to patients, families and carers, staff or organisations are so significant. Serious Incidents can extend beyond incidents which affect patients directly and include incidents which may indirectly impact patient safety or an organisation's ability to deliver ongoing healthcare. A list of Serious Incidents can be found via NHS Improvement, on Page 13 of NHS England's SIRI Framework *here.*

The occurrence of a Serious Incident demonstrates weaknesses in a system or process that need to be addressed to prevent future incidents leading to avoidable death or serious harm to patients or staff, future incidents of abuse to patients or staff, or future significant reputational damage to the organisations involved. Serious Incidents therefore require investigation in order to identify the facts that contributed towards the incident occurring and the fundamental issues that underpinned these.

The recognised method for conducting investigations, commonly known as Root Cause Analysis (RCA) should be applied for the investigation of Serious Incidents. **Root Cause Analysis (RCA)** is a systematic investigation technique that looks beyond the individuals concerns and seeks to understand the underlying causes and environmental context in which the incident happened.

Never Events are a sub-set of Serious Incidents and are defined as serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented by healthcare providers. The full list of Never Events can be found via NHS Improvement *here.*

'Near Miss' Incidents

Relying on outcome alone can present another problem as outcome does not always reflect the potential severity that could be caused should the incident occur again. The decision relating to whether or not a 'near miss' should be a serious incident should therefore be based on an assessment of risk that considers;

- Likelihood of the incident occurring again if current systems/process remain unchanged;
- The most likely outcome/ potential for harm to staff, patients and the organisation in terms of reputation and public confidence should the incident occur again.

This does not mean that every 'near miss' should be reported as a Serious Incident but where there is a significant existing risk of a system failing and something going

very badly wrong, the SIRI process should be used to understand and mitigate the risk.

Duty of Candour

As of 1st October 2014, Duty of Candour became a statutory requirement for all Health and Social Care Organisations. This new duty was implemented by Regulation 20 of the Health and Social Care Act 2008 which seeks to ensure that providers are open and transparent in relation to care and treatment provided to people who use their services.

Regulation 20 applies to all CQC registered providers and is a direct response to recommendation 181 of the Francis Inquiry report into Mid Staffordshire NHS Foundation Trust which recommended that a statutory Duty of Candour be introduced for Health and Social Care Providers.

The 'Duty of Candour' requirements reinforce the 'Being Open' principles by placing more emphasis on organisational responsibility. While the duty applies to organisations, not individuals, it is clear that individual PHNT staff must cooperate to ensure the duty is met.

'Being Open' was described by the National Patient Safety Agency (NPSA) in 2009 as 'discussing patient safety incidents promptly, fully and compassionately' adding that this 'can help patient and professionals to cope better with the after effects'.

In interpreting the Duty of Candour regulation we use the definitions of openness, transparency and candour used by Robert Francis in his report (Francis Inquiry report into Mid Staffordshire NHS Foundation Trust);

- **Openness** – enabling concerns and complaints to be raised freely without fear and questions asked to be answered.
- **Transparency** – allowing information regarding the Trust's performance and outcomes to be shared with staff, patients, the public and regulators.
- **Candour** – 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 questions raised.

The statutory Duty of Candour arises where there is believed or suspected to be, a "notifiable patient safety incident". Regulation 20 defines this as 'any unintended or unexpected incident that occurred in respect of a service user… that in the reasonable opinion of a healthcare professional could or appears to have resulted in;

- The death of the service user, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition;
- Severe/catastrophic harm;
- Moderate harm;
- Prolonged psychological harm to the patient.

It should be noted that the statutory Duty of Candour does not refer to recognised complications or undesirable outcomes that occur as part of the natural course of the patient's illness, but rather to safety incidents caused through the provision of care.

A list of Duty of Candour pragmatic examples can be found on Staffnet here.

4 Duties

Trust Board
The Trust Board is responsible for ensuring that appropriate systems are in place to enable the organisation to deliver its objectives in relation to this policy. This includes scrutinising the management of incidents within the organisation, ensuring that incident management processes are effective, compliant with legal, statutory and national requirements and support safety, learning and a just and open culture within the Trust. The Board fully endorses the principles of 'Being Open' and honest and actively promotes an open, honest and fair culture.

Chief Executive
The Chief Executive is responsible for ensuring the infrastructure is in place to report and manage incidents and is ultimately responsible for the process of managing and responding to the Duty of Candour process. The Chief Executive delegates responsibility for the Trust's governance arrangements to the Medical Director and Director of Nursing.

Medical Director and Director of Nursing
Have Executive responsibility for Quality Governance and report directly to the Board and the Chief Executive on all matters relating to Serious Incidents. The Medical Director and Director of Nursing will ensure the Trust has formal arrangements in place for the implementation of Duty of Candour principles.

Weekly Executive Directors Quality Governance Meeting

- Will review completed preliminary investigation reports in more detail and will propose the appropriate level of investigation. This will include confirmation if the incident meets the criteria for a Serious Incident Requiring Investigation (SIRI) and warrants a full Root Cause Analysis Investigation.
- Will provide scope of investigations for all Serious Incidents and are responsible for assigning appropriate Lead Investigators.
- Responsible for executive sign off of final RCA reports for submission to NEW Devon CCG for review and closure.
- Will act upon escalations of concern and will address instances where delivery against the SIRI management process and delivery of subsequent RCA agreed actions are delayed or not progressing.

Quality Governance and Learning Group
The Quality Governance and Learning Group will oversee and monitor the reporting of Serious Incidents and compliance with Trust policy, ensuring that recommendations arising from SIRI investigations are implemented as required and that organisational learning has taken place.

Care Group Management / Corporate Support Service Teams

- Promote incident reporting as part of a positive safety culture by proactively encouraging individuals and teams to be open and honest and learn from errors.

- Provide oversight that incidents are being reported, validated, investigated and that appropriate actions are taken to prevent recurrence within Service Lines.
- Hold Service Lines to account in instances highlighted by the Risk & Incident Team when they fail in their duty to identify, report and/or disclose patient safety incidents.
- Appropriately oversee the management of all moderate incidents within their Service Lines.
- Will act upon escalations of concern and will address instances where delivery against investigation actions are delayed or not progressing.
- Record any risks associated with delayed improvement, or significant continuing risks, on the Care Group Risk Register or escalate to Trust Management Executive via the Risk Management Review Group (RMRG) as required.

Service Line Management / Corporate Support Service Teams

- Promote incident reporting as part of a positive safety culture.
- Support staff who are involved in incident investigations, in line with the Trust‘s Supporting Staff Policy.
- Providing oversight to ensure immediate action has been taken to make the situation safe, preventing escalation of the incident.
- Support the Ward or Departmental Manager in the grading of all incidents on Datix appropriate to the nature and severity of the incident.
- Manage and investigate all moderate incidents within Service Lines, appropriate to the nature and severity of the incident reported.
- Report all serious/catastrophic and moderate incidents to their Care Group Managers/Heads of Nursing and the Risk & Incident Team.
- Support the Ward or Departmental Manager in undertaking the Duty of Candour conversation, ensuring good communication with the patient/family and other relevant persons.
- Responsible for the Duty of Candour written notification to patients/relevant person for ‘Moderate’ Incidents within 10 working days.
- Support the development and implementation of action plans arising from the incident investigation, monitoring the outcome and sharing lessons learned with all relevant staff groups.
- Review and monitor the completion of action plans at Service Line governance meetings.
- Record any risks associated with delayed improvement, or significant continuing risks, on the Service Line Risk Register or escalate to Care Group as required.

Ward/Departmental Manager

- Promote incident reporting as part of a positive safety culture.
- Support staff who are involved in incident investigations in line with the Trust‘s Supporting Staff Policy.
- Responsible for ensuring immediate action is taken to make the situation safe and prevent escalation of the incident.

- Review all Incidents for ward/ department and complete SBA(R)R fields on Datix within 72 hours of Incidents being raised and confirm the correct grading of the incident.
- Initiate an investigation appropriate to the nature and severity of the incident reported within the required timescale (see Appendix 2).
- Report all severe/catastrophic and moderate incidents to their direct Line Manager.
- Undertake Duty of Candour where the severity is moderate or above and document this in the patient's clinical record and on the incident reporting system.
- Interrogate all grades of incidents to identify themes and trends, and develop local action plans to address.
- Responsible for implementation of action plans arising from incident investigations; monitoring the outcome and sharing lessons learned with all relevant staff groups.
- Report the progress on action plans through service line governance meetings.
- Record any risks associated with delayed improvement, or significant continuing risks, on the department/ ward Risk Register or escalate to Service Line as required.

Clinical Governance Leads

- Coordination of the local reporting and management of moderate harm events.
- Ensure timely reporting of SIRIs to the Risk & Incident Team.
- Ensure that SIRI and moderate harm Investigation reports contain effective action plans that promote learning and lead to a reduction in the number and severity of future incidents, complaints and risks.
- Provide an overview on a quarterly basis of the management and learning from all SIRIs and moderate harm investigations supported by the Service Line Manager.
- Oversee the delivery of action plans arising from SIRIs and moderate harm Investigations, in collaboration with the Service Line and Care Group.
- Support the review and implementation of safety alerts.

It is the duty of all Clinical Governance Leads to lead by example and to hold themselves and others to account for complying with the legal and moral duties and contractual requirements placed on providers. Specifically;

- To uphold the principles of the Duty of Candour regulation and make a public commitment to 'Being Open'.
- Enforce the Trust's Policy on Duty of Candour and promote an organisational culture in which openness and learning from error can thrive.
- Ensure that the professional standards of all reporting clinical staff are maintained, including the professional Duty of Candour as it applies to registered clinical professionals.

All Staff

- Be vigilant in the identification of incidents.
- Responsibility to make the situation as safe as possible when an incident does occur and call for help if further assistance is needed.
- Report incidents or dangerous situations (including 'near misses') they are aware of to their Line Manager in a timely manner. If the incident occurs out of hours, this should be reported to the on-call Manager as appropriate.
- Record incidents at the earliest opportunity (and within 24 hours) on Datix.
- Be aware of and apply the principles of 'Being Open' and Duty of Candour.
- Where appropriate communicate with patients/families in line with the principles outlined in this policy and address all received concerns or complaints openly and honestly.
- Individual members of staff who are professionally registered are also subject to the professional Duty of Candour which is overseen by the professional regulatory bodies such as the General Medical Council (GMC), Nursing and Midwifery Council (NMC) and the General Dental Council (GDC). *See Section 11 for further information regarding professional Duty of Candour issued by the GMC and NMC.*

Risk and Incident Team

- Act as the first point of contact for staff to seek help and guidance with all matters relating to incident management.
- Monitor compliance with this Policy and encourage incident reporting as part of a positive safety culture.
- Responsible for the reporting of Serious Incidents to the Strategic Executive Information System (STEIS) system.
- Ensure that patients/ family members impacted by serious incidents are contacted ahead of Serious Incident investigations and are invited to contribute to the terms of reference, through the capture of their concerns and questions.
- Responsible for the Duty of Candour written notification to patients/relevant person for SIRIs within 10 working days.
- Facilitate Serious Incident investigations, providing support and advice to investigators throughout the process ensuring all Serious Incidents are robustly investigated using Root Cause Analysis methodology.
- Ensure that all completed Serious Incident investigation reports are disseminated amongst all relevant staff.
- Ensure that opportunities for learning that are identified through investigations are taken on board and shared across the Trust.
- Compile monthly SIRI reports, identifying themes and trends and escalate these as appropriate to Quality Governance & Learning Group and Safety & Quality Board.
- Ensure that appropriate Duty of Candour communications for all incidents graded moderate harm and above across the Trust have occurred with the patient/family at an early stage, with a written summary of the conversation provided within 10 working days.
- Ensure that an explicit procedure for the management of Duty of Candour disclosures across the Trust and related actions is in place, which includes processes for the monitoring and reporting of compliance.

- Provide Care Groups and Service Line management teams with a weekly status reports, providing details of all Incidents where Duty of Candour is applicable and has not yet been applied or not fully completed as per requirements.
- Alert Service Line & Care Group Management Teams of any cases where there is difficulty in the Duty of Candour process.

Quality Managers within the Medicine & Surgery Care Groups and nominated Leads within Women's and Children and Clinical Support Service Care Groups

- Support the Service Lines coordination of the initial incident response and opening lines of communication with the Risk & Incident Team.
- Support the Service Lines coordination of Duty of Candour processes.
- Support the Service Lines and Care Groups to investigate all moderate graded incidents.
- Support the Service Line teams' to monitor the delivery of agreed action plans and address and escalate instances where delivery of the agreed actions is delayed or not progressing.

RCA Lead Investigators

The Lead Investigator for Serious Incidents will be identified from the Trust's register of trained investigators who have received training in Root Cause Analysis. Lead Investigators are responsible for ensuring investigations are undertaken in accordance with the Incident's Terms of Reference in line with national timescales. Further detail can be found in the incident management processes in Appendix 1-3.

Action Holders

- Action holders for Serious Incident investigations will be held accountable for ensuring delivery of evidence to the Risk & Incident Team within the stated timescales.
- Any SIRI RCA actions past their due dates will be addressed during ward/department's assurance visits and escalated to overall action plan owners, Care Groups and the weekly Executive Directors governance meeting as appropriate.
- Action holders for moderate and below graded incidents will be held accountable for ensuring delivery of evidence to their Service Line Management Team within the stated timescales. Care Group Management Teams will act upon escalations of concern and will address instances where delivery against the delivery of Moderate investigation actions are delayed or not progressing.

Specialist Advisors

Experts for particular specialisms or subject areas will also be identified, when required, to work as part of the Investigation Team (Safeguarding, Tissue Viability, Falls, Infection Control, Pharmacy, Medical Devices Teams etc.).

Specialist Advisors will ensure the necessary expertise is available to inform the investigation, conduct investigatory meetings and support the analysis of findings.

Specialist Advisors will;

- Respond to individual incidents to offer advice and support to Service Lines, providing supportive challenge regarding incident grading, actions taken and learning.

- Liaise with Service Lines where the incident has occurred to deal with immediate actions.
- Review the findings of incident investigations to identify learning and support the development of action plans to prevent recurrence.

Health and Safety Team
The Health and Safety Team will;

- When required, complete RIDDOR forms regarding a range of incidents and report these to the Health & Safety Executive (HSE) within 15 days.
- Offer assistance and training regarding the Trust's RIDDOR responsibilities.
- Monitor the reporting of all Health and Safety related incidents.

Information Governance Team
The Information Governance Team will;

- Oversee the reporting of information governance serious incidents involving the Trust's Caldicott Guardian and Senior Information Risk Owner (SIRO) where appropriate as set out in Information Governance Serious Incident Requiring Investigation Handling SOP.
- Notify the Information Commissioner's Office (ICO) of all personal data breach serious incidents within 72 hours of identification.
- Be involved with agreeing the terms of reference for investigations and provide the expertise to the management, investigation and closure of all Information Governance Incidents.

5 Key elements

Investigating notifiable patient safety incidents is an integral aspect of good governance and an open and transparent process must underpin every investigation.

Investigations should be initiated appropriate to the nature and severity of the incident and should be completed within the required timescale. See Staffnet for further information *here*.

Supporting Staff

When something goes wrong all staff should have the confidence to be open; focusing on the 'what', 'how' and 'why', rather than necessarily 'who'. Responses should be supportive of individuals, proportionate and robust. The investigation process should focus on the learning that is to be gained from the incident.

Staff involved in incidents have the full support of the organisation. PHNT believes in systemic solutions rather than individual blame. Disciplinary action **will not** be invoked against any individual involved except where malicious intent is evident.

All staff are expected to report all incidents and near misses that they witness. If, for any reason, staff members do not feel empowered or supported to report incidents safely, they should raise their concerns through the Trust's whistle-blowing arrangements.

Duty of Candour; Being Open to Patients and Carers

The Duty of Candour requirements below should be implemented following any 'Moderate Harm' or above graded incident once it has occurred. *A summary of the Duty of Candour process can be found in Appendix 4.*

Choosing the Individual to communicate with patients and/or relevant person

The appropriate person must be identified for each incident.

Where it is felt a 'candour conversation' is required, the most appropriate person to conduct such a conversation, in most circumstances, would be the clinician with whom the patient has an active clinical relationship.

All staff involved in liaising with patients and families must have the necessary skills, expertise, and knowledge of the incident in order to explain what went wrong promptly, fully and compassionately.

The person(s) communicating with the patients and/ or relevant person should;

- Have a good understanding of the facts relevant to the case.
- Have excellent interpersonal skills, including being able to communicate with patients and/or relevant persons in a way they can understand. Avoid excessive use of medical jargon.
- Be willing and able to offer an apology, reassurance and feedback to patients and/or their carers.
- Be able to maintain a medium to long term relationship with the patient and/or their carers, where possible, and to provide continued support and information.
- Be culturally aware and informed about the specific needs of the patient and/or their carers.

The 'Candour' Conversation

It is important to acknowledge that other patients/service users may have been involved or affected by the incident and they must also be offered the appropriate level of support and involvement.

The Relevant Person

Once the most appropriate person has been identified to undertake the Duty of Candour conversation, they should inform the relevant person, in person as soon as reasonably practicable after becoming aware that a safety incident has occurred.

The regulations states that the "relevant person" means the service user (patient) or, in the following circumstances, a person lawfully acting on their behalf—
(a) On the death of the service user,

(b) Where the service user is under 16 and not competent to make a decision in relation to their care or treatment, or

(c) Where the service user is 16 or over and lacks capacity in relation to the matter.

A face to face discussion is best or a telephone call if the patient is currently not in Hospital. Verbal communication should always occur before a letter is sent.

The Detail
Provide an account of the incident which, to the best of your knowledge, is true of all the facts known about the incident at the date of the notification. Those involved will want to know:

- What happened?
- Why it happened?
- How it happened?
- What can be done to stop it happening again to someone else?

It is important to remember that you do not have to wait until the outcome of an investigation to speak to the patient, but you should be clear about what has and has not yet been established. Advise the relevant person what further enquiries will be made and identify a clearly nominated point of contact for patients and relatives involved.

It is important that if the patient and/ or relevant person was not spoken to at the time of the incident if it was not practically reasonable and you are unable to contact the person after to discuss the incident at a more convenient time then a clear written record must be kept of the attempts made to contact or speak to the relevant person. This should evidence every reasonable effort that was made to contact the person by stating how many attempts were made, by whom and when.

The Apology
Where a patient safety incident has caused harm, an apology must be offered to the relevant person – a sincere expression of sorrow or regret for any possible harm and distress caused. It is important to remember that saying sorry is not an admission of liability and is the right thing to do.

A key aim of the document is to help all health professionals to feel they can be open and honest whenever mistakes are made, and to not be reluctant to apologise to patients. The NHS Litigation Authority (NHSLA) encourages health care staff to apologise and clarifies that doing so is not an admission of liability. Guidance from (2009) states:

"It is both natural and desirable for clinicians who have provided treatment which produces an adverse result, for whatever reason, to sympathise with the patient or the patient's relatives; to express sorrow or regret at the outcome; and to apologise for shortcomings in treatment. It is most important to patients that they or their relatives receive a meaningful apology. We encourage this, and stress that apologies do not constitute an admission of liability. In addition, it is not our policy to dispute any payment, under any scheme, solely on the grounds of such an apology."

Reporting the Incident to Datix

Keep a written record of all communication with the relevant person which includes updating the patients' notes and Incident form to reflect what has happened and has been communicated.

The initial 'candour' conversation must be recorded in the patient's health records with a heading "Duty of Candour meeting" – Date, time, people present (including patient and family names), apology, what was discussed, concerns raised by the family, arrangements for further communication and support.

This same detail must be recorded on the Incident form. All staff must ensure that when reporting an incident to Datix that the Duty of Candour section is fully completed, by answering the following questions and providing detailed information:

- Has Duty of Candour been applied?
- Has the patient/family received an apology?
- Include the name and job role of the person who spoke to the family and the date of the conversation. Also detail what was discussed, including what happened, why it happened and how it happened (if known).
- Has the patient's notes been updated to reflect discussions?
- Has the patient received a letter within 10 working days? Record the date the letter was sent to the patient.

The Written Notification

For 'Moderate' graded Incidents, Service Line Management Teams are required to follow up the conversation, by giving the same information (as discussed as part of the candour conversation) in writing and providing an update on enquiries within 10 working days of the incident being reported.

For Serious Incidents Requiring Investigation (SIRIs), the Risk & Incident Team will manage the written communication process with patients, following the initial candour discussion undertaken within Service Lines.

A signed copy of the written notification should be placed in the patient's clinical notes and a copy should be uploaded to the Datix incident form.

It is usual to share the findings of investigations with the patient and/ or relevant person afterwards in a letter and a meeting. Patients and/ or the relevant person are asked how they would like to be involved in an investigation and this occurs during the first correspondence. T*emplate letters can be found via Staffnet here.*

For some 'Moderate' incidents, it will be possible for Service Lines to forward one letter to the patient/ relevant person which will detail both the incident and subsequent actions taken to mitigate the risk of future recurrence *(see 5.7 for further detail).* This is often the case where all facts are known and no further investigation is required at the time of written notification to the patient/ relevant person*. Template letters can be found via Staffnet here.*

Exceptions

A judgment needs to be applied on a case by case basis to determine whether an incident meets Duty of Candour criteria. What may not appear to be a Duty of Candour incident at the outset may look very different when more information comes to light, and may therefore lead to an incident becoming notifiable under Duty of Candour.

There are exceptions to implementing Duty of Candour; however there must be very sound reasons which must be clearly recorded.

For incidents where Service Lines believe Duty of Candour should not be applied, clear rationale should be documented in the details box provided on the incident form.

All rationales will be documented and discussed at weekly governance meetings for consistency and will be taken forward appropriately.

Share Investigation findings

After completion of the incident investigation, feedback should take the form most acceptable to the patient. Normally this would be in a written format. Whatever method is used, the communication should include:

- A repeated apology for the harm suffered and any shortcomings in the delivery of care that led to the notifiable patient safety incident.
- Details of the patient's/ relevant person's concerns (if received in response to written notification letter).
- A chronology of events.
- A summary of the factors that contributed to the incident.
- Information on what has been and will be done to avoid recurrence of the incident and how these improvements will be monitored.

The investigation findings/ a copy of the final report should be uploaded to the Datix incident form and shared with the patient/ relevant person as soon as possible after approval of the final investigation report. An opportunity should be given for the patient/ relevant person to discuss the investigation findings with the Trust. T*emplate letters can be found via Staffnet here.*

The patient must be given sufficient time before the meeting so they can arrange to be accompanied, if they wish. It is often not appropriate for staff involved in the incident to be present and this should be carefully considered.

Learning from Serious Incidents

Internal Patient Safety Bulletin

The investigator should be responsible for identifying critical learning to be shared at any stage of the investigation process, they should not wait until completion of the investigation to highlight system weaknesses and share valuable learning which may prevent future harm.

Final Investigation Report

Investigation at any level should reveal the root causes of the incident and identify learning points. It is essential that all staff and patients receive feedback on the outcome of the investigation of incidents that they have reported or been involved in. A copy of the final investigation report will be shared with all staff involved and the patient/carers if requested.

Wider Learning

Internally

- Feedback and learning from SIRIs will be shared via Service Lines to all relevant staff groups and by the Risk & Incident team trustwide via REACT Learning Bulletins published in the Trust's 'Vital Signs' Newsletter.
- Anonymised final investigation reports are also available for all staff to access through the Risk & Incident Team pages on Staffnet *here*.

Externally

- All Patient Safety Incidents (inc. Serious Incidents) are reported to the National Reporting and Learning System (NRLS). Reports are then produced by the NRLS which are used for both benchmarking and learning across the Trust.
- Reporting of all Patient Safety Incidents to the Care Quality Commission via the NRLS.
- Review of all SIRIs by NEW Devon CCG and reporting of SIRIs to external agencies as required.
- Monthly assurance visits with NEW Devon CCG at which various aspects of Serious Incidents are discussed to provide assurance on organisational learning.

6 Training

Awareness of the role of all staff in reporting incidents forms a part of the Trust's mandatory training programme and all staff are informed of their responsibilities through the Trust's Corporate Induction process.

In addition the Risk & Incident Team will ensure provision of training as required to managers and staff, to enable them to carry out their duties and responsibilities relating to incident management.

All staff should be aware of the 'Being Open' principles and the Duty of Candour regulation. Duty of Candour forms part of the Trust annual update which all staff are required to complete.

Further Duty of Candour training and guidance can be found via Staffnet *here*.

7 Overall Responsibility for the Document

The Risk and Incident Manager is responsible for developing and reviewing this Incident Management Policy.

8 Consultation and Ratification

The design and process of review and revision of this policy will comply with The Development and Management of Trust Wide Documents.

The review period for this document is set as default of five years from the date it was last ratified, or earlier if developments within or external to the Trust indicate the need for a significant revision to the procedures described.

This document will be approved by the Weekly Executive Directors Quality Governance Meeting and the Quality Governance and Learning Group and ratified by the Director of Nursing.

Non-significant amendments to this document may be made, under delegated authority from the Director of Nursing, by the nominated author. These must be ratified by the Director of Nursing and should be reported, retrospectively, to the approving Quality Governance and Learning Group.

Significant reviews and revisions to this document will include a consultation with named groups, or grades across the Trust. For non-significant amendments, informal consultation will be restricted to named groups, or grades who are directly affected by the proposed changes.

9 Dissemination and Implementation

Following approval and ratification, this policy will be published in the Trust's formal documents library and all staff will be notified through the Trust's normal notification process, currently the 'Vital Signs' electronic newsletter.

Document control arrangements will be in accordance with The Development and Management of Trust Wide Documents.

The document author will be responsible for agreeing the training requirements associated with the newly ratified document with the named Nursing Executive Director and for working with the Trust's training function, if required, to arrange for the required training to be delivered.

10 Monitoring Compliance and Effectiveness

For patient related incidents, compliance with this Policy will be monitored by the Risk & Incident Team. The output of this monitoring will be reported to the Quality Governance & Learning Group (QG&LG) together with recommendations for improvement and actions to address any issues arising. The Quality Assurance Committee (QAC) acts as the coordinating committee, seeking assurance on the effectiveness of the Trust's healthcare governance arrangements. QAC will seek assurance as part of the Quality Governance compliance assessment that all Serious Incidents are addressed appropriately.

The QG&LG and weekly Executive Directors Governance meeting will act upon escalations of concern and will address instances where delivery against the SIRI management process and delivery of subsequent RCA agreed actions are delayed or not progressing.

For incidents relating to staff, visitors, contractors, volunteers, and non-clinical incidents relating to patients, compliance with this SOP will be monitored by the Health and Safety Advisor under the delegated authority of the Director of Corporate Business. The output of this monitoring will be reported to the Health and Safety Committee monthly together with recommendations for improvement and actions to address any issues arising. The Health and Safety Committee will monitor delivery of the action plan and will determine the frequency of updates to be reported to them based on the severity of the issues arising.

11 References and Associated Documentation

Duty of Candour further guidance:

- CQC Handbook – Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20.
  http://www.cqc.org.uk/content/regulation-20-duty-candour
- GMC/NMC Guidance – Openness and honesty when things go wrong: the professional Duty of Candour.
  http://www.gmc-uk.org/guidance/ethical_guidance/27233.asp
- NPSA – 'Being Open' framework
  http://www.nrls.npsa.nhs.uk/beingopen/?entryid45=83726
- The Royal College of Radiologists – Duty of Candour in relation to diagnostic radiology: position statement: Issued 22nd October 2015. https://www.rcr.ac.uk/posts/duty-candour-relation-diagnostic-radiology-position-statement

Serious Incident further guidance:

- NHS Screening Programmes: Managing safety incidents in NHS Screening Programmes guidance - https://www.gov.uk/government/publications/managing-safety-incidents-in-nhs-screening-programmes
- NHS England's Serious Incident Framework 2015/16:
  https://improvement.nhs.uk/resources/serious-incident-framework/
- NHS England's Never Events List 2015/16:
  https://improvement.nhs.uk/resources/never-events-policy-and-framework/

Duty of Candour process summary

Appendix 1

Dissemination Plan — Appendix 2

Core Information	
Document Title	**Incident Management Policy**
Date Finalised	14/04/2015
Dissemination Lead	Information Governance Team.
Previous Documents	
Previous document in use?	Incident Management Standard Operating Procedure Apr 2012 Management of Adverse Events Apr 2013 Root Cause Analysis (RCA) for Adverse Event Investigation Standard Operating Procedure June 2012.
Action to retrieve old copies.	Ratifying lead to confirm previous documents can be archived. To be managed by the Information Governance Team.

Dissemination Plan

Recipient(s)	When	How	Responsibility	Progress update
All staff		Email	Document Control	
All staff		Vital Signs	Document Control/ Comms Team	

Equalities and Human Rights Impact Assessment — Appendix 3

Core Information	
Manager	Rachel Newport
Directorate	Quality Governance
Date	14th April 2015
Title	Risk & Incident Manager
What are the aims, objectives & projected outcomes?	To set out the procedure for recognising, managing, reporting and investigating incidents and the resulting action planning and implementation of changes.

Scope of the assessment

To set out the procedure for recognising, managing, reporting and investigating incidents and the resulting action planning and implementation of changes.

Collecting data	
Race	There is no evidence to suggest that there is a negative impact on race regarding this policy. This will be monitored via Listening to You, Datix and patient feedback.
Religion	There is no evidence to suggest that there is a negative impact on Religion or belief and non-belief regarding this policy. This will be monitored by Listening to you, Datix and patient feedback.
Disability	There is no evidence to suggest that there is a negative impact on Disability regarding this policy. This will be monitored via Listening to you, Datix and patient feedback.
Sex	There is no evidence to suggest that there is a negative impact on Gender regarding this policy. This will be monitored via Listening to you, Datix and patient feedback.

Gender Identity	There is no evidence to suggest that there is a negative impact on Gender Identity regarding this policy. This will be monitored via Listening to you, Datix and patient feedback.
Sexual Orientation	There is no evidence to suggest that there is a negative impact on Sexual Orientation regarding this policy. This will be monitored via Listening to you, Datix and patient feedback.
Age	There is no evidence to suggest that there is a negative impact on Age regarding this policy. This will be monitored via Listening to you, Datix and patient feedback.
Socio-Economic	There is no evidence to suggest that there is a negative impact on Socio-Economics regarding this policy. This will be monitored via Listening to you, Datix and patient feedback.
Human Rights	There is no evidence to suggest that there is a negative impact on Human Rights regarding this policy. This will be monitored via Listening to you, Datix and patient feedback.
What are the overall trends/patterns in the above data?	Not Applicable
Specific issues and data gaps that may need to be addressed through consultation or further research	Not Applicable
Involving and consulting stakeholders	
Internal involvement and consultation	Internal consultation and involvement was undertaken via email and various forums with the following staff groups; Executive Governance Team Quality Governance Management Team Risk & Incident Team Heads of Nursing Quality Managers Care Group Managers All Matrons
External involvement and consultation	Not Applicable
Impact Assessment	
Overall assessment and analysis of the evidence	

Action Plan

Action	Owner	Risks	Completion Date	Progress update
Monitoring feedback for equality issues relating to the policy	Risk & Incident Manager; OD Facilitator		Ongoing	