Northamptonshire Healthcare NHS
NHS Foundation Trust

Incident Policy (Including near miss incidents)

CRM002

Table of Contents

Why we need this Policy

The collation and analysis of data on incidents and near misses is an intrinsic part of patient safety as it provides valuable opportunities to learn and improve. This policy describes the Trust's arrangements for reporting incidents of all types and of any significance and the actions expected to manage and follow-up such incidents. This relates to any incidents involving staff, patients and others.

This policy supports the Risk Management Strategy and must also be read in conjunction with the following Policies:-

- Complaints and Concerns Policy (CRM003)
- Claims Management and Legal Advice Policy (CRM004)
- Analysis, Improvement and Learning Lessons Policy (CRM005)
- Being Open Policy (CRM006)
- Investigation Policy (For incidents, Complaints, Concerns and Claims (CRM008),
- The Reporting and Management of Serious Incidents Policy (CRM010).

This policy applies to all Trust services and to all Trust-employed staff, visitors and others who may be affected by incidents or near misses that occur in connection with the Trust's activities.

Staff may choose to report incidents in confidence or anonymously through the Trust's whistle blowing policy HR009 Guidance for Staff Raising Issues of Concern. (Freedom to Speak Up).

What the Policy is trying to do

The Trust is committed to supporting and embedding a positive reporting culture within the organisation to enable the organisation to learn when things have gone wrong.

An incremental method of grading and investigating reported incidents will be applied using a standard framework outlined in CRM008 Analysis, Improvement and Learning Lessons Policy.

In particular the Trust will:

Ensure a "Fair Blame" culture is promoted to ensure that staff are assured that the Trust will have an open and just environment and that it is the Trust Policy.

Ensure all incidents are managed in a timely and organised manner.

Ensure robust record keeping and reporting mechanisms are in place.

Ensure clear lines of accountability and responsibility are identified for all elements of incident management.

Ensure that all relevant staff, including bank, locum and agency staff are aware of the communication systems in place for the management of all types of incidents, via induction and training.

Establish key communication mechanisms with patients, family and/or carers in line with the Being Open Policy.

Ensure all appropriate levels of debrief and support to staff and publicity of lessons learned take place following incidents.

Ensure all relevant internal and external Stakeholders, Agencies, and Regulatory bodies are engaged, involved and informed in line with National guidelines.

Ensure lessons are learned from reported incidents, and take appropriate action to avoid a recurrence, including making changes to practice and/or the environment to improve patient and staff safety where appropriate.

Ensure no disciplinary action will result from reporting an incident (including mistakes and near misses), unless there is evidence of

- Criminal or malicious activity.
- Professional malpractice.
- Acts of gross misconduct.
- Repeated mistakes.
- Or where errors or violations have not been reported.

Under these circumstances, disciplinary action will be considered.

Which stakeholders have been involved in the creation of this Policy

- The Trust's Executive Team
- Patient Safety Team
- Health and Safety Risk Committee

Any required definitions/explanations

The following definitions detail all types of incidents that must be reported as incidents/near misses:

A **Hazard** is defined as 'Anything which has the potential to cause harm'. **Example:** A wet corridor is a hazard, the risk is that a patient or member of staff could slip and fall.

An **Incident** is defined as 'Any unexpected or unintended event, which gives rise to, or has the potential to produce harm, loss or damage'. **Examples:** equipment malfunction, breach of confidentiality, violence, abuse and aggression, needle stick injury, slips, trips and falls, medication error, failure of a medical device, communication failure, delay in risk assessment.

A **Near Miss** is defined as the situation 'Where an incident was prevented resulting in no harm, but had the potential to harm'. **Example:** Medication was about to be administered to a patient when it was realised that it was the wrong patient.

RIDDOR refers to the 'Reporting of Injuries, Diseases and Dangerous Occurrences Regulations' (2013) and requires employers and others to report accidents and some diseases that arise out of or in connection with work. Mandatory reportable incidents include:

- Deaths
- Specified injuries (including as a result of physical violence)
- Injuries lasting more than 7 days (where an employee or self employed person has an accident and the person is away from work or unable to work normally for more than seven days)
- Injuries to members of the public where they are taken to hospital
- Work related diseases and dangerous occurrences (i.e. accidental release of any substance which may damage health).

Pressure ulcer A localised injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear.

Root Cause Analysis (RCA) is a methodical approach to investigations and is endorsed by the National Patient Safety Agency (NPSA) who recommend that NHS organisations use this systematic way of investigation to seek to look beyond individual actions and identify if there have been any systemic failings within the organisation that need to be addressed. RCA also promotes the identification of learning, the monitoring of and assurances that should be sought on actions taken to improve safety (see Analysis, Improvement and Learning Policy).

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Key duties

- **Chief Executive** will have**:**
- Overall responsibility for the implementation of this policy.

- **Trust Board of Directors** will:
  - Receive exception reports on key risks on a bi-monthly basis.
  - Delegate responsibility for consideration of risk management reports that contain incident information to the Governance Committee.
  - Consider any independent investigation reports conducted.

- Commit to the requirement to follow the Being Open requirements as determined by the NPSA.

- **The Quality and Governance Committee** will:
  Consider patient safety reports on incident management and learning.

- **Director of Nursing and Quality** will:
  Ensure that this policy is implemented through robust systems and processes and that there are effective reporting and monitoring processes in place.

- **All Directors** will:
  - Ensure that internal and external reporting requirements are met.
  - Ensure that all incidents are investigated according to the severity of the incident (please refer to the Investigation Policy).
  - Ensure that effective analysis and learning systems are in place within their care pathway and that assurance and monitoring takes place.
  - Ensure that their care pathway follows 'Being Open' with all those affected by an incident, together with effective support mechanisms for staff.
  - Consider incident and aggregated data in the identification of risks and address risks through risk reduction measures and to improve quality of services.
  - Ensure that staff attend training to comply with the requirements of this policy according to the training needs analysis shown in HR025 Trust's Core Skills Training Policy.
  - Adhere to policies of commissioning organisations, taking responsibility for producing reports that meet the required timescale and to report to the Trust Board of Directors on investigation findings and learning.

- **Heads of Service/General Managers** will:
  - Have systems and processes in place to deliver on the required duties of directors as listed above.
  - Ensure that all staff within their area are aware of and understand this policy.
  - Ensure that all incidents are reported and investigated according to the severity of the incident.

  - **Corporate Systems Manager**
  - Quality assure the reporting and approach to grading of incidents and provide feedback reports to managers where there are issues of concern, offering support and re-training.
  - Produce bi-monthly (and at other requested intervals) incident reports for Directors for analysis.

- **The Patient Safety Manager / Team**
  - Work with and support care pathway operational groups that consider incidents, providing incident information as required.
  - Have In liaison with and as required provide training and support to staff on all aspects of incident management.

- Have co-ordinated and centralised records and files on incidents that contain all documents relating to the reporting, investigation, learning and communication with external stakeholders and others.
- Ensure that external reporting responsibilities are met by the organisation by liaising with the various leads shown in **Appendix 1**.

- **Specialist staff**
  Advise and assist in the reporting, investigation and actioning of incidents relevant to their role. Specialist staff can include; the Health and Safety Risk Manager, Patient Safety Manager, Manual Handling Lead, Infection Control Lead, Safeguarding Lead, Fire Officer, Occupational Health Lead, Local Security and Management Specialist, Emergency Planning Lead etc.

- **Medical Director**
  - Ensure that medical staff are fully aware of this policy.
  - As Caldicott Guardian, ensure that effective systems are in place to maintain the security of identifiable data.

- **Managers**
  - Ensure that they and the staff they are responsible for comply with the content of this policy.
  - Ensure that staff have access to training in the form of local induction covering incident reporting and further training identified, e.g. root cause analysis training (see Investigation Policy).
  - Ensure that staff report all incidents effectively and that where necessary, local investigations are undertaken and learning identified and implemented.
  - Consider incident data in risk assessments undertaken as part of the Risk Register process.
  - Grade incidents and approve them before submission to the risk management database, Datix.
  - Participate and ensure staff participation in any local incident investigation.
  - Support staff involved in and/or affected by an incident in line with the Supporting Staff Policy.
  - Ensure that lessons learned are fed into local forums and across the pathway. Review trends on a regular basis and where necessary, develop action plans to reduce likelihood (please refer to CRM005 Analysis, Improvement and Learning Lessons Policy).
  - Ensure a regular reporting mechanism exists with line manager, Matron or Head of Service.

- **ALL Employees**
  - Attend the required mandatory training relevant to this policy.
  - Read and comply with the content of this policy.
  - Report all incidents that they are involved in or witness/discover.
  - Not communicate directly with the media relating to incidents and should direct all enquiries from the media to the Trust Communication Lead or the Chief Executive's office
  - Comply with the requirements of CRM006 Being Open Policy in relation to incidents in communicating incident information to those affected.

- Participate in implementation of learning from incidents in line with CRM005 Analysis, Improvement and Learning Lessons Policy.
- Act on and report in accordance with this policy any incident that is brought to their attention by a patient, visitor or contractor.

Policy detail

- **Immediate Action Following an Incident**

  This guidance is for all staff. It also relates to any manager taking responsibility for the local investigation of an incident

  An incident reporting flow chart that includes timescales is attached at **Appendix 2.**

  - **Safety**

    The safety of patients, staff and the public must be priority. Any member of staff present when an incident is discovered must take immediate action within their competency to reduce risks and maintain safety of all.

    The manager of the area involved in the incident must ensure the environment is made safe to prevent any re-occurrence and deal with the immediate needs of patient/visitor/staff.

  - **Completion of incident forms**

    Every incident must be reported on the Trust's Incident Report Forms by way of DatixWeb Database. A paper form may be used for those staff who do not have access to DatixWeb. Supplies of the incident forms are available from the Corporate Systems Manager and training on reporting incidents via DatixWeb is available from the Patient Safety Manager/ Corporate Systems Manager and should also be part of local induction for new members of staff. Incidents should be reported within 24 hours of becoming aware of the event. This includes all types and grades of incidents. All sections of the form should be completed covering immediate post-incident actions.

  - **Immediate management of the Incident and communications**

    The senior member of staff in charge of the service area should be informed immediately. It is their responsibility to ensure that the incident has been dealt with and any necessary further reporting of the incident takes place. This includes ensuring that the next of kin have been contacted, where necessary, and an incident form has been correctly completed so that reporting to senior managers and Directors can take place if appropriate.

    Any patient and those involved, including staff, in the incident should be supported and given an explanation of the incident, its consequences as far as is known, the treatment available and what immediate actions are necessary to minimise further risk or injury. This communication should take place as soon as possible.

  - **Supporting staff**

The manager of the area will ensure that those involved in or affected by incidents are supported following an incident (CRM007 Supporting Staff Policy). The Trust values its staff and recognises that they are its most valuable resource. In support of this principle, all staff members involved or affected by a traumatic or stressful incident should be offered support from their line manager immediately or as soon as practically possible. The appropriate manager will need to assess the needs of the staff involved and where necessary implement a plan to assist in their recovery from any harmful or stress related reactions.

Where an incident of assault to a member of staff has occurred, the member of staff is also required to notify the Local Security Management Specialist (LSMS). This is automatically sent as a notification to the LSMS completed when an incident is reported via Datixweb.

- **Being open**
  The manager of the area or the staff member directly involved in an incident should comply with the requirements of CRM006 'Being Open Policy' as determined by the National Patient Safety Agency (NPSA). Staff should refer to and comply with the CRM006 Being Open Policy in terms of communicating and supporting individuals.

- **Guidance for staff who are unsure on how to raise concerns/external resources**
  The Trust recognises that some staff may find it stressful or traumatic to raise concerns about an event and that they may prefer to speak with an organisation outside of their own initially.

  Line Managers should ensure that staff are aware of HR009 - Guidance for Staff Raising Issues of Concern and also staff should be made aware of the Whistleblowing Helpline.
  NHS staff who have concerns and are unsure how to raise them or would like free, independent and confidential advice are able to call the new helpline provided by the Royal Mencap Society. The helpline is also open to employers for good practice advice. The new number is **08000 724 725**. The helpline is available weekdays between 08.00 and 18.00 with an out of hours answering service on weekends and public holidays.

  Public Concern at Work (PCaW) remain an independent whistle blowing charity offering advice, however they are no longer commissioned by the Department of Health to provide the national NHS helpline.

  Open disclosure by staff will be treated with confidence and support will be provided to staff who openly disclosure information connected to any incident or potential incident.

- **Management of incidents where more than one Department or Organisation is involved**
  Where an incident is discovered within a department, it is the responsibility of staff to report it in line with current NHFT policy. However, the incident may have occurred in another department, and where this is the case, you must inform your line manager who will liaise with the other department to ensure that appropriate actions are identified to reduce the likelihood of the incident recurring.

Where an incident is discovered which may have originated in another organisation who were involved in the care of the patient, the Patient Safety Manager should be contacted so that the appropriate stakeholders can be informed and involved in the investigation.

- **Information Governance Incidents and Assessing Severity**

  - **Assessing the severity of the incident**

    The immediate response to the incident and the escalation process for reporting and investigating will vary according to the severity of the incident. The Information Governance should be contacted to determine the level and severity of the incident using the national incident grading system.

  - **Informing Patients**

    Consideration should always be given to informing patients when person identifiable information about them has been lost or inappropriately placed in the public domain. Where there is any risk of identity theft it is strongly recommended that this is done. The Being Open Policy (CRM006) should be referred to.

    For further guidance on the management of information governance incidents please refer to CRM008 Investigation Policy (For Incidents, Complaints, Concerns and Claims)

- **Child harm incidents (significant)**

  Where a child has been significantly harmed but not died as a result of, the following considerations need to be explored as to whether the incident is an SI or not.

  Has the harm occurred on NHS premises, as a result of NHS funded care, or caused by the direct actions of healthcare staff? If no to all the above, it's useful to consider whether or not the child has been in receipt of healthcare within the last 12 months. If so the case will need to be reported as an SI as well as to the LSCBN.

  Any child under the age of 16 admitted to an adult mental health ward must be notified to Safeguarding for Children, reported on Datix and declared an SI

- **Safeguarding Adults**

  A vulnerable adult is someone over the age of 18 years in need of services by reason of mental or other disability who is unable to take care of or protect themselves against harm or exploitation. All incidents of abuse including neglect to a vulnerable adult are notified through Safeguarding Adults procedures as well as recording on Datix

  Cases of death or significant harm, the case may also be investigated as a Serious Case Review under Safeguarding Adults procedures. The interagency decision to investigate as a SCR should

not delay the investigation as an SI. The SI report will form the basis of any SCR individual management report.

Guidance for staff on the investigation of safeguarding related serious incidents should be referred to within the Investigation Policy CRM010

- **Healthcare Associated Infections.**

It is essential that all identified infections are reported on Datix. This automatically alerts the Infection Control Team who will take appropriate action. Any additional information can be obtained directly from the Infection Control Team .

- **Screening Incidents**

National screening programmes are public health interventions, which aim to identify disease or conditions in defined populations in order to either reduce morbidity or mortality. Screening programmes are sometimes made complicated because the activity of screening often takes place within pathways across several organisations.
Often there are a wider range of organisations involved including those at a national level and organisations who externally quality assure the screening programmes.

Pressure Ulcers

Guidance on reporting details connection with pressure ulcers can be accessed via Nene CCG Policy for the Reporting and Management of Serious Incidents or from the Patient Safety Team. Further guidance is available in CLPg 003 Guidelines for Prevention and Management of Pressure Ulcers in all Care Settings

. The NHS Safety Thermometer tool used by clinicians in the Trust feeds into assurance mechanisms with the quality support team.

Pressure ulcers are graded 'avoidable' and 'unavoidable'. Avoidable means that the person receiving the care developed a pressure ulcer and the provider of care did not do one of the following; evaluation the person's clinical condition and pressure ulcer risk factors; plan and implement interventions that are consistent with the persons needs and goals, and recognised standards of practice; monitor and evaluate the impact of the interventions; or revise the interventions as appropriate (Department of Health). Unavoidable are those patients who are at the final stages of end of life and the intervention needs to be balanced against their comfort and dignity and in all cases where services report unavoidable pressure ulcers at levels 3 and above, these will be subject to clinical review by the Pressure Ulcer Lead Nurse and Patient Safety Manager for assurance. This will also be shared with Commissioners.

Staff are required to report 'inherited' pressure ulcers which is an ulcer defined when the patient has come into the care of the Trust or developed within 72 hours of coming into the Trust's care.

An acquired (new) pressure ulcer is defined as being a pressure ulcer that developed 72 hours or more after the patient comes into the care of the Trust.

The reporting to the CQC is managed and co-ordinated by the Quality Support Team.

- **Reporting to the Department of Health**

  Commissioners will be responsible for notifying the Department of Health of any category 1-5 incident reported by forwarding details to the appropriate dedicated mailbox established within the Department of Health. Once an incident has been reported to the Department of Health any subsequent details that emerge relating to the investigation and resolution of the incident should also be supplied.

  The Department of Health will review the incident and determine the need to brief Ministers and/or take other action at a national level.

- **Reporting to the Information Commissioner or other Bodies.**

  The Information Commissioner should be informed of all Category 2 or above incidents using the national incident reporting tool. The decision to inform any other bodies will also be taken, dependent upon the circumstances of the incident, e.g. where this involves risks to the personal safety of patients, the National Patient Safety Agency (NPSA) may also need to be informed.

- **Records Management and Confidentiality**

  It is essential that incident forms are completed accurately and that all relevant information relating to the incident is documented. The information recorded on the incident form should be factual and accurate; supposition, inappropriate opinion or unverifiable facts should not be recorded.

  Incident forms can contain sensitive patient and staff related information. As such, the Trust has a duty of care in relation to confidentiality and a legal obligation in relation to the Data Protection Act 1998 to ensure that all such sensitive personal data is stored in a secure location.

  Incident forms are not considered part of the patient's medical records and as such should not be stored with them. However, incident forms can become subject to external scrutiny via access to data requests, freedom of information requests (Freedom of Information Act 2000), H M Coroner Inquests, complaints, claims etc. As such, it is important to ensure that the incident form contains details of the actual incident; however any information regarding the care of the patient during and after the incident should be made in the body of the medical records, including any communication with relatives. The recording of the incident form number within the medical records can often be helpful.

The Trust has a legal obligation to retain paper versions of incident forms for a period of 10 years; incident forms relating to the under 18's should be retained for a period of 25 years. Compliance with this requirement is undertaken centrally by the Risk Management Department and as such, all other paper copies of the incident form may be destroyed and disposed of via the confidential waste after they have been dealt with locally. Electronic versions of the incident forms via DatixWeb are retained indefinitely in the Datix Database.

- **Grading of Incidents**

  Grading incidents or risk evaluation is a key component of the risk management process. Incidents need to be graded for severity in order to establish the level of investigation and the appropriate action required to reduce or eliminate the risk.

  Grading or risk evaluation should be undertaken locally within the reporting area so that teams can decide upon the level of investigation that is required.

  Guidance on the grading of incidents is aligned to the model used by the NPSA and throughout the Trust for all Risk Management processes and can be found at **Appendix 5**

- **Investigations**

  Incident investigations should be conducted at a level appropriate and proportional to the incident. The level of investigation should relate directly to the severity of an incident ensuring that sufficient time and energy is afforded to those incidents that are deemed significant.

  This section provides brief guidance on investigation requirements and must be read in conjunction with CRM008 Investigation Policy (for Incidents, Complaints, Concerns and Claims).

  The actions taken following an incident to enquire what, how and why an incident has occurred. Investigations may be termed as local, when undertaken by staff or managers of the area involved or as RCA investigations where a more detailed level of investigation is required.

  Investigations are necessary to provide a retrospective review of events. The singular or aggregated analysis, whether at local or Trust-wide level can be used to identify areas for change, recommendations and sustainable solutions, to help minimise re-occurrence in the future (please refer to CRM005 Analysis, Improvement and Learning Lessons Policy).

- **Independent Investigations**

  Commissioners will review the initial management review report and arrange a meeting with the Trust and any other stakeholders to discuss the internal investigation process and likelihood of an independent investigation.

Following receipt of the Trust internal investigation report Commissioners will confirm whether the incident meets the criteria to commission an independent investigation and what the terms of reference and scope of the investigation will be. The scope and process for the independent investigation will take into consideration the quality and findings of the Trust's internal investigation.

Please refer to CRM010 The Reporting and Management of Serious Incidents Policy

I**nvestigations**

Details of investigation requirements are summarised in this policy and the Investigation Policy should be referred to for investigation incidents based on the grading of severity.

- **Learning from Incidents**

  Details of analysis and learning requirements are summarised in this policy and the Analysis, Improvement and Learning Policy should be referred to in order to ensure that learning is identified from incidents and implemented.

- **Risk Management Report covering learning**

  The Patient Safety Manager will produce bi-monthly reports that will summarise analysis of incident data and outcomes identified through audits. Learning will also be identified from external sources, such as the NPSA National Reporting and Learning System Feedback Reports and will make recommendations for learning or risk reduction measures.

- **Incident Reports to Specialty Leads/Groups/Organisations**

  The Patient safety Team will provide:

  - Incident reports on categories requested by and for submission to managers and/or the directorate operational groups for the consideration of risk management issues.

- **Audit of Incident Reporting**

  The Patient Safety Manager will audit the quality of incident reporting and produce feedback reports to managers for implementation of learning on reporting, grading and investigation of incidents that are outside of the SI process.

- **Health and Safety Incidents**

  If the incident appears to be RIDDOR reportable it must be notified to the Health and Safety Risk Manager within 24 hours or on the next working day, in addition to completion of an incident report form. This is the responsibility of the person authorising the incident form. The Health and Safety Risk Manager will determine if this is reportable to the Health and Safety Executive and be responsible for this external reporting and supporting the manager in conducting an investigation.

For further guidance, please access the following link: http://www.hse.gov.uk/riddor/

- **DUTY OF CANDOUR**

  Regulation 20

  CQC Regulation 20 states that a Health Service body must act in an open and transparent way with relevant persons in relation to care and treatment provided to services users in carrying on a regulated activity.

  As soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred, a health service body must notify the relevant person and provide reasonable support to the relevant person. This must be followed by written notification and apology for the incident.

  The Trust must keep a copy of all correspondence with the relevant person in a secure place.

  An account should be provided of all the facts the Trust knows about the incident as at the date of the notification and any further facts as they arise.

  The Trust should make every reasonable effort to contact the relevant person through various communication means, if the relevant person declines to contact the provider, their wishes should be respected and a record of this kept.

  There may be occasions where it may not be appropriate to contact the relevant persons, for example during a Police investigation of an incident – advice should then be sought from the Patient Safety Team

Training requirements associated with this Policy

- **Mandatory Training**

  Training required to fulfil this policy will be provided in accordance with the Trust's Training Needs Analysis. Management of training will be in accordance with the Trust's Core Skills Training Policy HR025.

- **Specific Training not covered by Mandatory Training**

  Ad hoc training sessions based on an individual's training needs as defined within their annual appraisal or job description.

How this Policy will be monitored for compliance and effectiveness

The table below outlines the Trusts' monitoring arrangements for this document. The Trust reserves the right to commission additional work or change the monitoring arrangements to meet organisational needs.

Aspect of compliance or effectiveness being monitored	Method of monitoring	Individual responsible for the monitoring	Monitoring frequency	Group or committee who receive the findings or report	Group or committee or individual responsible for completing any actions
Duties	To be addressed by the monitoring activities below.				
How all incidents and near misses involving staff, patients and others are reported.	Audit of 10% of incidents reported.	Corporate Systems Manager	Quarterly and annually via reports.	Quality & Governance Committee	Quality & Governance Committee
Reporting of incident information to external agencies.	10% sample of different types of incidents for assurance of reporting.	As above	As above	As above	As above
That staff are able to and where this is necessary, have raised concerns through routes such as whistle blowing, open disclosure etc.	Review with HR Directorate of matters reported to them linked to incidents.	As above	Annually	As above	As above
Staff have completed training associated with this policy in line with the TNA	Training will be monitored in line with the Statutory and Mandatory Training Policy.				

Where gaps in compliance are identified through monitoring, the responsible committee will identify required actions and a lead and will monitor further actions to ensure that full compliance is achieved through further assurance reports to the individual/committee.

For further information

Please contact the Director of Nursing and Quality

Equality considerations

The Trust has a duty under the Equality Act and the Public Sector Equality Duty to assess the impact of Policy changes for different groups within the community. In particular, the Trust is required to assess the impact (both positive and negative) for a number of 'protected characteristics' including:

- Age;
- Disability;
- Gender reassignment;
- Marriage and civil partnership;
- Race;
- Religion or belief;
- Sexual orientation;
- Pregnancy and maternity; and
- Other excluded groups and/or those with multiple and social deprivation (for example carers, transient communities, ex-offenders, asylum seekers, sex-workers and homeless people).

The author has considered the impact on the protected characteristics. Equality issues are recorded on Datix and the expectation is that these are raised and discussed through service/team meetings.

Reference Guide

Never Events Framework (January 2012 update) (NPSA).

High Quality Care for All – NHS Next Stage Review Final Report (Department of Health, June 2008).

An Organisation with a Memory (Department of Health, 2000).

Building a Safer NHS for Patients (Department of Health, 2001).

Safety First (Department of Health, 2006).

NPSA's Being Open Framework (2009) and the Patient Safety Alert issued in November 2009 (NPSA/2009/PSA003).

NHSLA Acute, Community, Mental Health & Learning Disability and Independent Sector Standards – 2011/12

Reporting of Injuries, Diseases and Dangerous Occurrence Regulations (Health and Safety Executive, 1996).

Freedom of Information Act 2000.

Seven Steps to Patient Safety – the full reference guide (NPSA, 2004).

Doing Less Harm (Department of Health and NPSA, 2001).

Health and Safety at Work Act 1974.

Management of Health and Safety at Work Regulations (Health and Safety Commission, 1999).

Police Officers and Health and Safety Executive (Department of Health, 2001).

Department of Health Circulars HSG/94/27 and HSC/98/197.

Mental Capacity Act 2005

Data Protection Act 1998

Freedom of Information Act 2000

Care Quality Commission Guidance for NHS bodies on the fit and proper person requirement for directors and the duty of candour consultation. July 2014.

Document control details

Author:	Patient Safety Manager
Approved by and date:	Trust Policy Board 10.01.17
Responsible Committee:	Health, Safety and Risk Committee – approved 8.12.16
Any other linked Policies:	CRM001 - Risk Management Strategy CRM003 - Concerns and Complaints Policy CRM004 - Claims Management and Legal Advice Policy (inc statement template) CRM005 - Analysis, Improvement and Learning Lessons Policy CRM006 - Being Open Policy CRM008 - Investigation Policy (for Incidents, Complaints, Concerns and Claims) CRM010 – The Reporting and Management of Serious Incidents Policy HSC002 - Policy and Guidance for the Use of Risk Register HRp013 Management of Stress in the Workplace - HR017 - Policy and procedure for dealing with employee incapability – sickness absence PH10 - Trust Emergency Plan CLP047 - Policy for Safeguarding Children (Child Protection) CLP055 - Policy for Safeguarding Vulnerable Adults MMG001 - Guidelines for Controls of Medicine Policy HR025 - Core Skills Training Policy HR009 – Staff Raising Issues of Concern (Freedom to Speak Up) Information Governance Incidents see CRM008 Investigation Policy
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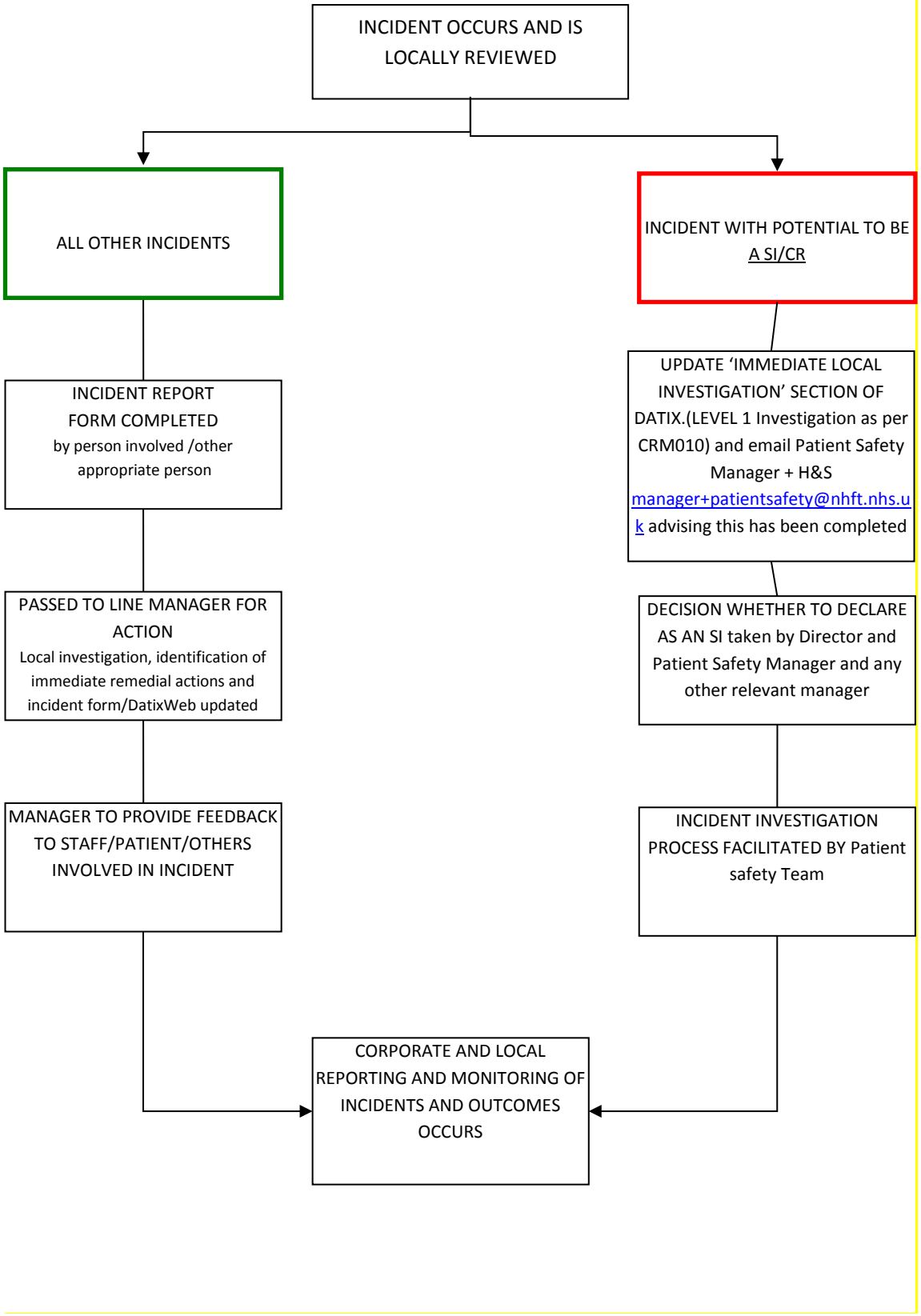
Version No.	**Date Ratified/ Amended**	**Date of Implementation**	**Next Review Date**	**Reason for Change (eg. full rewrite, amendment to reflect new legislation, updated flowchart, minor amendments, etc.)**
2.0	10.01.2017	10.01.2017	10.01.2020	New governance of trust policies template.

APPENDIX 1 – EXTERNAL STAKEHOLDERS

Area of concern	Responsible Body	Reporting Responsibility
Serious Incident	Relevant Commissioners	Patient Safety Manager
Most Serious Events	Relevant Commissioners	Patient Safety Manager
Medical Devices	Medicines and Healthcare Products Regulatory Agency (MHRA)	Medical Devices Lead
Reporting of Diseases and Dangerous Occurrences	Health and Safety Executive	Health and Safety Risk Manager
Litigation	NHS Litigation Authority	Deputy Director of Corporate Services
Unexpected death of patient / Responses to Regulation 28 Recommendations	H M Coroner and H M Coroner's Officers	Patient Safety Manager and Responsible Director
Media interest	The Media	Communications Lead and Chief Executive
Medication issues	Medicines and Healthcare Products Regulatory Agency (MHRA)	Pharmacy Lead
Safety alerts	Central Alert System (DoH)	Health and Safety Risk Manager
Patient safety incidents	National Patient Safety Agency	Corporate Systems Manager
Criminal matters	Police	Director, senior staff and the Local Security Management Specialist
Fire related issues	Northamptonshire Fire and Rescue	Fire Officer
Safeguarding	Nene CCG/ Northamptonshire County Council	Safeguarding Lead
Estates and Facilities	NHS Estates	General Manager – Facilities/Fire Safety Advisor
Copies of independent investigation reports by external agency.	Care Quality Commission	Director/Chief Executive
Incidents that meet the criteria for exception reporting to MONITOR	MONITOR	Director of Nursing and Quality
Audit information on suicides and homicides	National Confidential Enquiry into Suicide and Homicide by People with Mental Illness	Suicide Prevention Lead
Security incidents (fraud)	NHS Counter Fraud Service (CEAC)	Trust Security Lead (LSMS)
Unexpected death of patients under a section of the The Trust Act 1983.	The Trust Act Commission (now the Care Quality Commission)	The Trust Mental Health Act Manager
General Medical Council	Concerns in relation to medical staff practice/conduct	The Medical Director
Nursing and Midwifery Council	Concerns in relation to nursing staff practice/conduct	Director of Nursing and Quality
Health Professions Council	Concerns in relation to practice of allied healthcare professionals	Director of Human Resources and Organisational Development / or Professional Lead

APPENDIX 2 – INCIDENT REPORTING FLOWCHART



APPENDIX 3 – GUIDANCE ON PRODUCING STATEMENTS FOR H.M. CORONER AND STATEMENT FORMAT

If you are unsure about whether a statement is necessary, or what should be contained within that statement, please contact the Patient Safety Team before compiling your statement.

- Where possible statements should be typed and if more than one page is used all pages must be signed and dated
- Statements should ideally be written within 24 hours of a serious incident occurring but no later than 10 days
- Original statements should be dated, signed and time of statement given. This should then be forwarded to Patient safety Team

What your statement should contain

- Facts only
- Who you are – name, grade, ward/specialty
- Where the incident occurred
- Time of the incident
- Your involvement in the incident
- What happened
- What you knew about the patient or member of staff at the time of the incident
- What you found on examination/on seeing the patient or member of staff
- The situation with which you perceived you were dealing
- What you did/did not do
- Why/why not?

What your statement should not contain

- Opinion
- Petulant comment
- A verbatim regurgitation of the entries made in the clinical records – statements are designed to 'flesh out' information contained therein

PLEASE NOTE

Statements made following an adverse incident – if litigation has not been intimated at the time the statement is written – the statement will be disclosable if the case subsequently becomes the subject of a claim, i.e. the affected person's legal team will have access to the statement. For that reason, it is important that if any member of staff is unsure whether to write a statement, or the format of that statement, they should contact the Patient Safety Manager for advice.

Please also note that emails written between staff members, before legal action has been intimated, would be disclosable to the affected person's legal team should the case become the subject of a claim.

Staff are entitled and supported to seek advice from their respective professional organization/union/manager when producing a statement.

Statement of: (*insert name of staff member*)

Relating to: (*insert name of patient*) **D.O.B of patient**:

Date of Incident: **Time of Incident:**

Occupation of (*insert name of staff member and job title*):
employed by Northamptonshire Healthcare NHS Foundation Trust at (insert name and address of site and description of service i.e. acute the Trust directorate)

Give your background covering your qualifications in relation to your role and how long you have been in your current post.

Give the background knowledge that you have of the person this statement relates to and then detail your involvement in the incident. Do not use abbreviations.

Signature Date

Print Name: Time of statement Page of

This statement is disclosable under the Data Protection Act 1998 and Freedom of Information Act 2000

APPENDIX 4 – ORGANISATIONAL RISK GRADING

Q1. Identify the highest consequence of this risk, taking account of the controls in place and their adequacy, how severe would the consequence by of such an incident? Apply a score according to the following scale:

Descriptor	1 Negligible	2 Minor	3 Moderate	4 Major	5 Catastrophic
Patient harm / outcome / experience	▪ No obvious harm. ▪ Patient dissatisfaction.	▪ Minimal harm. ▪ Experience readily resolvable. ▪ 1-2 people affected	▪ Some harm. ▪ Mismanagement of patient care. ▪ Short-term effects <week. ▪ 3-15 people affected.	▪ Permanent harm. ▪ Serious mismanagement of care. ▪ Misdiagnosis/poor prognosis. ▪ 16-50 people affected. ▪ Increased level of care (> 15 days)	▪ Death/life threatening. ▪ Totally unsatisfactory outcome/experience. ▪ > 50 people affected (e.g. screening concerns, vaccination errors).
Staff / Visitor etc. Injury / Psychological / Social	▪ No injury/illness not requiring first aid.	▪ Minor Injury/Illness requiring first aid/minimal treatment or care. ▪ Short-term staff sickness (< 3 days) ▪ 1-2 people affected.	▪ Moderate injury/illness requiring medical intervention. ▪ Staff sickness (> 3 days) - RIDDOR ▪ 3-15 people affected	▪ Major injury/illness requiring long-term treatment/incapacity/disability. ▪ Long-term sickness ▪ > 15 people affected.	▪ Death. ▪ Life threatening injury/illness. ▪ Permanent injury/damage/harm.
Health Inequalities (Equity of access to care and/or inequity in wider public health)	▪ Possible/minor loss of potential for reducing health inequalities,	▪ Unable to investigate, develop/pilot future improvements in services/activities that are likely to reduce health inequalities.	▪ Unable to implement intended developments in services/activities that have significant potential to reduce health inequalities.	▪ Reduced effectiveness of existing service/activity that is targeted at reducing health inequalities.	▪ Probability of increase in health inequalities OR permanent loss of existing service/activity targeted to reduce health inequalities.
Complaint/Litigation	▪ Locally resolved complaint.	▪ Justified complaint peripheral to patient care. ▪ Litigation unlikely.	▪ Justified complaint involving lack of appropriate care. ▪ Litigation/enforcement action possible. ▪ Below excess.	▪ Multiple justified complaints. ▪ Claim above excess level. ▪ Litigation/enforcement action expected.	▪ Multiple claims or single major claim. ▪ Unlimited damaged. ▪ Litigation/prosecution certain.
Business/Service Loss	▪ Minimal impact. ▪ No service disruption.	▪ Minor loss/interruption (> 8 hours)	▪ Moderate loss/interruption (> 1 day)	▪ Significant loss/interruption (> 1 week) ▪ Temporary service closure.	▪ Permanent loss of service/facility. ▪ Impact in further areas.
Staffing & Skill Level	▪ Short-term low staffing level that temporarily reduces service quality.	▪ On-going low staffing level reduces service quality.	▪ Late delivery of key objectives/service due to staffing levels. ▪ On-going unsafe staffing level, skill level ineffective.	▪ Uncertain delivery of key objective/service due to staffing levels. ▪ Unsafe staffing levels, skill levels inadequate.	▪ Non-delivery of key objective/service due to lack of staff. ▪ Serious incident due to insufficient training.
Financial	▪ Small loss	▪ Loss > 0.1% of budget.	▪ Loss > 0.25 of budget. ▪ £500,000 loss of contractual income.	▪ Loss > 0.5% of budget. ▪ £1M loss of contractual income.	▪ Loss > 1% of budget. ▪ £2M loss of contractual income.
Reputation/Publicity	▪ No adverse publicity or loss of confidence in the Trust.	▪ Local Media – short term low impact on confidence and effect on staff morale.	▪ Local media – long term relations with public affected. ▪ Moderate loss of confidence in the Trust and significant effect on staff morale.	▪ Widespread adverse publicity. ▪ National Media (< 3 days) ▪ Major loss of confidence in the Trust.	▪ National Media (> 3 days) ▪ MP concern – questions in the House. ▪ Major loss of confidence in the Trust. ▪ Viability of the Trust threatened.
Governance (Inspection/Audit & Policy Compliance)	▪ Minor non-compliance with standards. ▪ Minor recommendations.	▪ Non-compliance with standards. ▪ Recommendations given.	▪ Reduced rating. ▪ Challenging recommendations. ▪ Non-compliance with core standards, legislation.	▪ Low rating. ▪ Enforcement action. ▪ HSE intervention. ▪ Critical report. ▪ Major non-compliance with core standards, legislation.	▪ Zero rating. ▪ Prosecution. ▪ Severely critical report. ▪ Loss of contracts. ▪ Public enquiry.
Objectives & Projects	▪ Insignificant cost increase/schedule slippage. ▪ Barely noticeable reduction in scope or quality.	▪ < 5% over budget/schedule. ▪ Minor reduction in quality/scope.	▪ 5-10% over budget/schedule slippage. ▪ Reduction in scope or quality.	▪ 10-25% over budget/schedule slippage. ▪ Failure to meet secondary objectives.	▪ 25% over budget/schedule slippage. ▪ Doesn't meet primary objectives.
Estates & Environmental	▪ Inconsequential damage to buildings/environment/historic resources that requires little or no remedial action.	▪ Recoverable damage to 'non-priority' buildings/environment/historic resources.	▪ Recoverable damage to 'priority' buildings, or loss of 'non-priority' buildings/environment/historic resources.	▪ Loss of or permanent damage to 'priority' buildings/environment/historic resources. ▪ Affecting part of the site.	▪ Loss of or permanent damage to 'priority' buildings/environment/historic resources. ▪ Affecting the whole site.

Q2. How likely is it that such an incident could occur? Score according to the following scale:

Level	Likelihood	Description
1	Rare	The event may only occur in exceptional circumstances
2	Unlikely	The event is not expected to happen
3	Possible	The event may occur occasionally
4	Likely	The event is likely to occur
5	Almost certain	A persistent issue

Instructions for use

Define the risk(s) explicitly in terms of the adverse consequence(s) that might arise from the risk.

Use question 1 to determine the consequence score(s) (C) for the potential adverse outcome(s) relevant to the risk being evaluated.

Use question 2 to determine the likelihood score(s) (L) for those adverse outcomes. If possible, score the likelihood by assigning a predicted frequency of occurrence of the adverse outcome. If this is not possible, assign a probability to the adverse outcome occurring within a given time frame, such as the lifetime of a project or a patient care episode. If it is not possible to determine a numerical probability then use the probability descriptions to determine the most appropriate score.

Risk Grade is then automatically completed based upon the above.

APPENDIX 5 – Duty of Candour Checklist

DUTY OF CANDOUR CHECKLIST

Patient Name: …….

Steis No. ……..

Date of Incident: ……..

Investigating Manager: ……..

Signature: ……..

Date: ……

	Check box	Date(s)	Contractual Requirement
1	☐		The patient or their family/carer was informed that a suspected or actual patient safety incident had occurred **within 10 workings days** of the incident being reported to local systems
2	☐		The initial notification was verbal **accompanied by an offer of written notification** with the notification recorded for audit purposes
3	☐		Patients or their carers/families have been given all the facts known at the time, and are or have been kept up to date throughout the process of the investigation
4	☐		An apology has been provided – **verbally and in writing**
5	☐		A step by step explanation of what happened, in plain English, based on the facts, was offered as soon as was practicable
6	☐		**Full written documentation** of any meetings have been and will be maintained including where these have been declined
7	☐		Incident investigation reports will be shared **within 10 working days** of being signed off as complete and the incident closed (with both Patient/Family and NHFT Teams involved)
8	☐		Documentation and information will be available to demonstrate compliance with these contractual requirements.

Once checklist has been completed please ensure it is returned to the Patient Safety Team (@nhft.nhs.uk) with the following:-

- Copies of all written correspondence / minutes / meeting or telephone notes.
- Evidence of feedback and sharing of the anonymised report with the relevant teams.
- Evidence of feedback and sharing of the anonymised report with the patient / family / carers.