Pennine Care
NHS Foundation Trust

DOCUMENT CONTROL	
Title:	**Incident Reporting, Management & Investigation Policy**
Version:	**13**
Reference Number:	**CO010**

Scope:

The policy applies to all staff employed or managed by the Trust i.e. agency staff, seconded staff, students and volunteers, contractors and employees of other organisations working on the Trust's estate, in the event of an incident involving staff, patients, service users and carers.

Purpose:

The purpose of this policy is:

- To provide information and guidance for staff on the management of incidents within Pennine Care NHS Foundation Trust. This includes those incidents which:
    - Occur on Trust premises
    - Occur off Trust premises but involve persons employed by the Trust (or managed by the Trust i.e. agency staff, seconded staff, students and volunteers), whilst on Trust business.
    - Involve any patient receiving care from the Trust – including joint services with local authorities (community and mental health), where an incident relates to the health and social care provision of the service user.
    - Concern someone known to services (within the previous 6 months), but not currently on an open caseload.
    - Concerns the homicide by a former service user
        - This would generally include those in receipt of care within the last 6 months, however this is a guide and each case should be considered individually.
    - Concern the security or damage to the Trust estate or property.

- To support a consistent and systematic response to incidents and near misses in all parts of the Trust
- Provide information on requirements and timescales for reporting incidents and investigations in line with the NHS England Serious Incident Framework (NHS England, 2015)
- Provide guidelines to ensure that all incidents are reported to the relevant bodies to ensure full investigation.
- Draw together legal and regulatory requirements associated with the management and reporting of serious incidents to national organisations and partners such as the Care Quality Commission (CQC) and National Reporting and Learning System (NRLS)

Requirement for Policy	
To meet the requirements of the NHS England Serious Incident Framework, 2015	
Keywords:	
Incident; Serious incident; Investigation; StEIS; Being open; Duty of Candour; RIDDOR; Deaths, Homicides	
Supersedes:	
Version 12	
Description of Amendment(s):	
Updated in light of: • National Guidance on Learning from Deaths**.** • Revised Never Events policy and framework, • New Just Culture Guide • Appointment of the Freedom to Speak up Guardian • Information added Re RIDDOR • Additional information added Re Duty of Candour • In line with changes to Data Protection (GDPR)	
Owner:	
Risk Manager – Ann-Marie Malley	
Individual(s) & group(s) involved in the Development:	
This document has been developed in collaboration with the following interested parties: • The Information Governance Assurance Manager • The Trust Records Manager • Trust Violence Reduction Manager / Core & Essential Skills Training Manager • Trust Chief Pharmacist • Trust Lead Pharmacist – Community Services • Trust Health, Safety and Emergency Planning Lead	
Individual(s) & group(s) involved in the Consultation:	
The document has been circulated for consultation and comments have been taken into consideration and the document amended accordingly: • The Trust Patient Safety & Improvement Group • Trust Infection Prevention & Control Leads • Trust Associate Director of Nursing and Health Care Professional • Trust Professional Lead – Safeguarding • Trust Mental Health Law Manager • Trust Security Manager, Security Management Specialist & Police Liaison Officer	
Equality Impact Analysis:	
Date approved:	26th September 2018
Reference:	CO010 – EIA010

Freedom of Information Exemption Assessment:	
Date approved:	22nd of October 2018
Reference:	POL2018-46
Information Governance Assessment:	
Date approved:	22nd of October 2018
Reference:	POL2018-46
Policy Panel:	
Date Presented to Panel:	23rd of October 2018
Presented by:	Ann-Marie Malley
Date Approved by Panel:	23rd of October 2018
Policy Management Team tasks:	
Date Executive Directors informed:	20th of November 2018
Date uploaded to Trust's intranet:	16th of November 2018
Date uploaded to Trust's internet site:	16th of November 2018
Review:	
Next review date:	October 2021
Responsibility of:	Risk Manager

Other Trust documentation to which this policy relates (and when appropriate should be read in conjunction with):	
CO119	Learning from deaths policy
CL065	Death of patient policy (Inpatient Mental Health and Community)
CL066	Death of a Service User in Community Policy (Mental Health and Physical Health Services)
CO009	Health and Safety policy
CO044	Information Governance Policy
CO028	Missing Paper Records Procedure
CL123	Inpatient Falls Risk Management Policy
HR012	Freedom to Speak Up Policy
Policy Associated Documents:	
TAD_CO010_01	Trust Incident Management and Investigation Process
TAD_CO010_02	Being Open at a Glance
TAD_CO010_03	Harm impact of incidents and communication requirements

TAD_CO010_04	Learning embedded throughout process of serious incident reporting and investigation
TAD_CO010_05	What needs to be reported
TAD_CO010_06	Root Cause Analysis Investigation Report
TAD_CO010_07	Concise Investigation Report
TAD_CO010_08	Regional Investigation Teams
TAD_CO010_09	IR Action Plan
TAD_CO010_10	Systems based investigations table
TAD_CO010_11	IG Serious Incident Process and Procedure
Other external documentation/resources to which this policy relates:	
NHS Resolution Saying Sorry guidance	https://resolution.nhs.uk/wp-content/uploads/2017/07/NHS-Resolution-Saying-Sorry-Final.pdf
Reporting Accidents and Incidents at Work - RIDDOR	http://www.hse.gov.uk/pubns/indg453.pdf
Duty of Candour patient / family information leaflet	https://www.avma.org.uk/?download_protected_attachment=Duty-of-candour-web-version.pdf
A Just Culture Guide	https://improvement.nhs.uk/documents/2490/NHS_0690_IC_A5_web_version.pdf
CQC Regulations **This guideline supports the following CQC regulations:**	
Regulation 12	Safe care and treatment
Regulation 17	Good Governance
Regulation 20	Duty of candour

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1. INTRODUCTION

Pennine Care NHS Foundation Trust is committed to providing the highest standard of care. In line with this aim, the Trust is continually working to improve services, and provide a safe and healthy environment for all service users, staff members and the general public.

Learning from events, identifying when things have gone wrong, and understanding the underlying cause of errors and failures (if apparent), is essential to this process, to ensure that learning leads to action, change and improvement.

This Policy describes the Governance and Risk Management systems in place within Pennine Care, which provide:

- A unified process for reporting and investigating when things go wrong.
- An open culture, in which errors or service failures can be reported and discussed.
- Robust systems to ensure that, where lessons are identified, the necessary changes are put into practice, and monitored for effectiveness.
- Shared learning across all parts of the organisation, and with people and agencies outside the Trust when appropriate.
- Principles of being open when things go wrong.
- Requirements of the statutory Duty of Candour.
- Support for staff and patients when incidents occur.

2. SCOPE OF THE POLICY

The policy applies to all staff employed or managed by the Trust i.e. agency staff, seconded staff, students and volunteers, in the event of an incident involving staff, patients, service users and carers.

3. PURPOSE

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- To provide information and guidance for staff describe on the management of incidents within Pennine Care NHS Foundation Trust. This includes those incidents which:
    - Occur on Trust premises
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- Provide information on requirements and timescales for reporting incidents and investigations in line with the NHS England Serious Incident Framework (NHS England, 2015)
- Provide guidelines to ensure that all incidents are reported to the relevant bodies to ensure full investigation.

Draw together legal and regulatory requirements associated with the management and reporting of serious incidents to national organisations and partners such as the Care Quality Commission (CQC) and National Reporting and Learning System (NRLS)

4. DEFINITIONS

- **Incident** – 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 member of the public.
- **Serious Incidents** in healthcare are adverse events, where the consequences to patients, families and carers, staff or organisations are so significant or the potential for learning is so great, that a heightened level of response is justified. Further detailed explanation can be found in the Serious Incident Framework (NHS England, 2015) https://www.england.nhs.uk/patientsafety/serious-incident/
- **Patient Safety Incident** - Any unintended or unexpected incident (mistake / act or omission) that could have led or did lead to harm for one or more patients receiving NHS-funded healthcare.
- A '**notifiable safety incident'** – An unintended or unexpected incident… that could result in, or appears to have resulted in the death of a service user… or severe or moderate harm or prolonged psychological harm to the service user.
- A **near miss** is an event or circumstance that could have resulted in unnecessary damage, loss or harm such as physical or mental injury to a patient, staff, visitors or members of the public, however this was narrowly avoided.
- **Never Events** – Never Events are serious incidents that are wholly preventable as guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers. Further detailed explanation can be found in the revised Never Events Policy and Framework (NHS England, 2018). https://improvement.nhs.uk/resources/never-events-policy-and-framework/
- A **personal data breach** means a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise processed.

5. ROLES, RESPONSIBILITIES & DUTIES

Chief Executive

The Chief Executive Officer, through the Board of Directors, has overall responsibility for the provision of adequate systems for the management of Health & Safety, including the reporting and managing of incidents, accidents and near miss events.

Executive Director of Nursing, Healthcare Professionals and Quality Governance

The Executive Director of Nursing & Quality is the designated Board of Directors' lead for incident reporting and the implementation of Being Open and the Duty of Candour where appropriate

Risk Manager and Patient Safety Lead

The Risk Manager and Patient Safety Lead are responsible for the operational management of the Serious Incident process including:

- Ensuring all SIs are managed and investigated appropriately ensuring robust and timely action plans are produced
- Chairing the Patient Safety Improvement Group
- Escalating incidents as agreed.

Managing Directors and Associate Directors

The Managing Directors and Associate Directors are responsible for ensuring that:

- All staff within their sphere of responsibility are aware of the need to complete the electronic incident forms,
- Appropriate staff are in place to undertake an appropriate and proportionate investigation, lesson learnt are identified, appropriate actions are put in place, , and actions arising from investigations are completion and implemented.
- Learning is shared There is appropriate communication in line with Duty of Candour requirements.
- Staff are supported following serious incidents
- Opportunities for quality improvement are supported.
- Escalating incidents as agreed

CEQIT

The CEQIT will identify relevant policies, NICE Guidance and National and Local Clinical Audit results and outcomes to support investigations.

The CEQIT will receive any actions relating to Serious Untoward Incidents requiring clinical audit and revisions to Trust policy.

Local Quality Leads and Governance Managers

The Quality Leads / Governance Managers will support quality governance processes including incident reporting, review of incidents, appropriate and proportionate investigation of incidents, identification of learning, and completion of actions arising from investigations, and learning from incidents within their locality and service area.

This will include:

- Monitoring incident numbers, themes and trends.
- Ensuring that the Being Open and Duty of Candour Policy is implemented

- Escalating significant incidents to the Managing Director and or Associate Director, Patient Safety Lead and Risk Manager
- Ensuring that relevant staff receive a debrief on investigation findings and lessons learned
- Identifying opportunities for quality improvement initiatives.

Quality Governance / Governance Administrators

The Quality Governance / Governance administrators will support Quality Governance / Governance Leads to ensure that quality governance processes are in place locally and the responsibilities of the Quality Governance / Governance Lead are achieved.

Health, Safety & Emergency Planning Lead

The Reporting of Injuries, Diseases and Dangerous Occurrences Regulation (RIDDOR) requires a named 'Responsible Person' on behalf of the Trust to report to the local office of the Health and Safety Executive (HSE). The Health and Safety Lead has been designated as the 'Responsible Person' on behalf of the Trust. The Health and Safety Lead will:

- Be responsible for ensuring the statutory notification of those specified incidents to the Health and Safely Executive (HSE)
- Oversee the process of RIDDOR reportable incidents.

The Subject Matter Experts

Subject Matter Experts must:

- Log on to the incident system on receipt of a web incident notification being automatically emailed to them, review the incident, provide feedback, comments and support to assist the management of the incident and decision making as to the need for further investigation.
- Evidence review of incidents within the electronic incident system
- Monitor incident numbers, themes and trends.
- Identify immediate learning opportunities
- Lead on specific incident investigations as required.
- Contribute to and support incident investigations
- Support the wider sharing of learning identified via incident review.
- Escalating incidents as agreed.

Service and Team Managers

Service and Team Managers must:

- Log on to the system on receipt of a web incident notification being automatically emailed to them and complete and submit the Manager's Form within 48 hours of the incident occurring.
- Review all incidents and the put in place mitigating actions to maintain safety of individuals and prevent its reoccurrence.
- Ensure that immediate learning is identified.
- Comply with the Duty of Candour for all incidents which are classified as a notifiable safety incident and have a level of harm of moderate or higher.
- Complete as designated or support the completion of an incident investigation.

Line Managers

Line managers must ensure that all incidents regardless of type, damage or injury are accurately reported, using the Electronic Incident Form via the Trust's electronic incident reporting system, as soon as is reasonably practicable, but within 24 hours of the incident (or becoming aware of the incident) by the most appropriate person in their service.

Line managers must ensure staff are competent to input an incident form.

All staff

All staff are responsible for reporting all incidents on the Trust Electronic Incident system e.g. accidents, incidents, health and safety issues, security issues, alleged clinical negligence or malpractice and alleged abuse of patients, staff and property.

All staff are required to:

- Work in an open and transparent way ensuring:
    - Honesty with patients when things go wrong
    - Incidents are reported.
    - Full contribution to the review and investigation of incidents.
- Whilst professional staff are subject to a Professional Duty of Candour which builds on requirements within professional codes of practice: http://www.gmc-uk.org/guidance/ethical_guidance/27233.asp
- Ensure the prompt reporting of all incidents/near misses on the Trust electronic Incident system (Ulysses Safeguard) in an accurate and timely manner (within 24 hours).
- Ensure that incidents are reported to line managers in accordance with the requirements of the policy.
- Ensure understanding of the content of the Incident Reporting, Management and Investigation Policy and the associated procedures.
- Maintain competency in incident reporting by utilising the Incident Reporting E-Learning training.
- Maintain competency in incident investigation (as appropriate) by accessing Trust investigation training.

6. COMMITTEES AND GROUPS WITH RESPONSIBILITIES

Board of Directors

The Board of Directors has responsibility for ensuring the adequate provision of systems for the management of Health & Safety, including the reporting and managing of incidents, accidents and near miss events.

Quality Committee

The Quality Committee is responsible for providing assurance to the Board of Directors that the framework for the reporting of incidents is being managed effectively and that organisational learning is taking place.

Trust Wide Quality Group

The Trust Wide Quality Group is responsible for providing assurance to the Quality Committee that the framework for the reporting of incidents is being managed effectively and that organisational learning is taking place.

Director Serious Incident Review Panel (SIRI)

The purpose of the panel is to provide executive oversight of serious incidents, and support in relation to numbers, timescales, duty of candour, family involvement, closure of action plans and themes emerging.

The panel will receive reports from the Patient Safety Improvement Group (PSIG), and report to the Trust Quality Committee

The Patient Safety Improvement Group (PSIG)

The Patient Safety Improvement Group (PSIG) has delegated responsibility from the Executive Directors to review all Pennine Care NHS Foundation Trust Serious Untoward Incidents (SUIs). The Group supports the Trust risk management policies and processes to improve patient safety following a patient safety incident. The Patient Safety Improvement Group receives all patient safety investigation reports completed following Serious Untoward Incidents.

In addition, the Group will:

- Review and approve incident reporting systems, procedures and policy.
- Review of procedures and systems for reporting of incidents to STEIS (Strategic Executive Information System).

The aim of the Patient Safety Improvement Group is to identify learning to improve systems and the quality and safety of patient care in Mental Health services.

7. INCIDENT MANAGEMENT AND INVESTIGATION PROCESSES WITHIN THE TRUST

The Trust processes are detailed in (TAD_CO010_01) and have been developed to meet the requirements of the revised Serious Incident Framework published in March 2015 (Figure 1).

7.1 Immediate management of an incident

The immediate post incident management should concentrate on making sure that:

- People involved in the incident are comfortable and safe, and have access to appropriate care and treatment (considering the need for immediate medical attention or follow up)
- Immediate action is taken to try to prevent a reoccurrence, and make the environment/clinical area safe
- Appropriate people are informed of the incident, (including next of kin and line manager if necessary).
- A detailed contemporaneous record of the event and subsequent actions is documented
- If a staff member is involved consider if fit/able to continue working, and make appropriate arrangements if needed.

- As appropriate consider and if required make arrangements for the support of patient's peers e.g. if incident occurs on inpatient unit.
- Consider and make arrangements for staff support.
- In light of the specific circumstances of the incident, there is appropriate review of the patient's care management plan by clinical team.

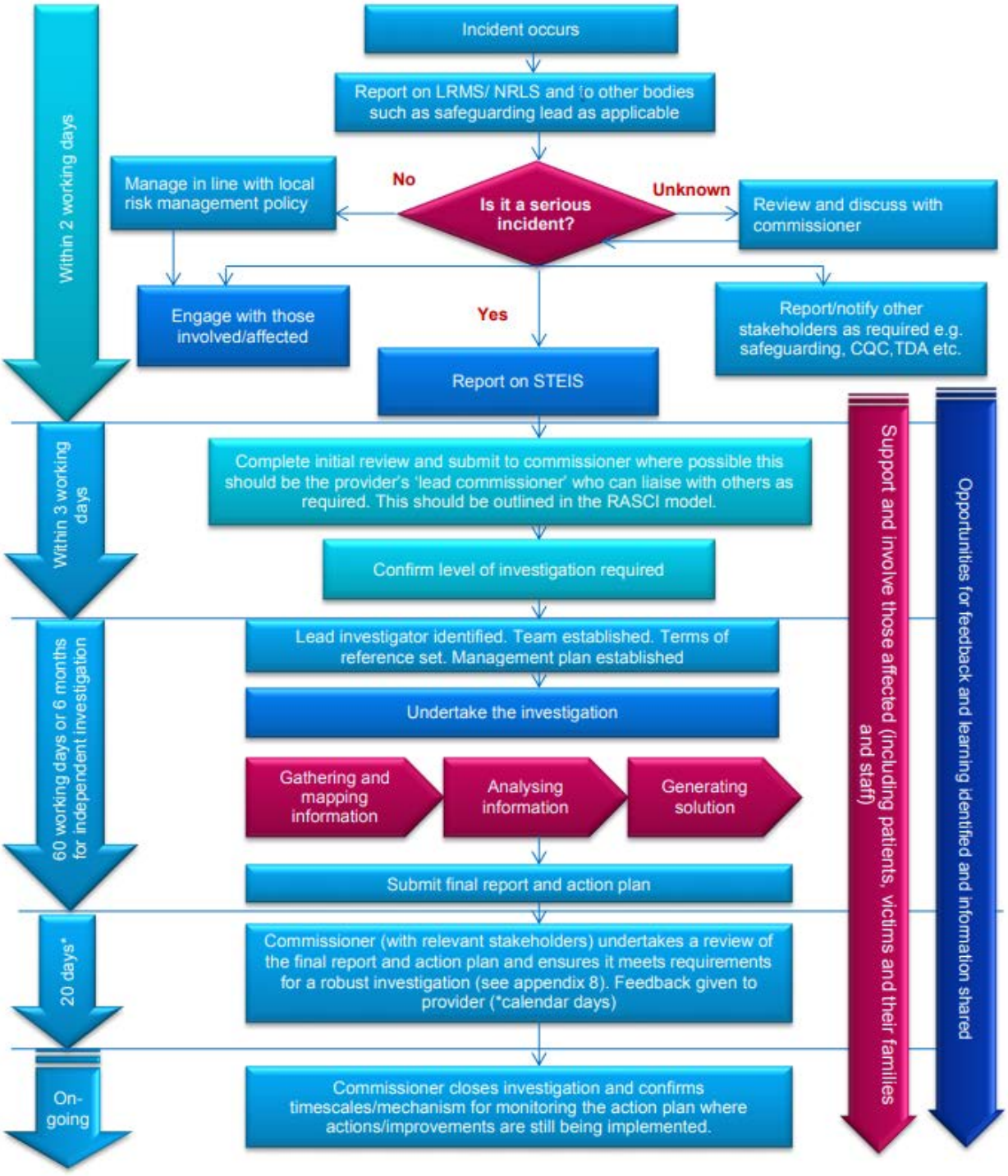


Figure 1: Serious Incident Management Process

It is the responsibility of the senior person on duty within the team / ward or department to organise and manage the immediate situation. When necessary he / she should seek advice and guidance from the Line Manager or On Call Manager.

All serious incidents (Homicides, unexpected inpatient deaths serious staff / patient injury, suspected suicides, inpatient sexual assault allegations etc.) must be reported immediately to the Service Manager or on-call Senior Manager out of office hours. This is to ensure that there is sufficient seniority and authority for decision making within the management of the incident. The Service Manager or on-call manager should ensure that the relevant Borough and Trust Senior Managers and Executives are informed immediately if a serious incident occurs.

In the event that there is no manager or senior member of staff in the immediate vicinity of the incident, staff present should contact a manager by telephone.

The Manager contacted should oversee the immediate incident management and provide advice and direction to the staff present.

The Manager should commence information gathering to support incident reporting, internal communication, and decision making in regards to the further actions required. This should include:

- A clear description of the incident details known at the time.
- Details of the involvement of emergency services.
- A summary of the patient's history and contact with Pennine Care NHS Foundation Trust services.
- Details of other services supporting service user's care.
- Details of immediate finding in regards to care and level of service provided.
- Details of actions taken by Pennine Care NHS Foundation Trust and other organisations.
- Details of contact with family/carers
- Details of contact with any external agencies
- Details of any further actions planned
- Details of media involvement

7.2 Medical Intervention

If urgent medical attention is required for injuries or physical illness, the service user / staff member should be supported to access appropriate medical attention.

In the case of a medical emergency the CRASH Team and / or emergency services dependent on site vicinity should be called in accordance with local arrangements. If the patient is detained on a section of the Mental Health Act, Section 17 leave may be authorised retrospectively.

7.3 Potential Criminal Act

If a criminal act has been committed, or is suspected, the Police should be informed immediately. In the event of a death where there are any concerns regarding the possible involvement of another person or persons, then the deceased and surrounding areas must be preserved as a potential 'scene of crime' and the Police and the local on-call managers who should then inform the on-call Trust Executive immediately.

Ongoing support of the alleged perpetrator must also be considered.

7.4 Securing the Safety of the Environment

Any damage to the area which renders the environment unsafe should be reported to the Estates Department, on-call Estates Manager if action is required urgently, or in accordance with any local

Estates arrangements. Any unsafe areas should be made inaccessible to service users, staff, and the public.

If a piece of equipment or part of the clinical environment, such as a ligature point (where a person has used a point to self-harm by hanging) is considered part of the incident, the person in charge must ensure that the area/ equipment is made inaccessible and that any evidence is preserved.

When an incident has health and safety implications, this should be reported to the Trust Health, Safety and Emergency Planning Lead during office hours or the Senior Manager on call for the Trust outside office hours. He / she should decide whether an incident should be reported to outside Agencies i.e. Health & Safety Executive, and ensure that this is done.

7.5 Information Sharing

The Manager in charge or Team Leader should consider when it might be appropriate to inform other members of the patient's multi-disciplinary team about an incident, (including the service users Consultant and medical team, Care Coordinator and Social Worker etc.). If this is felt to be appropriate, a member of staff should be designated to contact members of the multi-disciplinary team as soon as possible within working hours.

In addition, consideration should be given to the informing the services supporting others who may be adversely affected as a consequence of a serious incident so support needs can be identified e.g. informing the care coordinator of a service user who's partner has died unexpectedly.

The Trust Information Governance Team should be consulted if there is any doubt or concern as to the level of information that should be shared, and with whom.

7.6 The Health Record

When an incident at grade 4 or 5 has occurred, the person who is managing the incident (Manager in Charge/ Team Leader) must document his / her immediate actions and decisions taken in the health record. They should also arrange for all other staff involved in or witnessing the incident to document a contemporaneous account of their involvement in the health records, as soon as possible after the incident, whilst events are most clearly remembered. All accounts should be legible, signed, dated and timed.

In the event of a patient's death, the person in charge should arrange for the patients' Health Record to be placed in a secure location.

A copy of the Health Record should be taken by the appropriate person such as the Governance Manager, Service Lead, or Safeguarding Team which will be made available for staff to refer to when completing subsequent reports or coroner's statements. The original and copy notes should be kept in a locked cupboard.

8. REPORTING AN INCIDENT

When things go wrong in care, it is vital incidents are recorded to ensure learning can take place.

Organisations that report more incidents usually have a better and more effective safety culture. This is because we can't learn and improve if we don't know what the problems are.

All incidents and near misses involving staff, service users and others must be reported through the Trust incident reporting system (as an e-form via the Trust Electronic Incident Reporting System). This will require staff to provide information including:

- What happened and when
- Where the incident happened
- People involved in the incident
- What actions have been completed
- If there has been being open communication
- The Incident grade and actual impact.

A comprehensive incident matrix has been developed to help staff decided on the severity of incidents reported and to identify the incident grade. Grading enables incidents to be identified and investigated according to the level of severity.

Incidents are graded on a scale of 1 – 5.

1. (negligible risk) - Incidents resulting in no injury or damage
2. (minor risk) – Incidents resulting in very minor injury, damage or loss
3. (moderate risk) – Incidents resulting in moderately serious injury, damage or loss
4. (major) – Incidents resulting in grievous harm. Potentially life threatening to a person or substantial damage or loss.
5. (very high risk / catastrophe) major incidents resulting in life threatening events, extremely serious harm or death, substantial damage or loss).

- Police Involvement

Those reporting incidents should be mindful that a factual account is required therefore do not assign blame to colleagues or other services, and avoid making assumptions about the circumstances of the incident or the motivation of others.

The Manager in Charge /Team Leader is responsible for ensuring that an incident is completed and submitted on the electronic system by a member of staff that has sufficient knowledge and understanding of the incident. In order to meet national reporting requirements the recording of the incident must be completed within 24 hours of the incident occurring or being reported.

The notification rules set up in incident reporting system mean that the appropriate local manager is alerted to the incident. The manager is required to check the incident within the incident reporting system and 'sign off' the incident within 48 hours. This includes checking:

- Checking that the detail of the information in the incident report is factual and accurate
- Confirming the correct cause group/code has been selected
- Confirming the incident has been correctly graded
- Ensuring that there has been appropriate communication with the patient and/or relatives in line with being open or duty of candour
- Ensuring that appropriate support is identified for service user/s and staff.
- Ensuring that action required to maintain the safety of service users, staff and others have been identified and completed.
- Opportunities for learning have been identified
- That appropriate immediate actions to reduce the opportunity for a similar incident to occur have been taken or are planned.

Those completing the initial incident report should ensure they provide as much information as possible to enable the reviewers to make an assessment of any immediate actions or onward reporting that may be required. The information should be fact, not opinion based, and should not involve excessive confidential information. When necessary it may be appropriate to attach relevant documentation to the incident report. This can be facilitated by your local governance team or the Trust Risk Department.

Guidance and E-Learning

Further detailed guidance on incident reporting and grading can be found on the Trust intranet http://portal/risk/Pages/ERS.aspx

All staff are required to complete E-Learning training on a 3 yearly basis to support their competence to report an incident.

9. INVOLVING AND SUPPORTING THOSE AFFECTED

9.1 Involving patients, victims and their families/carers

Communicating effectively with service users and/or their carers is a vital part of the process of dealing with errors or incidents. The needs of those affected should be a primary concern for those involved in the response to and the investigation of serious incidents. However the CQC have recently found that families and carers often have a poor experience of investigations and are not always treated with kindness, respect and honesty (CQC, 2016) It is important that affected patients, staff, victims, perpetrators, patients / victims' families and carers are involved and supported throughout the investigation.

Being open

Involvement begins with a genuine apology, or in instances when an act or omission has not been identified, an expression of sympathy for the outcome of the incident e.g. condolences for the patient's death. The Trust fully supports the NHS Being open principles of communication with service users and their families and carers when service users are harmed. A Summary of the Being open guidance 'Being open at a glance' is available in TAD_CO010_02, whilst the full guidance is available via the following link:
http://www.nrls.npsa.nhs.uk/resources/?EntryId45=83726

Being open means apologising and explaining what happened to service users who have been involved in a patient safety incident, (and/or their carers when this is appropriate to do so), confirming that the incident is being investigated, and inviting them to contribute their views and concerns to the investigation process.

Being open about a patient safety incident is more than a one off event it is a communication process with a number of stages (Figure 2). The duration of the process will depend on the incident, the needs of the patient, their family and carers, and how the investigation into the incident progresses.

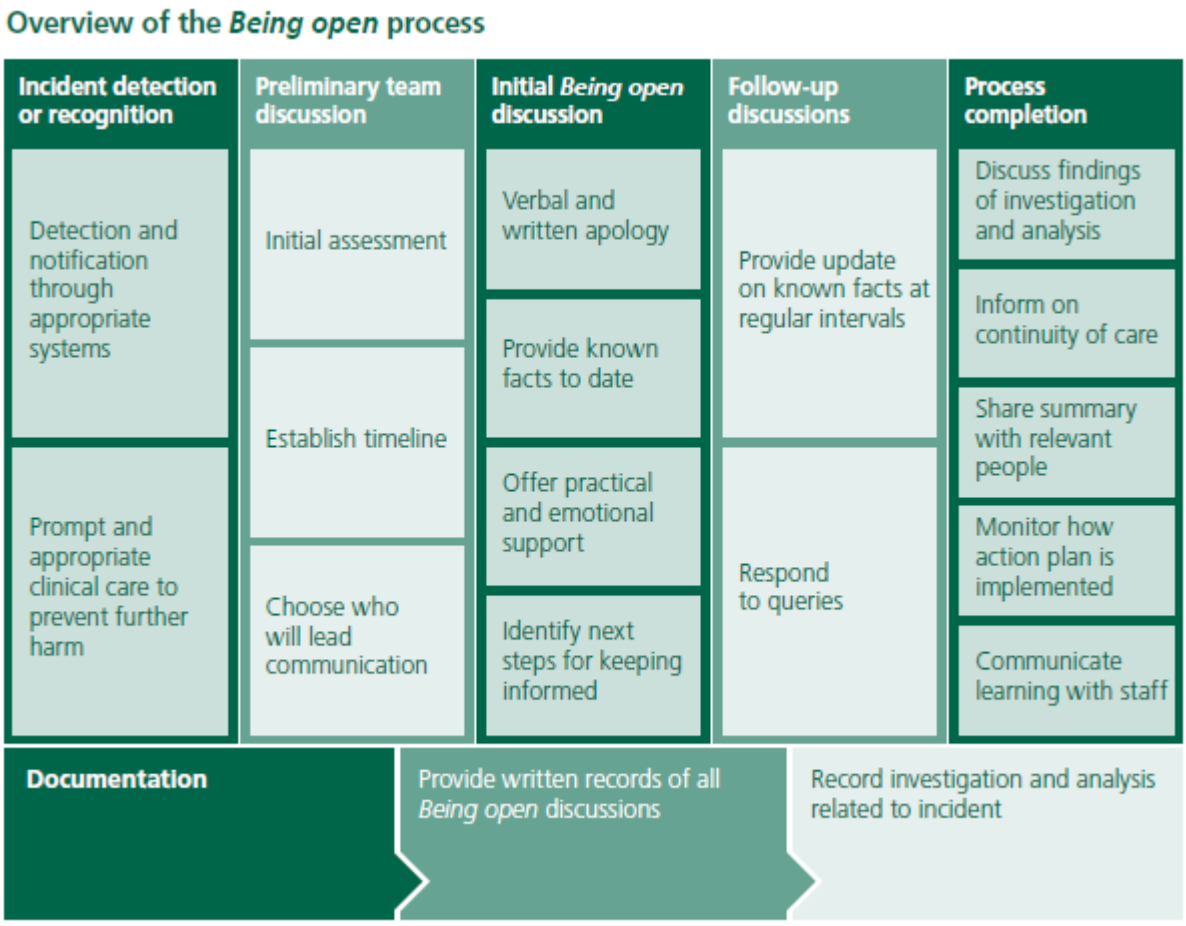


Figure 2: The being open communication process

All staff involved in liaising with and supporting bereaved and distressed people following serious incidents must have the necessary skills, expertise, and knowledge of the incident in order to explain what happened (including what went wrong if an error is identified), promptly, fully and compassionately. The appropriate person must be identified for each case. This can include clinicians involved in the incident but this is not always appropriate and should be considered on a case-by-case basis.

An early meeting must be held to explain what action is being taken, how they can be informed, what support processes have been put in place and what they can expect from the investigation. This must set out realistic and achievable timescales and outcomes.

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?

Duty of Candour

The department of Health's policy on Duty of Candour adds a further statutory duty for health organisations, and the staff who work for them, to be open and honest about the care and treatment provided to service users.

The Duty of Candour applies to patient safety incidents that occur during care provided and that result in moderate harm, severe harm, prolonged psychological harm or death. In practice NHS organisations are required to tell the patient (or their re representative) about any incident where the care or treatment may have gone wrong and appears to have caused significant harm, or has the potential to result in significant harm in the future.

Moderate harm - any patient safety incident that resulted in a moderate increase in treatment and significant but not permanent harm (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 (such as intensive care).
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
Severe harm - a patient safety incident that appears to have resulted in permanent harm (a permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including brain damage, that is related directly to the incident and not related to the natural course of the service user's illness or underlying condition
Death - an incident that directly resulted in the patient's death. rather than to the natural course of the service user's illness or underlying condition,

Examples of incidents meeting duty of candour requirements:

A confused elderly patient was supposed to have 1:1 supervision on an inpatient ward. The patient was left unsupervised for a period of time whilst the shift change was occurring, and the patient fell out of bed, sustaining a severe head injury from which they later died.	**This would be an example where an incident resulted in death**
A patient incurs an extravasation injury (soft tissue burn) from an intravenous line causing irreversible scarring and bone damage.	**This would be an example where an incident appeared to have resulted in severe harm**
A patient developed a small grade 2 pressure ulcer during an admission for rehabilitation. Although they were now fully mobile, they need district nursing visits after discharge home to check and dress the ulcer until healing was complete two weeks later	**This would be an example where an incident appeared to have resulted in moderate harm**
A patient on a mental health unit completed suicide after lapses in risk assessment and observation.	**This would be an example where an incident resulted in death**
Prescribing error on a mental health ward resulted in a patient being given twice her normal dose of Lithium for several days. She became symptomatic for Lithium toxicity which required inpatient admission. She made a full recovery.	**This would be an example where an incident appeared to have resulted in moderate harm**
A distressed, aggressive patient required physical restraint whilst receiving an injection of anti-psychotic medication. During the restraint, the patient's arm was broken which required manipulation and treatment in plaster for 6 weeks. He made a full recovery from the injury.	**This would be an example where an incident appeared to have resulted in moderate harm**
A 71 year old woman with apathy and memory loss is diagnosed with dementia. She is treated for several months in the memory service before she is re-evaluated and diagnosed with depression which responds to antidepressant treatment.	**This would be an example of an incident leading to prolonged psychological harm**

The Duty of Candours requires that there should be:

- Notification of the incident to the service user or a person acting on their behalf

This should include:

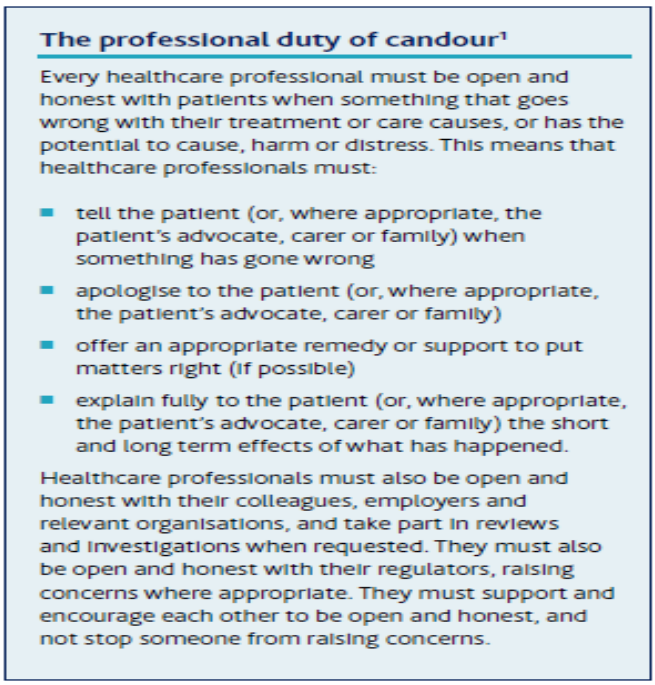
- Provision of relevant support
- And provide:
    - The facts available at the time of notification.
    - Details of the further steps planned to investigate the circumstances of the incident.
    - An apology – The NHS Litigation 'Saying Sorry' leaflet provides information to healthcare staff on providing a meaningful apology

The notification must be verbal and ideally face to face. This must be followed by written notification to the service user or a person acting on their behalf.

The service user / relative must be informed of the potential or actual incident within 10 days of the incident being reported.

The professional duty of candour

All healthcare professionals have a professional responsibility to be honest with patients when things go wrong.



The professional duty of candour[1]

Every healthcare professional must be open and honest with patients when something that goes wrong with their treatment or care causes, or has the potential to cause, harm or distress. This means that healthcare professionals must:

- tell the patient (or, where appropriate, the patient's advocate, carer or family) when something has gone wrong
- apologise to the patient (or, where appropriate, the patient's advocate, carer or family)
- offer an appropriate remedy or support to put matters right (if possible)
- explain fully to the patient (or, where appropriate, the patient's advocate, carer or family) the short and long term effects of what has happened.

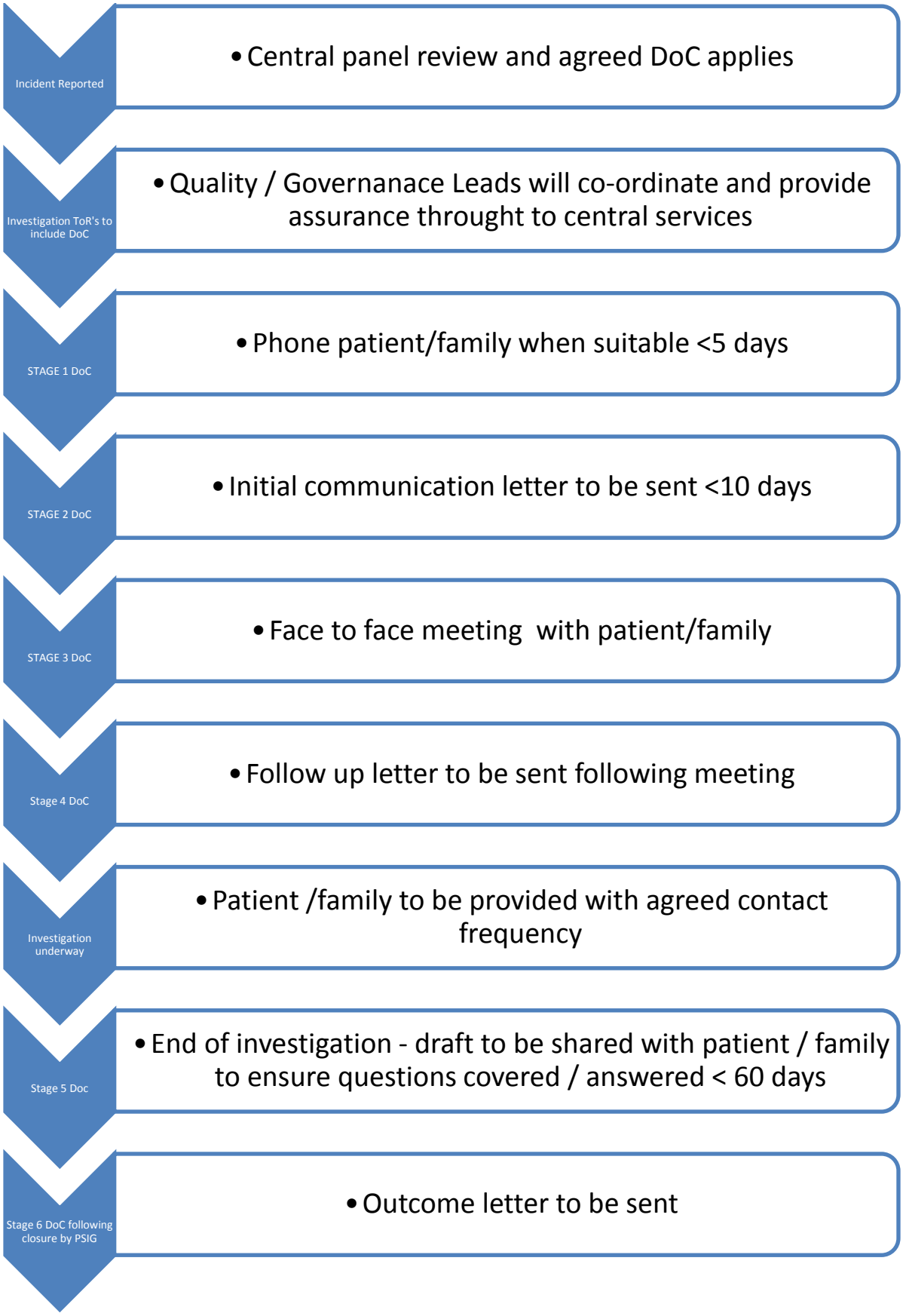
Healthcare professionals must also be open and honest with their colleagues, employers and relevant organisations, and take part in reviews and investigations when requested. They must also be open and honest with their regulators, raising concerns where appropriate. They must support and encourage each other to be open and honest, and not stop someone from raising concerns.

The communication guidance within the Being Open Framework should support the communication requirements of the Duty of Candour:

If any organisation registered with the CQC fails to comply with the duty of candour, they could face regulatory action from the CQC and, in the most serious or persistent cases, even criminal prosecution.

The incident reporting system contains prompts to ensure staff are mindful of the communication requirements following patient safety incidents. The corporate team will support decision making in regards to which incident require DoC communication. The following steps will be required:

Statutory Duty of Candour process



In principle incidents with an outcome of moderate to severe harm will require DoC communication.

Further information including template letters to support communication immediately following the incident, following a face to face meeting, and on completion of the investigation is available via the Trust intranet. http://portal/risk/Pages/Policies-and-guidance.aspx

See TAD_CO010_03 for harm impact of incidents and communication requirements.

E-Learning

Training on 'being open' is freely available through an electronic e-learning tool which can be found via the link below:

https://report.npsa.nhs.uk/boatoolelearning/course/courselaunch.htm

See the external link on Duty of Candour which may be useful to support what this means for patients and their families.

9.2 Other Patients / Service Users

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.

9.3 Supporting staff following an incident

It is important to recognise that serious incidents can have a significant impact on staff who were involved or who may have witnessed the incident. Like victims and families they will want to know what happened and why and what can be done to prevent the incident happening again.

Pennine Care NHS Foundation Trust has a responsibility to provide support to the staff involved in an incident. This includes staff directly affected by an incident, through injury or trauma. It also includes support for staff providing information to any subsequent investigation. The level and extent of support required will be dependent upon each situation. The need to arrange debriefing for staff and support for other service users affected by the incident should be considered. Staff involved in the investigation process should have the opportunity to access professional advice from their relevant professional body or union, staff counselling services and occupational health services. They should also be provided with information about the stages of the investigation and how they will be expected to contribute to the process.

For any staff in training including trainee doctors/ student nurses and other health care professional's appropriate educational contacts should be notified as appropriate

Following any serious incident, managers should ensure healthcare teams and staff are informed of outcomes of investigations. Where an incident investigation report has been produced, this should be fed back to staff as soon as possible by the service manager.

In the case of training doctors this will be via the use of a nominated individual within the borough selected by the Medical Education Lead. The nominated individual will be the lead support for that Training Doctor ensuring continuity if they have moved to another organisation. This nominated individual will then contact the Training Doctor once an internal investigation is completed to arrange a face to face meeting to discuss the finding and any learning from the incident including reflective practice. This will be the responsibility of the nominated person.

In the case of non-medical students this will be via the mentor or clinical educator with the support of the practice education facilitator (PEF) and the relevant college or higher education institution where required. When a non-medical student's placement within the Trust has ended, the PEF will liaise with the student's college or university link lecturer to ensure feedback is given, the college/university can also request that a PEF attend.

Just culture and consideration of concern about an individual staff members actions

A just culture guide (NHS Improvement, 2018) has been produced to support a consistent, constructive and fair evaluation of the actions of staff involved in patient safety incidents. The guide supports a conversation between managers about whether a staff member involved in a patient safety incident requires specific individual support or intervention to work safely. Action singling out an individual is rarely appropriate - most patient safety issues have deeper causes and require wider action.

The actions of staff involved in an incident should not automatically be examined using the just culture guide, but it can be useful if the investigation of an incident begins to suggest a concern about an individual action. The guide highlights important principles that need to be considered before formal management action is directed at an individual staff member.

9.4 Violence and aggression against members of staff

Pennine Care NHS positively promotes the reporting of acts of violence and aggression against staff including those involving offensive language. The Trust is a participant in the joint protocol established between all Greater Manchester NHS Trusts, Greater Manchester Police and Greater Manchester Crown Prosecution Service. Assistance will be given by managers and Security Manager in terms of co-operation, and providing evidence and witness statements by members of staff in those cases where the aggrieved member of staff supports Police action.

10. INVESTIGATION OF INCIDENTS

The fundamental purpose of patient safety investigation is to learn from incidents, and not to apportion blame.

10.1 Initial Management Review:

The incident reporting system allows for automatic notification of incidents to relevant service leads, local governance and clinical leads, Trust leads, and subject matter experts including:

- Local and Trust Safeguarding Leads
- Trust Infection Prevention Control Leads
- Trust Pharmacy Leads
- MH Law Manager
- Trust Information Governance Lead
- Trust Resuscitation Lead
- Trust Managing Violence & Aggression Lead
- Trust Estates Lead
- Trust Local Security Management Specialist
- Trust Fire Officer
- Health, Safety and Emergency Planning Lead

- Information Governance Manager
- Departmental Managers

This ensures that there is appropriate management, review, and scrutiny of all incidents reported, immediate actions are completed, and the need for further review and investigation is identified. It is expected that SMEs documents within the incident to evidence review and actions taken.

The Risk Department Incident Administrators will complete a quality review on all incidents reported within the incident reporting system. Any incidents which indicate inappropriate classification or grading are highlighted to a manager within the risk team.

Following all adverse events, a rapid internal service management review should take place (usually within 72 hours). This Initial Management Review should identify and action any immediate changes which are necessary to ensure safety (e.g. ligature point removal, review of staffing levels, changes to procedures). This should also incorporate a clinical review of the patient's care and treatment, if appropriate, and local investigation of the circumstances of the adverse event.

10.2 Incidents or near misses graded 1, 2, and 3

As per incident notification rules set within the electronic incident reporting system, the appropriate local clinical, management and governance / quality leads will be notified of incidents as they are reported. It is expected that this should prompt review, appropriate action and identification of learning.

For incidents or near misses graded 1,2, and 3, the ward / team manager is responsible for ensuring that an appropriate initial management review takes place, learning is identified and any necessary action is completed and documented, (e.g. within the patients notes, on the incident documentation). It is expected that local governance / quality leads will have a knowledge of incidents in their locality and will support the escalation of safety concern (as appropriate) to Service Manager Managing Director and / or Associate Director, and consider the need to share learning from incidents with other Trust departments or boroughs.

Subject Matter Experts are Trust personnel employed because of qualification and/or experience in the field the incident is concerned with. This can be Safeguarding, Resuscitation, Pharmacy, Violence Reduction etc. These staff will also try to provide feedback and review of low graded incidents, to reinforce to the incident reporter that there report has been read, to provide feedback and guidance on potential lessons learned and acknowledge the good practice that staff undertake when managing an incident and its consequences.

10.3 Incidents graded 4 & 5

As per incident notification rules set within the electronic incident reporting system, the appropriate local clinical, management and governance / quality leads will be notified of incidents as they are reported. It is expected that this should prompt review, appropriate action, identification of learning and escalation.

Any serious incident (grade 4 & 5), are reviewed by a manager within the risk team to determine if the circumstances of the incident meet the definition of a serious incident and if there are significant opportunities for learning. To support this process the risk management team request further information to aid decision making. This is supported by a review of the pertinent clinical documentation, additional questionnaires added to specific incident types within the incident

reporting system (unexpected deaths, pressure ulcer), and requests for further information to evidence the context of the incident and whether any weaknesses in a system or process contributed to the incident occurring (including acts or omissions in care)

It is recognised that the following circumstances may not require further investigation via the serious incident framework.in the following circumstances:

- Where death is unexpected but cause of death is established to be natural causes and or physical health related
- Where cause of death is established and is due to a long standing physical health condition.
- Expected death and those service users who have been on end of life care pathway
- Out of area admissions

However it has been recognised that within the NHS there may be opportunities to learn in order to improve care in particular, the deaths of individuals affected by a learning disability or mental illness (CQC, December 2016, NQB, 2017). Therefore the Trust will consider and support the opportunity to learn from deaths via the LEDER (Learning Disability Mortality Review programme and SJR processes. In response to The Mazars report (Mazars, 2015) the Risk Team will bring any incidents of reported deaths to the weekly Patient Safety Improvement Group to support decision making in regards to the need for further review or investigation.

10.4 Identification of Serious Incidents

As defined by the Serious Incident Framework (NHS England 2015):

'Serious incidents are events in health care where the potential for learning is so great, or the consequences to patients, families and carers, staff or organisations are so significant, that they warrant using additional resources to mount a comprehensive response. …Serious incidents can be isolated, single events or multiple linked or unlinked events signalling systemic failures within a commissioning or health system'.

Serious Incidents in the NHS include:

- Acts and/or omissions that result in:
    - Unexpected or avoidable death of one or more people. This includes:
        - Suicide / self-inflicted death
        - Homicide by a person in receipt of mental health care within the recent past;
    - Unexpected or avoidable injury that has resulted in serious harm;
    - Unexpected or avoidable injury that requires further treatment by a healthcare professional in order to prevent:
        - The death of the service user.
        - Serious harm.
    - Actual or alleged abuse where:
        - Healthcare did not take appropriate safeguarding action/intervention.
        - Where abuse occurred during the provision of NHS-funded care.

- A Never Event - Further detailed explanation can be found in the revised Never Events Policy and Framework (NHS Improvement, 2018).

  https://improvement.nhs.uk/resources/never-events-policy-and-framework/

- An incident (or series of incidents) that prevents, or threatens to prevent, an organisation's ability to continue to deliver an acceptable quality of healthcare services, including (but not limited to) the following:
    - Failures in the security, integrity, accuracy or availability of information often described as data loss and/or information governance related issues.
    - Property damage.
    - Security breach / concern.
    - Incidents in population-wide healthcare activities like screening and immunisation programmes where the potential for harm may extend to a large population;
    - Inappropriate enforcement/care under the Mental Health Act (1983) and the Mental Capacity Act (2005) including Mental Capacity Act, Deprivation of Liberty Safeguards (MCA DOLS);
    - Systematic failure to provide an acceptable standard of safe care (including incidents which necessitate ward/ unit closure or suspension of services)
    - Activation of Major Incident
    - Major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare or an organisation.

However there is no definitive list of events/incidents that constitute a serious incident and lists should not be created locally as this can lead to inconsistent or inappropriate management of incidents.

The Risk Management Team (in discussion with Executive Leads, Senior Managers and subject matter experts) will review the detail and circumstances of all grade 4 & 5 incidents to determine if the incident meets the criteria of a serious incident. Decision making will be based on the following questions:

Is the patient open / known to PCFT (or discharged within 6 months) Y/N

- Did the individual suffer any significant harm, or potentially have suffered significant harm? Y/N
- Is there any opportunity to learn significantly from this incident? Y/N
- Is there significant risk to the Organisational reputation (e.g. media interest) Y/N
- Any acts or omissions;
    - Were the actions / plans intended Y/N
    - Were any adverse consequences intended Y/N
    - Were policies, protocols and safe procedures in place Y/N
    - Did the individual /team follow agreed protocols/policies/procedures Y/N

In many cases it will be immediately clear that a serious incident has occurred and further investigation will be required to discover what exactly went wrong, how it went wrong (from a

human factors and systems-based approach) and what may be done to address the weakness to prevent the incident from happening again. However a serious outcome (such as the death of a patient), is not necessarily a serious incident. The NHS strives to achieve the very best outcomes but this may not always be achievable. Upsetting outcomes are not always the result of error/ acts and/ or omissions in care.

When it is not clear whether or not an incident fulfils the definition of a serious incident, the incident will be discussed at the weekly Patient Safety Improvement Group to assist decision making, and if necessary the Trust will discuss the incident with its commissioners to agree the appropriate and proportionate response.

The case assessment approach will also support the identification of error/ acts and/ or omissions in care, and the focus of any further investigation required.

Serious Incidents meeting the serious incident framework criteria (NHS England 2015), will be declared as soon as possible and immediate action will be taken to establish the facts, ensure the safety of the patient(s), other services users and staff, and to secure all relevant evidence to support further investigation. Serious Incidents should be disclosed as soon as possible to the patient, their family (including victims' families where applicable) or carers.

The commissioner will be informed (via STEIS and/or verbally if required) of a Serious Incident within 2 working days of it being discovered. This will be completed via the Risk Management Team.

If a serious incident is declared but further investigation reveals that the definition of a serious incident is not fulfilled- for example there were no acts or omissions in care which caused or contributed towards the outcome- the incident can be downgraded. This can be agreed at any stage of the investigation and the purpose of any downgrading is to ensure efforts are focused on the incidents where problems are identified and learning and action are required

10.5 Incident Review & Investigation

It is recognised that organisations need to establish the incidents that indicate the most significant opportunities for learning and prevention of future harm. The need for further investigations will therefore be agreed in accordance the NHS Serious incident Framework (NHS England 2015), and Trust priorities. The initial management review of the incident and supporting information by Governance and Risk Leads, subject matter experts and senior clinical staff will endeavour to identify those incidents when:

- Case management was reasonable or good
- Scope for improvement is identified
- Serious lapses in practice and / or systems and processes are evident (Figure 3).

In accordance with the NHS Framework the level of review and investigation will be proportionate to the individual incident. Therefore review and investigation to identify learning will be completed internally via the following processes:

Completion of action plan

- Case assessment

- Structured judgement review
- Concise investigation / Internal Review (IR)
- Comprehensive investigation (RCA).

Whilst the Trust will also support external review and investigation via LEDER, safeguarding processes, HM Coroner and Criminal justice processes.

In some cases the review /investigation may be seen as a journey on a continuum from action plan to comprehensive review. With the level of investigation completed in the majority of cases being appropriate to identify any lessons learned and action required and the review / investigation stopping there. But in other cases issues may be required that necessitate the need for further in depth investigation (e.g. the completion of a case assessment or SJR identifying issues which require further in depth investigation e.g. a concise IR or a comprehensive investigation).

Necessitating a higher level of investigation which the and in a continuum of investigation level if required):

Action plans

The completion of action plans will be requested primarily for low / no harm medication errors; however the potential for harm could have been significant e.g. the omission of critical medication). The requirement for further review and the completion of an action plan or concise investigation will be supported by review of the incident by the Trust Pharmacy Leads.

The action plan requires identification of the cause of the incident (how and why the incident occurred), plus the formulation of actions to improve practice, and requires sign off by the appropriate subject matter expert – See TAD_CO010_09.

Case Assessment review

The need to review serious incidents for learning and improvement opportunities as well as to enable open disclosure to patients and families when care and management has not been optimal is well understood. The challenge however is to work out which serious incidents need an in-depth review and those which based on an initial case assessment can be ‘stood down’ because this analysis demonstrates optimal care and treatment and no contribution to the incident by the healthcare provider. The Serious Incident Framework for England (2015) gives permission for Trusts to stand down serious incidents where it can be demonstrated there is little to no learning value in conducting an in-depth RCA investigation.

The case assessment approach evidences the review of care and treatment by appropriate clinician/s in order to identify any lapses in practice and / or systems and processes, learning, immediate actions required, and considered approach to determining the need for any subsequent investigation needed.

Those incidents which identify **serious** lapses in practice and / or systems and processes will be prioritised for further investigation via the RCA approach. Whilst cases where scope **for improvement** is identified will be considered for further investigation, however this will be dependent on whether or not the pertinent issues have been identified and appropriate actions put in place.

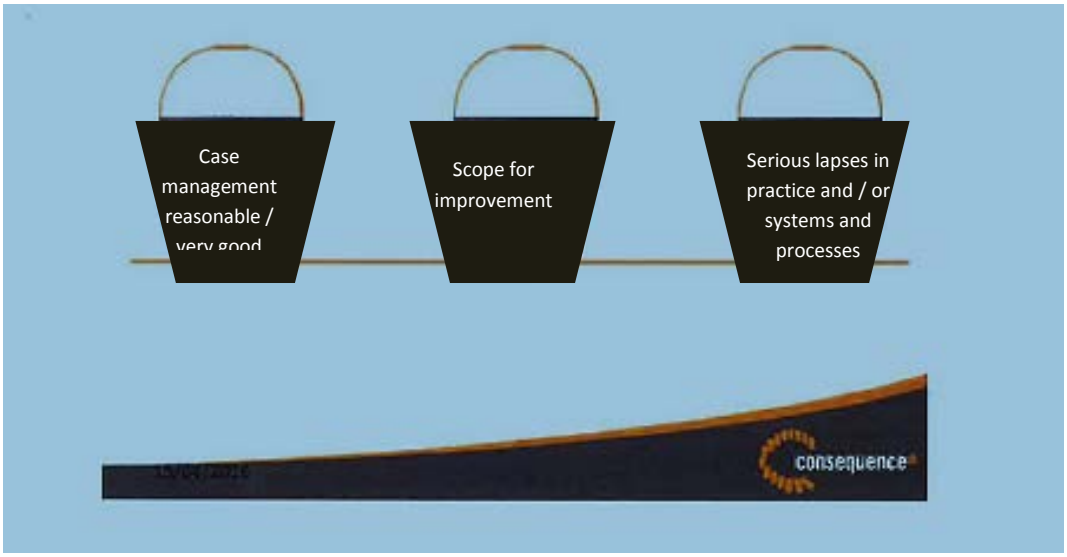


Figure 3: The investigation process

Adapted from the Investigating Adverse Events Half Day Workshop manual (Consequence UK, 2016

Structure judgment review

In line with the National Quality Board National guidance on learning from deaths (NQB, 2017) the Trust has adopted the Structured Judgement Review (SJR) case note review methodology to review care and identify learning following the premature deaths of those with a severe mental illness. This review approach will be utilised in unexpected death incidents when there is no information to suggested that the death is a patient safety incidents.

Again those incidents which identify significant lapses in practice and / or systems and processes will be prioritised for further investigation via the RCA approach.

Investigation

The level of any investigation agreed and response required will be decided based on the NHS England Serious Incident guidance TAD_CO010_10.

The Trust may utilise its own subject matter experts or external reviewers with appropriate skills and qualifications in the investigation of higher graded incidents.

The recognised system-based method for conducting investigations, commonly known as Root Cause Analysis (RCA), should be applied for the investigation of Serious Incidents.

All investigation completed will evidence the system investigations approach for the investigation of serious incidents outlined by NHS England (Figure 5) looking to establish:

- What happened – what went wrong -acts omissions
- How it happened – the contributory factors
- Why it happened – the fundamental issues

In order to identify solutions and actions required.

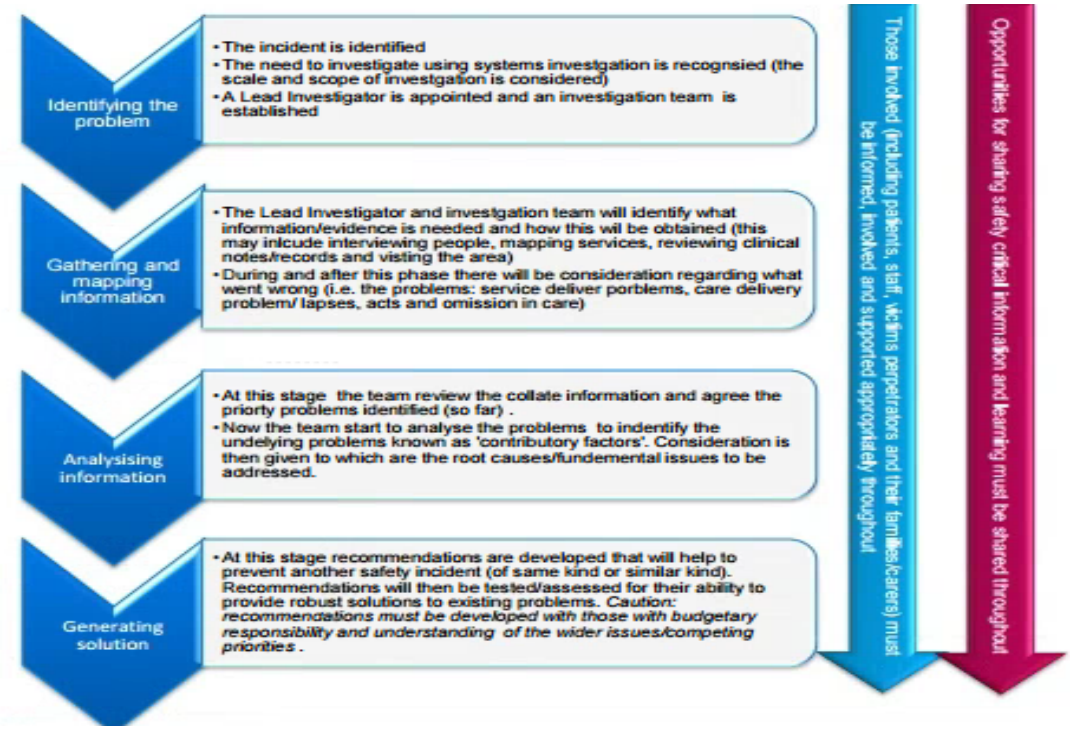


Figure 5: The systems approach to investigations

10.6 Concise investigation

Concise investigations are considered suited to less complex incidents which can be managed by individuals or a small group of individuals at a local level.

If this is required, the Risk Department will send a written request to the relevant borough (by email), that a local concise investigation is required. A template for the concise report can be at TAD_CO010_07.

All requests for investigations will be supported by terms of reference.

As there may be variation of staff responsibilities and designation of duties in each borough, it is the responsibility of the Managing Director, Associate Director and Local Governance Manager / Quality Lead to make appropriate local arrangements for responding to these requests, that investigations are complete and robust, that learning has been identified, that any immediate actions identified have been completed, that any further actions planned are SMART (specific, measurable. achievable, relevant and time-bound) and that the report is returned to the Risk Department in a timely manner (in order to meet the current 60 day timeframe of SI investigation completion).

Designated investigation leads are expected to complete the concise investigation report and send to the Divisional Governance Manager / Quality Lead within a reasonable time frame to allow Governance Managers / Quality Leads to quality check the report, action any required amendments, seek appropriate Managing Director / Associate Director (or delegated officer) sign off, and subsequently forward to the Risk Department. In appropriate cases incident investigations may be signed off by a subject matter expert e.g. Mental Health Law Manager, Trust Information Governance Lead. Reports submitted to PSIG without the above checks will only be accepted in exceptional circumstances. Appropriate supporting information should be submitted alongside the investigation e.g. care plan, risk assessment, applicable clinical record.

The Governance Lead / Quality Governance Lead needs to be mindful of any parallel investigation into the incident (Coroners inquiry, Safeguarding review, Human Resources, Complaints investigations etc.), and ensure that information available within the Trust is consistent with the findings of the Trust investigation. Although the duplication of investigation is to be avoided an internal investigation report is required for all StEIS reportable incidents addressing all the terms of reference (ToRs) identified by the Trust risk and patient safety leads, unless otherwise agreed by the relevant commissioners and NHS England.

On receipt of the report the Risk Department will ensure that the report is placed on the next available Patient Safety Improvement Group (PSIG) agenda for scrutiny.

In some instances, further information or clarification may be required to supplement the information in the investigation report before the report can be signed off at PSIG. When this is required, the local Governance Manager / Quality Governance Lead will action the request and resubmit the report at the earliest opportunity.

All correspondence relating to incidents will be channelled through the local Governance Manager/ Quality Governance Lead. Similarly, Human Resources, Complaints investigations Coroners inquiries, safeguarding and other external multi-agency, or police investigations may provide additional information for consideration.

10.7 Comprehensive Investigation

Comprehensive investigations will be generally be commissioned in the following incidents:

- Homicides by service users in receipt of care by mental health services.
- Inpatient suicides.
- In addition any incidents when it is established that acts or omissions in care or service deliver have significantly contributed to serious harm or death.

However it is recognised that effective investigation is a journey and in these cases an initial concise investigation would still be requested from services to identify and immediate actions. The comprehensive investigation would then build on the concise investigation report.

In addition an incident investigation may move from a concise to a comprehensive investigation at any stage in the investigation process as information comes to light, and the need for a more comprehensive investigation is identified.

The Trust Risk Management Team (with oversight from Executive Leads), will issue terms of reference for each comprehensive incident investigation, providing guidance on key issues to be considered, the scope of the investigation, the investigation lead and the membership of the investigation team.

The nominated investigation lead will coordinate the completion of the comprehensive investigation, whilst oversight of the comprehensive investigation will be via the Medical Director and Director of Nursing and Allied Health Professionals.

Review and sign off of the completed comprehensive report will be via the Patent Safety Improvement Group (PSIG) and supported by the Trust Serious Incident Panel and Director of Nursing and Allied Health Professionals.

A template for the comprehensive investigation report can be found at TAD_CO010_06.

However in order to avoid unnecessary copy and pasting of the investigation report into this format the concise investigation report can be adapted to evidence that a comprehensive investigation has been completed. This would mean adding the following fields to the concise investigation report:

- Involvement and support provided for staff involved
- Information and evidence gathered
- Care and service delivery problems
- Contributory factors
- Root causes

10.8 Investigation timeframes

Serious incident reports and action plans must be submitted to the relevant commissioner within 60 working days of the incident being reported to the relevant commissioner, With this in mind the process for completion, scrutiny and closure of all reviews and investigations report by the PSIG should be completed in line within this requirement. Clear management plans should be developed and agreed by the local governance manager / quality governance lead and appointed investigator at the start of the process to avoid delays. This should take into consideration the time required for local and corporate review and the requirement for being open and duty of candour communication.

Providers can request extensions to the StEIS report submission deadline, but there must be compelling reasons for doing so; for example, new information coming to light which requires further investigation. The SI framework gives the following specific criteria for extension requests:

- Enforced compliance with the timetable of an external agency, such as police, Coroner, Health and Safety Executive or Local Children Safeguarding Board or Safeguarding Adult Board;
- Investigation of highly specialised and multi-organisation incidents, such as those involving a national screening programmes; or
- Incidents of significant complexity.

Extensions must be agreed and confirmed by the appropriate commissioner in advance of the original deadline. Extensions are effective from the day on which the serious incident report was due for submission.

A request for an extension to this timeframe can be requested via the Risk Department. This should be completed clearly detail the reason why an extension is required e.g. details of the complexities of the investigation, aspects of case requiring further exploration, opportunity to complete being open/ duty of candour communication in the timeframe required by patient (and/ or family / carer) and returned to the risk department for submission to the appropriate commissioner.

The progress of all grade 4 and 5 incidents will be tracked via local governance processes. This will be supported by the RAG report detailing each Directorate / Locality's outstanding investigation submitted to Local Governance Lead / quality governance lead on a weekly basis.

11. DISCLOSURE OF INCIDENTS, INVESTIGATION REPORTS, AND ACTION PLANS

Trust Commissioners

Incidents considered to meet the criteria of a serious incident will be shared with the Trust commissioners following closure at PSIG. The report will be reviewed within the CCG SI review meeting and will only be closed when the commissioners are satisfied that the investigation report and action plan meets the required standard.

Care Quality Commission

In line with Regulation 12: Safe care and treatment, the CQC will regularly review patient safety incidents reported in line with NRLS reporting requirements, and serious incidents reported externally in line with StEIS reporting requirements. As such this may prompt further information requests e.g.

- Requests for assurance that incidents have been appropriately reviewed by appropriate trust leads and subject matter experts,
- Clarification of lessons learned and actions completed and required.
- Clinical information – risk assessment, care plan, pertinent clinical records
- Team / service information – rotas, training records
- Policies and guidance
- Completed investigation reports

Ultimately the CQC can prosecute for a breach of this regulation or a breach of part of the regulation if a failure to meet the regulation results in avoidable harm to a person using the service or if a person using the service is exposed to significant risk of harm. Additionally, the CQC may also take other regulatory action, and must refuse registration if providers cannot satisfy us that they can and will continue to comply with this regulation.

HM Coroner

Established Coroner processes require Trust investigations are often requested by the Coroner to support coronial processes. As such trust investigations may be disclosed to interested parties including relatives as part of the coronial processes. In line with being open and duty of candour requirements those completing investigations need to be mindful of this and the need to ensure that families are fully supported to contribute to trust internal investigations and to receive the details of service users involvement and investigation findings in the way they would wish.

Those completing investigations must also be mindful of the need to ensure all PCFT services involved have contributed to the investigation report, and information contained in investigation reports is consistent with information in the clinical record and any statements submitted to the Coroner.

Safeguarding investigations

Trust internal investigations will be completed in order to support multiagency Safeguarding investigations. The Trust Safeguarding Lead and the local safeguarding team will be notified of any incidents which contain safeguarding concerns. Liaison between the Trust Risk and Safeguarding Leads will ensure that there is appropriate management and investigation of any

safeguarding incidents in line with both the requirements of the Serious Incident Framework and the Local Authorities via Local Safeguarding Children Boards or Local Safeguarding Adult Boards.

Those completing investigations must also be mindful of the need to ensure all PCFT services involved have contributed to the investigation report, and information contained in investigation reports is consistent with information in the clinical record, multiagency report, and any statements submitted to the Coroner.

12. MENTAL HEALTH CARE RELATED HOMICIDES

As outlined in the NHS England Serious Incident Framework this would concern incidents '*When a homicide has been committed by a person who is, or has been, subject to a care programme approach, or is under the care of specialist mental health services, in the past 6 months prior to the event'.*

The investigation of any mental health care homicide reported within the Trust will be in accordance with NHS England's Standard Operating Model and overseen by the regional investigations team.

Further information is available in TAD_CO010_08 taken from the Serious Incident Framework:

13. SHARED LEARNING

Learning is centrally facilitated by the following routes:

- Review of all investigation reports at the Trust Patient Safety Improvement Groups.
- Discussion of incidents and investigation reports at appropriate trust forums/ groups e.g.:
    - Resuscitation committee
    - Suicide Prevention and Self Harm Group
    - Inpatient Falls Group
    - IPC Committee
    - Trust Quality Group and committee.
- Continuous learning forums
- 7 minute briefings
- Via Subject matter expert bulletin

See TAD_CO010_04 for Learning Embedded Throughout Process of Serious Incident Reporting and Investigation

14. STAFF TRAINING AND PROMOTING AN OPEN AND HONEST CULTURE

All employees have a role to play in identifying and minimising inherent risks. This can only be achieved if there is a progressive, honest and open working environment, where near misses and untoward incidents are identified quickly and acted upon in a constructive way, without unnecessary recourse to disciplinary procedures.

Training in incident reporting is provided for staff within the Trust Induction programme and through the risk department. This will include information on reporting systems, investigation processes, the Duty of Candour, and *Being open* principles

Training in the principle of investigations will be provided when required, to maintain sufficient capacity and expertise within the Trust to undertake this important work.

Training on 'Being open' is freely available through an electronic e-learning tool which can be found via the link below:

https://report.npsa.nhs.uk/boatoolelearning/course/courselaunch.htm

Staff are also able to access further guidance on incident investigation via NHS England:

http://www.nrls.npsa.nhs.uk/resources/collections/root-cause-analysis/

This includes a Root Cause Analysis (RCA) eLearning Programme (RCA Toolkit) which has been created by the as a tool for guiding NHS staff through the process of conducting an RCA investigation.

http://www.nrls.npsa.nhs.uk/resources/rca-conditions/

Opportunities for investigation training will be advertised via the Trust Learning and Development Department

http://penn-web/training/course-list-3-2.asp

Further bespoke training in case assessment and structure judgment reviews will be coordinated by the Trust Risk Leads with attendance supported by local governance / quality leads.

15. NOTIFICATION OF INTERESTED BODIES

National Reporting and Learning Systems

Pennine Care reports all patient safety incidents through the National Reporting and Learning System (NRLS). The Trust electronic incident database (Safeguard) is linked to the NRLS and enables the Trust to report incidents to the National NHS patient safety team. This is completed by the Risk Management Team.

Strategic Executive Information System

The commissioner must be informed (via STEIS (the Strategic Executive Information System, NHS England's web-based serious incident management system) or its successor system and/or verbally if required) of a Serious Incident within 2 working days of it being discovered. This is completed by the Risk Management Team.

Health and Safety Executive (HSE) and RIDDOR

The Trust has a statutory duty to report certain kinds of accidents, violent incident dangerous occurrences and occupation ill health under the Health and Safety at Work Act 1974 and in accordance with the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) 2013.

RIDDOR requires employers and others to report deaths, certain types of injury, some occupational diseases and dangerous occurrences that **'arise out of or in connection with**

work'. Generally, this covers incidents where the work activities, equipment or environment (including how work is carried out, organised or supervised) contributed in some way to the circumstances of the accident.

See TAD_CO010_04 for information regarding the Health and Safety Executive (HSE) and RIDDOR.

Information governance serious incidents, Caldicott and data protection

All Information Governance breaches should be reported to the Information Governance Manager, either via completion of an incident report, or where the incident is thought to have potentially serious consequences via telephone as soon as practicable from the discover of the incident.

When an Information Governance incident has occurred and been reported, the IG SME will follow the processes and procedures laid out in TAD_CO010_11.

For serious incident this will include assessment of the incident in accordance with the statutory requirement to onward report via the Data Protection & Security Tool (DSPT) to the Information Commissioner's Office (ICO) within 72 hours of the incident occurring.

Missing Records

Unavailable, missing or lost records are a serious risk to the Trust as they may contain personal confidential data. It is therefore vital that tracing procedures are undertaken at all times. If records are 'missing' when required for a clinical intervention; SAR; complaint; investigation; disciplinary etc. the incident should be graded a 4 and the missing records procedure followed (cross reference policy) with every effort made to locate the record and if not found we have a duty to inform the client/member of staff. Template letters are available via the Records Manager.

When a set of paper records has been missing for 6 months, it is reasonable to assume that the original set of paper records has been lost.

Other regulatory, statutory and advisory bodies

Regulatory, statutory and advisory bodies, such CQC, Monitor or NHS Trust Development Authority, must also be informed as appropriate without delay. Discussions should be held with other partners (including the police or local authority for example) if other externally led investigations are being undertaken. This is to ensure investigations are managed appropriately, that the scope and purpose is clearly understood (and those affected informed) and that duplication of effort is minimised wherever possible.

Further guidance from NHS England in regards to external notification including:

- CQC
- The Information Commissioner's Office
- Controlled Drugs
- Coroner
- Defects and Failures
- Health and Safety Executive (HSE)
- Health Education England
- Local Authorities
- Medicines and Healthcare products Regulatory Agency (MHRA)
- Monitor

- NHS Protect
- NHS Trust Development Authority
- Police
- Professional regulators and professional misconduct
- Public Health England
- Serious Adverse Blood Reactions and Incidents (SABRE)

Further information is contained within TAD_CO010_09.

16. INCIDENTS INVOLVING HUMAN RESOURCES (HR) INVESTIGATIONS

Where an incident involves a staff member employed by Pennine Care NHS Foundation Trust and requires investigation by HR an Incident must still be completed and graded accordingly. Where there may be a HR investigation following a Serious Incident the Risk Management Team will liaise with the service manager to decide on which route of investigation is appropriate either HR or through an incident investigation. Where appropriate HR will send the Risk Department feedback, and any recommendations.

17. MEDIA REPORTING OF INCIDENTS

The Trust Communication Team should be notified of any incident which is or likely to generate media interest.

Staff should **not** attempt to provide any response to enquiries from the media nor engage in any discussion. Any requests for information from the media or public following a serious incident should be directed to the Communications Manager for Pennine Care based in Trust Headquarters. Further information is available within the Trust Media Protocol:

http://portal/comms/Pages/Guidance-documents.aspx

The Trust's communications team should contact the Commissioners immediately if there is the possibility of adverse media coverage in order to agree a media handling strategy.

(a) If an incident occurs, which the patient may be unaware of, e.g. medication error, breach of confidentiality. The person who identifies the error, in consultation with their line manager, must inform the patient prior to the media.

(b) Where an incident comes to light several months after it has occurred, involving a patient, every effort must be made to contact and inform the patient prior to the media.

18. FREEDOM TO SPEAK UP

All employees have a duty to draw to the attention of the Trust any concern or reasonable suspicion of damage or risk to the interests of service users, the public, or other staff. This includes reporting incidents which caused harm or had the potential to cause harm. In the first instance, where possible, it is best to try and raise any concerns as soon as possible within your teams and/or with your line manager, supervisor or mentor - either informally or formally. However In some situations the person raising the concern may feel that they need support or protection from possible reprisals or victimisation.

The Trust has an appointed Freedom to Speak Up (FTSU) Guardian whose role is to support staff to raise and handle issues effectively and help create a culture of openness; where staff are encouraged to speak up, lessons are learnt and care improves as a result. The Freedom to Speak Up (FTSU) Guardian is a contact for to whom all staff can speak to in confidence if they have questions about a public interest concern or concerns that are not being taken seriously, or dealt with effectively, by their manager or other appropriate person.

Full details of the Trust Procedures for reporting concerns are included in the Freedom to speak up Policy HR012.

19. EQUALITY IMPACT ANALYSIS

As part of its development, this document was analysed to consider / challenge and address any detrimental impact the policy may have on individuals and or groups protected by the Equality Act 2010. This analysis has been undertaken and recorded using the Trust's analysis tool, and appropriate measures will be taken to remove barriers and advance equality of opportunity in the delivery of this policy.

20. FREEDOM OF INFORMATION EXEMPTION ASSESSMENT

Under the Freedom of Information Act (2000) we are obliged to publish our policies on the Trust's website, unless an exemption from disclosure applies. As part of its development, this policy was assessed to establish if it was suitable for publication under this legislation. The assessment aims to establish if disclosure of the policy could cause prejudice or harm to the Trust, or its staff, patients, or partners. This assessment has been undertaken using the Trust's Freedom of Information Exemption Guide, and will be reviewed upon each policy review.

21. INFORMATION GOVERNANCE ASSESSMENT

This Policy has been analysed to ensure it is compliant with relevant information law and standards as in place at the time of approval, and are consistent with the Trust's interpretation and implementation of information governance components such as data protection, confidentiality, consent, information risk, and records management.

Compliance will be reviewed against any changes to legislation / standards or at the next review of this document.

22. SAFEGUARDING

All staff have a responsibility to promote the welfare of any child, young person or vulnerable adult they come into contact with and in cases where there are safeguarding concerns, to act upon them and protect the individual from harm.

All staff should refer any safeguarding issues to their manager and escalate accordingly in line with the Trust Safeguarding Families Policy and Local Safeguarding Children/Adult Board processes.

23. MONITORING

The effective application of this policy, including adherence to any standards identified within will be subject to monitoring using an appropriate methodology and design, such as clinical audit.

Monitoring will take place on a biannual basis and will be reportable to the Quality Group via the Clinical Effectiveness and Quality Improvement Team.

24. REVIEW

This policy will be reviewed three-yearly unless there is a need to do so prior to this; e.g. change in national guidance.

25. REFERENCES

Independent review of deaths of people with a Learning Disability or Mental Health problem in contact with Southern Health NHS Foundation Trust April 2011 to March 2015. 2015, Mazars

https://www.england.nhs.uk/south/wp-content/uploads/sites/6/2015/12/mazars-rep.pdf

Serious Incident Framework 2015, NHS England Patient Safety Domain

https://www.england.nhs.uk/patientsafety/wp-content/uploads/sites/32/2015/04/serious-incidnt-framwrk-upd2.pdf

Never Events policy and framework, Revised January 2018. NHS Improvement

https://improvement.nhs.uk/resources/never-events-policy-and-framework/

Regulation 20: Duty of candour. Information for all providers: NHS bodies, adult social care, primary medical and dental care, and independent healthcare March 2015, Care Quality Commission

https://www.cqc.org.uk/content/regulation-20-duty-candour

Openness and honesty when things go wrong: the professional duty of candour (June 2015) General Medical Council | Nursing and Midwifery Council

http://www.gmc-uk.org/static/documents/content/DoC_guidance_english.pdf

https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/candour---openness-and-honesty-when-things-go-wrong/about-this-guidance

National Patient Safety Agency (2009) Being open: communicating patient safety incidents with patients, their families and carers

http://www.nrls.npsa.nhs.uk/resources/collections/being-open/?entryid45=65077

National Patient Safety Agency (2008) Independent investigation of serious patient safety incidents in mental health services

http://www.nrls.npsa.nhs.uk/resources/?EntryId45=59836

Learning, candour and accountability A review of the way NHS trusts review and investigate the deaths of patients in England, CQC, December 2016

https://www.cqc.org.uk/sites/default/files/20161212-learning-candour-accountability-summary.pdf

National Guidance on Learning from Deaths. A Framework for NHS Trusts and NHS Foundation Trusts on Identifying, Reporting, Investigating and Learning from Deaths in Care. National Quality Board March 2017

https://www.england.nhs.uk/wp-content/uploads/2017/03/nqb-national-guidance-learning-from-deaths.pdf