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. Incident Reporting Policy and Procedure (including Serious Incident Procedure

Classification :	Policy		
Authors Name:	Policy		
Authors Job Title:			
Authors Division:	Head of Risk and Clinical Governance		
Departments/Group this Document applies to:	All staff		
Approval Group: Management Board June 2015, Clinical Board – June 2015, Trust Documentation Committee – March 2013, Clinical Risk Management Committee – May 2009		**Date of Approval:**	Jun 2015
		Last Review:	Mar 2021
		Review Date:	May 2024
Unique Identifier: RM/GL/17	**Status:** Approved	**Version No:** 9.2	
Policy to be followed by (target staff): All employees of the Trust, including contractors and temporary/agency staff are responsible for assisting in the implementation of this policy.			
To be read in conjunction with the following documents: Investigators ***must*** refer to the trial protocol for specific reporting arrangements of the clinical trial in question			
CQC Fundamental standards: Regulation 12 – Safe care and treatment Regulation 17 – Good governance Regulation 20- Duty of Candour			

Disclaimer

Since every patient's history is different, and even the most exhaustive sources of information cannot cover every possible eventuality, you should be aware that all information is provided in this document on the basis that the healthcare professionals responsible for patient care will retain full and sole responsibility for decisions relating to patient care; the document is intended to supplement, not substitute for, the expertise and judgment of physicians, pharmacists or other healthcare professionals and should not be taken as an indication of suitability of a particular treatment for a particular individual.

The ultimate responsibility for the use of the policy, dosage of drugs and correct following of instructions as well as the interpretation of the published material **lies solely with you** as the medical practitioner.

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Policy Statement

The Trust recognises that learning from incidents requires timely incident reporting which in turn requires a fair, open, and just safety culture that rejects blame as a tool. The Trust accepts that the reporting of any incidents is essential to healthcare safety in order that the Trust may learn and act to reduce the risk of harm to patients, staff and public and to take opportunities to improve the quality of the service provided.

Incident and concern reporting is one of the mechanisms for identifying risks. Those incidents or concerns that cannot be managed satisfactorily will follow the Trust's Risk Management Processes (see the Trust's Risk Management strategy)

This Trust recognises and accepts that accurate reporting of incidents will only occur in an environment that is open, honest, and 'just', where risks, accidents, mistakes and 'near misses' are detected and acted upon in a timely, positive, and constructive way. The reporting of incidents, accidents, mistakes or 'near-misses' will not result in disciplinary action unless or until there is evidence of professional malpractice or acts of gross misconduct.

The Trust supports a 'Being Open' culture and has a policy in place to demonstrate this (see link below) and encourages all staff to be open and honest in the event of an incident/claim or complaint.

http://portal.mkhospital.nhs.uk/Guidelines/Non%20Clinical%20Documentation/Risk%20Management/Risk%20Management%20Polices%20and%20Guidelines/Being%20Open%20Policy.doc

Executive Summary

Incident reporting is a key part of the safety culture at Milton Keynes University Hospital. It is the way in which the Trust collects information about adverse events, including near misses, ill health, and hazards to support organisational learning to prevent harm to patients, staff, and others. It underpins the safety culture in the Trust to ensure that the safety of patients is paramount. As such, this policy identifies:

- the process for reporting all internally and externally reportable incidents/near misses involving staff, patients and others
- the types of incidents to be reported.
- the importance of intervening quickly to reduce the effects of an incident that affects a patient, visitor, or member of staff.
- how the information from reported incidents is used to improve patient care and the learning shared across the organisation.
- the process to ensure lessons learned from an incident in one part of the Trust will be applied generally wherever appropriate, so that recurrence is reduced, and subsequent loss avoided.
- the systems in place to analyse trends, provide feedback to each ward/ unit/ department, monitor progress against action plans and assess effectiveness and sustainability of any action required as a result of an incident whether affecting patients, staff, visitors, or contractors.
- the process for identifying, assessing, grading, and monitoring an incident consistently and documenting any required actions. All incidents will be graded and actioned according to their significance (actual or potential)
- the process for effective reporting to statutory and relevant external agencies

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- the process to monitor compliance with the requirements of this policy.
- To identify areas where care or service delivery could be improved by raising issues (confidentially if the matter is sensitive) or by using the Trust's Whistle blowing Policy.

  http://portal.mkhospital.nhs.uk/Guidelines/Non%20Clinical%20Documentation/Human%20Resoures/HR%20Polices%20and%20guidelines/Whistle%20Blowing%20Policy%20(02.2017).pdf

- To cross transfer risks arising from incidents to the risk registers
- to meet the appropriate regulatory requirements and standards (i.e.: Care Quality Commission (CQC), and Information Governance, Health & Safety legislation).

The objectives of this policy will underpin all actions taken in respect of incidents, in an open and fair culture, in order to share and learn from all incidents that occur.

1.0 Roles and Responsibilities:

Every member of staff has an individual responsibility to report incidents, near misses or concerns at the time or upon discovery

1.1 The Chief Executive (CEO) has

- Overall Board level responsibility
- Corporate responsibility for incident , and concern reporting which is part of Risk Management
- Receive incident and concern reporting trend data, including Serious Incidents, RIDDORS (Reporting of Injuries, Diseases and Dangerous Occurrences Regulations) and assurance that agreed actions have been embedded and sustained

1.2 Director of Corporate Affairs

The Director of Corporate Affairs is the executive director with executive responsibility for the Risk Management Team and works collaboratively with the Medical Director and Chief Nurse in ensuring that robust processes and resources are in place for effective risk management, and has responsibility for internal/external communications in respect of risk management and incidents

1.3 Executive Team responsibility is devolved as

- Patient Safety and Health & Safety Incidents – Director of Patient Care/Chief Nurse and Medical Director

- Business Incidents (relating to finance or contractual requirements) - Director of Finance

- The Serious incident (SI) lead team are responsible for confirming SI status and taking appropriate action as follows:
  - Director of Patient Care/Chief Nurse and/or Medical Director: patient related incidents
  - Deputy CEO: Incidents involving building or equipment or violence and aggression, IT or Information Governance
  - Director of Finance: incidents involving financial matters e.g. fraud
  -

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- Identified Executive Directors are responsible for commissioning Comprehensive Root Cause Analyses (RCA) and monitoring any resulting action plan
- All SI RCA reports will be approved by the executive chaired Serious Incident Review Group (SIRG) before submitting to the commissioners

The Medical Director is responsible for agreeing for independent reviews as/where appropriate, for meeting with parents and families following SIs where appropriate and for approving all never event related SI reports before submission.

All never event investigation reports must be 'signed off' by the Director of Patient Care/Chief Nurse and/or the Medical Director.

1.4 Communications Team

- In the case of an incident which is reported in the Press, the Communications Team are responsible preparing, in consultation with the Director of Corporate Affairs, a press statement and for liaising with external agencies in relation into media interest

1.5 Duty Hospital Managers/Manager on call

- Are responsible for reporting to the Manager on Call in respect of any incident which may be classified as a Serious Incident. The Manager on Call is responsible for informing the Executive Director on call

1.6 Head of Risk and Clinical Governance

- Is responsible for the day-to-day operational management and all aspects of the Incident Reporting process and is the Trust lead for Serious Incidents

1.7 Risk & Systems Manager

- The Risk & Systems Manager is responsible for managing and producing reports from the Trust Risk Management System (RADAR), including aggregated incident, claim and complaint reports

1.8 Clinical Governance Leads/Clinical Service Unit (CSU) Triumvirate Leads

- Are responsible for the monitoring, evidence collation and closure of root cause analysis (RCA) action plans from SI and relevant incidents trends within their CSU

1.9 Staff member involved in an incident

- Must ensure the safety of the individual involved in the incident as a priority and document the effect, any treatment necessary and any communication with the family in the patient's medical record

- Must ensure that any equipment contributing or potentially contributing to the incident occurring is removed from use and reported to the appropriate professional (e.g. clinical engineering, manufacturer, estates specialist etc.) for investigation.

- For patient incidents, inform the person in charge of the ward/department. If applicable, contact the relevant medical team to assess the patient's clinical condition and likelihood of any detrimental effect on their care, or immediate action required

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- Consultants/Senior Sister responsible for patients involved in serious incidents are responsible for maintaining open and regular communication with the patient and their family in line with the Duty of Candour regulations

1.10 Divisional/Associate Directors of Operations/Clinical Directors

- Are responsible within their area of responsibility to ensure that processes are in place for appropriate investigation, taking actions and enabling shared learning and staff receive the appropriate support as part of the investigation process

1.11 Senior Sisters, Matrons (or nominated lead) and Heads of Departments (HODs)

- Are responsible for investigating incidents at the appropriate level set out by this policy, taking any necessary action and sharing lessons learned. They are also responsible for feeding back to staff, patients/relevant persons any actions taken to address reported incidents and concerns and copying any reports to the Head of Risk and Clinical Governance so that Trust wide learning can take place

1.12 Risk & Systems Manager/Risk & Safety Officer/Health & Safety Advisor

- Are responsible for reporting incidents to such external bodies as the National Patient Safety Agency (NPSA), the Health and Safety Executive (HSE), Medicines and Healthcare Products Regulatory Agency (MHRA), RIDDOR Management Systems. All RIDDOR reportable incidents must be approved for external reporting by the CEO and will be brought to the attention of the relevant Divisional Manager/General Manager

1.13 Risk & Safety Coordinator

- Support the Head of Risk & Clinical Governance in ensuring incidents, accidents, alerts and other safety data are effectively investigated and quality checking RADAR entries

1.14 Specialty specific incidents responsibilities:

- Facilities report relevant plant, devices and buildings fabric incidents to Department of health (DH) via Environmental Resources Management (ERM) information website

- Counter Fraud Security (CFSMS) is reported by the Finance Team

- Pathology report blood transfusion incidents for Serious Hazards of Transfusion (SHOT) and Serious Adverse Blood Reaction Events (SABRE). For more information please refer to Pathology Standard Operating Procedure (SOP) Ref: GEN/QPEVALCI.

- Imaging Service Lead reports ionising radiation incidents in line with IRMER (Ionising Radiation Medical Exposure Regulations) requirements

  The Chief Pharmacist receives all medication related incident investigations, escalating any significant concerns. For any adverse drug reaction (ADRs), a reference is made to the MHRA's Yellow Card reporting, available online via www.yellowcard.mhra.gov.uk or by using the paper form in the BNF.

- Infection Prevention and Control are responsible for reviewing all infection related incidents

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- Security – Police reports as appropriate

1.15 Quality and Clinical Risk Committee

This committee will:

- Facilitate the process for sharing any lessons learnt from incidents including a gap analysis and appropriate integration into existing practice, service work streams as far as are reasonably practicable.
- Monitor progress against agreed risk reduction plans
- Monitor their impact on recurrence and or severity of similar occurrences.
- Escalates reports to the Management Board and Trust Board

2.0 Implementation and dissemination of document

This policy will be placed on the Trust's Intranet Site and disseminated to the Executive team, all Consultants, Divisional Managers, Heads of Departments, Matrons and Senior Sisters and all employees.

3.0 Incident Reporting Procedure

Each member of staff employed by the Trust is expected to comply with all aspects of this policy and ensure that all incidents, including near misses, are reported in a timely manner. The safety of the patient is paramount and without reporting no learning can take place to identify the means to reduce the risk of incident recurrence.

NB. **Low levels of incident reporting do not indicate a safe system.**

Evidence of an effective reporting system is one where the number of incidents increases but the severity of the events goes down. This indicates that staff are risk aware and can identify events early, often before permanent harm is caused, at the stage where interventions can be made to reduce the adverse effect.

3.1 Definitions

'Being Open'.
Being open is a set of principles that healthcare staff should use when communicating with patients, their families and carers following a patient safety incident in which the patient was harmed. A culture of openness, honesty, and transparency includes apologising and explaining what happened to patients, carers, and relatives. It is aimed at ensuring that a patient who is affected by an incident knows and understands what has happened, and that actions will be taken to prevent such incidents from happening again.

The benefits of 'Being Open' are widely recognised and supported by policy makers, professional bodies, and litigation and indemnity bodies, including the Department of Health, General Medical Council (GMC), National Health Service Litigation Authority (NHSLA), Medical Defence Union (MDU) and the Medical Protection Society (MPS).

The NHS Constitution for England embeds the principles of 'Being Open' as a pledge to patients in relation to complaints and redress. It states:

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"The NHS also commits when mistakes happen to acknowledge them, apologise, explain what went wrong and put things right quickly and effectively."

'Being Open' Patient Safety Alert: NPSA/2009/PSA003 – 19 November 2009

Duty of Candour
The Duty of Candour requires all health and adult social care providers registered with CQC to be open with people when things go wrong. Providers should establish the duty throughout their organisations, ensuring that honesty and transparency are the norm in every organisation registered by the CQC.

This is currently a commissioning requirement with our local commissioning team's NHS Standard Contract – Service condition 35 (Duty of Candour for serious incidents for reportable patient safety serious incidents where there is moderate/severe harm or SI). For all reported SI, the Trust must further provide evidence to support compliance with the duty of candour with each failure to notify the patient/next of kin of a suspected or actual reportable patient incident will result in a financial penalty in the recovery of the cost of the or £10,000 if the cost of the episode of care is unknown or indeterminate.

From 1 October 2014 this also became legislative and it is a criminal offence for any registered medical practitioner, or nurse or allied health professional or director of an authorised or registered healthcare organisation to knowingly obstruct another in the performance of these statutory duties, provide information to a patient or nearest relative with the intent to mislead them about such an incident or dishonestly make an untruthful statement to a commissioner or regulator, knowing or believing that they are likely to rely on the statement in the performance of their duties.

From 27 November 2014 CQC Regulation 20 'Duty of Candour' was published supporting the standard NHS contract referenced above and all Trusts are required to evidence compliance with this standard as part of the regulatory control.

Care Quality Commission (2015) *Regulation 20: Duty of candour: information for all providers: NHS bodies, adult social care, primary medical and dental care, and independent healthcare.* [Online]. Available from: https://www.cqc.org.uk/sites/default/files/20150327_duty_of_candour_guidance_final.pdf [Accessed 16 April 2019]

Please see appendix 14 and 16 for guidelines to support this.

Health & Safety Incidents
An event or circumstance that could have/did cause unexpected or unwanted harm, loss or damage to any individual(s) involved (including patients but not related to clinical care, staff, visitors etc.) or damage to/loss of property/premises for which the Trust is responsible.

Incident
An event or circumstance that could/did lead to unintended or unexpected harm, loss or damage to a patient, member of staff, volunteer, visitor or contractor, buildings, or equipment.

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Major harm
Hazard to life or function of an organ, requiring lifesaving intervention (surgical / medical) or will shorten life expectancy.

Major Incident/Accident
Defined as a major external event involving a number of different service providers and is covered by the Major Incident Policy and not this policy/procedure.

Medication incident
Incidents which actually caused harm or had the potential to cause harm involving an error in the process of prescribing, dispensing, administration or storage of medications.

Near Miss
Where an incident was prevented before harm was caused

'Never Events'
Serious Incidents that are 'serious largely preventable patient safety incidents that should not occur if the available preventative measure had been implemented by healthcare providers' (NHS Improvement Never Events Policy and Framework)

See appendices 8 and 13 for guidelines to support this.

Patient Safety Incidents
Cover anything related to diagnosis, treatment, and outcome for the patient.

Permanent harm
Directly related to the incident and not related to the natural course of a patient's illness or underlying condition is defined as permanent lessening of bodily functions, including sensory, motor, physiological or intellectual.

Serious Incident (SI)
Serious incidents are events in healthcare where there is the potential for learning is so great or the consequences to patients, families, carers, staff, or organisations are so significant that they warrant using additional resources to mount a comprehensive response.

There is no definitive SI list and incidents should be considered on a case-by-case basis however the following set out circumstances in which an SI **must** be declared:

Acts/Omissions occurring as part of NHS funded healthcare that result in:

- Unexpected or avoidable death
- 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 death/serious harm.
- Actual or alleged abuse (sexual, physical, or psychological) or acts of omission which constitute neglect, exploitation, financial or material abuse, discrimination and organisational abuse, self-neglect, domestic abuse, human trafficking, and modern-day slavery where the healthcare provided did not take appropriate action/intervention to safeguard against abuse occurring or it occurred during the provision of NHS funded care (includes Serious Case Reviews (SCR) and externally led enquiries)

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- All Never Events
- An incident or series of events that prevents or threatens to prevent an organisation's ability to continue to deliver an acceptable quality of healthcare services.
- Major loss of confidence in the service including prolonged adverse media coverage or public concern about the quality of healthcare or an organisation.

Severe Harm
A patient safety incident that appears to have resulted in permanent harm (as defined above) to one or more persons receiving NHS-funded care.

STEIS
Strategic Executive Incident System is a single reporting structure which allows for management information to be shared across the country and for organisations to benchmark its performance against others.

The National Reporting and Learning System (NRLS)
The NRLS is the world's largest and most comprehensive patient safety incident reporting system. The Trust reports all patient safety incident reports to the NRLS on a weekly basis, once the investigation has been approved. Serious Incidents are reported to the NRLS on submission to STEIS and are then re-submitted once the investigation has been approved.

Trigger Events
These are events that may be agreed by CSUs, Divisions and or the Trust to raise awareness of particular incidents which should always be reported within the CSU.

3.2 Procedure for reporting

The staff member discovering the incident must take immediate steps to reduce further harm to the person(s) involved and or affected, seeking medical/other appropriate attention/review.

Any medical device or other equipment involved should be taken out of use and retained for inspection. A record of the make, model and serial number should be retained.

Any medication incident should include the medication the incident concerned and the prescribing doctor where applicable.

All incidents involving actual or prevented harm/injury (near-miss) should be reported verbally immediately to the reporter's Line Manager/Supervising Clinician if available. If not, to the most immediate Manager/Supervisor and if out of hours, to the Manager on Call.

For all notifiable safety incidents an apology and explanation must be given to the patient/relevant person as soon as is reasonably practicable (and within 10 working days) patient to ensure compliance with the Duty of Candour (appendices 16 and 19)

It is not a requirement that prevented and 'no harm' incidents are discussed with patients; however it is seen as best practice.

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All incidents, must be reported using the on-line RADAR Incident Form, or the paper form (where on-line facilities are not available or there is a period of downtime of more than three hours) providing all the required details within 48 hours of the event (appendix 9)

If there is a possibility this could be a SI identify relevant witnesses and request a statement of the facts based on their recollection of the incident.

3.3 Procedure for Line Manager/Supervisor – post incident report

The Line Manager/Supervisor should take any further immediate action to prevent further damage/harm from the incident.

All Line Managers should check RADAR within 24 hours of receiving an e-mail notification of an incident being submitted completing the following:

- Check the free text boxes of the incident report ensuring all identifiable data such as staff, patient or third-party names must be replaced with titles.
- Where appropriate other 'responsible areas' must be notified. The category and sub-category must be checked.
- Actual severity of harm to the patient should be checked. The worst realistic outcome (severity) should be added.

All incidents will be investigated to a level appropriate to their grading using the guidance contained in the Investigating Incidents Procedure (appendix 4)

The reported degree of harm and chosen level of investigation requires justification by the reporter and investigator.

Moderate severity: Notify your Matron or Departmental Head for level of investigation guidance

Major or catastrophic severity: Line manager must immediately escalate to Divisional or On-Call Manager, to consider Serious Incident classification possibility (see flow chart appendix 12)

The Line Manager should complete the investigation section of the Incident Form as fully as possible on-line, noting actions taken and contributory factors and provide feedback to the reporting member of staff.

The severity of all RADAR incident reports will be reviewed by Head of Risk and Clinical Governance/Risk and Systems Manager and either escalated as automatic SIs or further information requested via a 72-hour report (or summits for patient falls and pressure ulcers), where staff have three working days to undertake a preliminary investigation.

All SIs are escalated to the Executive Team of CEO, Medical Director, Director of Patient Care/Chief Nurse and Director of Corporate Affairs. The CEO or delegated deputy only can give authorisation for SI and STEIS reporting.

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3.4 Procedure for reporting specific incident types

Serious Incidents including Never Events.
All serious incidents should be reported via RADAR.
In hours: The Divisional/Department Manager and

a) A patient related incident - to the Director of Patient Care/Chief Nurse and/or Medical Director

b) An incident involving buildings, equipment or violence and aggression, to the Deputy Director of Facilities

Out of hours: The Duty Hospital Manager will confirm the grading and seriousness of the incident with the appropriate Manager on Call. The Manager on Call will brief and inform the Executive on Call.

If a Serious Incident is confirmed then the SI Procedure should be commenced by the Executive staff member on call if not, continue with an appropriate level investigation.

Medication Incidents – Refer and follow the Medication Incidents procedure (Appendices 5 and 6); and complete the Medication Incident section on RADAR.

Adverse Drug Reaction – complete 'Commission on Human Medicines' (CHM) form from the back of the British National Formulary (BNF).

Medical Device and Equipment – Refer to and follow the Medical Equipment Procedure Flow Chart (appendix 7)

Information Governance – "A new incident reporting tool for data security and protection incidents has been launched within the Data Security and Protection Toolkit. This replaces the previous SIRI reporting tool which was part of the previous Information Governance Toolkit. The new incident reporting tool reflects the new reporting requirements of the General Data Protection Regulation (GDPR), and for relevant organization's the Networks and Information System (NIS) Regulations."

https://digital.nhs.uk/data-and-information/looking-after-information/data-security-and-information-governance/data-security-and-protection-toolkit

The severity of the incident must be assessed using the scale and severity factors outlined within the HSCIC guidance -annex A. All incidents which reach the threshold for a level 2 IG related serious incidents must be reported on STEIS as well as the IG toolkit and investigated appropriately.

Refer to the Information Governance policy for further information on IG compliance and the Health and Social Care Checklist Guidance for Reporting, Managing and Investigating Information Governance and Cyber Security Serious Incidents Requiring Investigation.

http://portal.mkhospital.nhs.uk/Guidelines/Non%20Clinical%20Documentation/Information%20Governance/Infromation%20Governance%20Polices%20and%20Guidelines/Information%20Governance%20Policy.doc

https://www.igt.hscic.gov.uk/resources/HSCIC%20SIRI%20Reporting%20and%20Checklist%20Guidance.pdf

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Information Commissioner Office (ICO) High Risk Data Protection Impact Assessment (DPIA) Notification
Under the Data Protection Act 2018 including GDPR, non-compliance with DPIA requirements can lead to fines imposed by the competent supervisory authority (ICO).

The Trust must inform the ICO prior to processing where a data protection impact assessment indicates that the processing would result in a high risk in the absence of measures taken by the Trust to mitigate the risk. Failure to carry out a DPIA when the processing is subject to a DPIA, carrying out a DPIA in an incorrect way, or failing to consult the competent supervisory authority (ICO) where required, can result in an administrative fine of up to 10M€, or in the case of an undertaking, up to 2 % of the total worldwide annual turnover of the preceding financial year, whichever is higher.

ICO Breach Notification
It is mandatory to report a personal data breach under the Data Protection Act 2018 including GDPR to the ICO within 72hours if it's likely to result in a risk to people's rights and freedoms. If it is unlikely that there is a risk to people's rights and freedoms from the breach, you do not need to report. The threshold to determine whether an incident needs to be reported to the ICO depends on the risk it poses to people involved. Personal data breach reporting has a strong public policy purpose. The law is designed to push public bodies to step up their ability to detect and deter breaches. What is foremost in regulators' minds is not to punish the organisations, but to make them better equipped to deal with security vulnerabilities. The ICO will have the ability to issue fines for failing to notify and failing to notify in time. Fines can be avoided if organisations are open and honest and report without undue delay, which works alongside the basic transparency principles of the Data Protection Act 2018 including GDPR.

Screening Programmes – Where incidents relate to any intended or unexpected incident/act of commission/act of omission that occurred during the delivery of an NHS screening programme that could have or did lead to harm to more than one person participating or to staff involved. These incidents should be reported to the appropriate Screening and Diagnostics Operational Manager and investigation follow the UK National Screening guidelines. All screening incidents are reported to the National Screening Quality Assurance (QA) Service and the Public Health England (PHE) Screening and Immunisation Team. All incidents that reach the threshold for an SI will be escalated and reported on STEIS and investigated in line with local and the specific screening guidelines.

Refer to the full policy from UK National Screening

https://www.gov.uk/government/publications/managing-safety-incidents-in-nhs-screening-programmes

Pressure ulcers – For all hospital acquired category two and above pressure ulcer a summit meeting must be arranged within 72 working hours to assess the key learning, areas of good practice and if the pressure ulcer is new hospital acquired or was present on admission Appendices 17 and 18 report the standard operating procedure (SOP) for the summit meetings and the template for reporting the collaborative discussions.

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Summit reports for hospital acquired category 3 or 4 pressure ulcers are subsequently presented at the weekly SIRG meetings to determine if the threshold for an SI (in relation to level of harm) should be investigated by an RCA and to ensure that any problems in care are identified, understood, and resolved to prevent a future recurrence.

A SI **must** be declared if serious harm from pressure damage arises using the following criteria:

- Loss of limb
- Loss of life
- Requires surgery for the pressure ulcer.
- Transfer for care of pressure ulcer e.g. to Plastics for treatment.
- Cluster of pressure ulcers in a clinical area
- At providers discretion

All summit reports must be attached to RADAR.

Falls – For all inpatient falls reported with a moderate harm grading a summit meeting must be arranged within 72 working hours to assess the key learning, areas of good practice and if the fall was avoidable/unavoidable. Appendices 19 and 20 report the standard operating procedure (SOP) for the summit meetings and the template for reporting the collaborative discussions.

Summit reports are subsequently presented at the weekly SIRG meetings to determine if the threshold for an SI (in relation unexpected/avoidable and level of harm) should be investigated by an RCA and to ensure that any problems in care are identified, understood, and resolved to prevent a future recurrence.

4.0 Incident Investigation Procedure (Table 1)

4.1 Levels of investigation including communication process

Investigations including arrangements for communication with patients', their relatives/ carers and staff should be conducted at a level appropriate and proportionate to the incident. The investigation level required cannot always be decided solely on the severity of the incident.

'Prevented and No harm' incidents

There is no requirement for 'prevented or no harm' patient safety incidents to be discussed with patients as it may add stress to patients and potentially lower confidence in the standards of care with negative effects on staff confidence and morale.

A major harm incident/near miss may not always need or be suitable for a Root Cause Analysis if the incident did not solely take place on MKHFT's premises or where the event was very simple. In these cases, the Head of Risk and Clinical Governance will liaise MKCCG to determine how best to investigate and if a collaborative approach is required.

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RCA templates
These can be accessed from the intranet via:
https://intranet.mkuh.nhs.uk/clinical-governance-risk-management-and-health-safety/risk-management/root-cause-analysis

A 72-hour report (initial investigation summary report) **must** be completed for all SIs and submitted to the CCG to provide immediate assurance that mitigation has been out in place to minimise a future occurrence and to provide more detail of the incident. This must be completed **within three working days (72 working hours)** of the incident occurring/being reported for submission to the NHSMK Commissioners.

72-hour reports may also be requested for any potential SIs to provide more detailed information that will help determine if the incident requires escalation and reporting as an SI.

All serious investigation reports must be presented and approved at the Serious Incident Review Group (SIRG) before submission, with prior discussion locally with CSUs. All SI for never event investigations must be 'signed off' by the Director of Patient Care/Chief Nurse and or the Medical Director.

External/independent Investigations
These may be utilised for those incidents of high public interest or attracting media attention. These would be commissioned and conducted by those independent of the hospital e.g. independent expert Consultant. The report from these would be reviewed by the Management Board and Board of Directors. Independent investigations should be considered in the following circumstances:

- SI where the organisation is unable to conduct an effective, objective, timely and proportionate investigation.
- Deaths (near misses resulting in severe harm) of those detained under the Mental Health Act (1983)
- Where Commissioner/provider/patient/family feel independent scrutiny is warranted
- Where incidents represent significant systemic failure leading to widespread public concern
- To examine the wider commissioning system or configuration of services
- Homicide of person subject to care/under care of specialist mental health services in the past six months

Decisions in relation to external investigations will be made by the Risk Management Team, the Executive Team and the CCG and may follow an internal investigation first.

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4.2 Procedure for Investigating Staff using Root Cause Analysis (RCA)

It is best practice that CSUs nominate an RCA lead investigator who is independent to the incident under investigation, that staff are asked to provide statements immediately post incident while things are 'fresh in their minds' and that all relates staff and specialties are included in the investigation process.

The Trust follows the NPSA framework for incident investigation. https://improvement.nhs.uk/resources/learning-from-patient-safety-incidents/

All RCA reports must be copied to the Head of Risk and Clinical Governance as well as to the person who has commissioned the investigation and all those involved in the process. The report should be electronically linked to the incident on RADAR. The RCA owner and relevant CSU are responsible for ensuring relevant local/cross specialty learning. Trust-wide learning will be facilitated by the Risk Management Team.

Actions arising out of incident investigations should be followed up by the relevant RCA owner and CSU and all evidence attached to the relevant SI on RADAR. CSUs may also choose to collate local evidence SI files.

CSUs will be held to account at SIRG meetings for any breaches of action plan evidence and recurring trends.

SIs will only be closed by the CCG and on STEIS on receipt of evidence showing that all actions in the RCA action plans have been completed. This must be received within 5 working days of the date of the last action by due date.

4.3 Involving patients and their families/carers

Involvement begins with a genuine apology in line with the Duty of Candour guidelines. 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?

They should have an opportunity to inform on the terms of reference for the investigation, be able to contribute to the investigation process and have an opportunity to respond/comment on the findings/recommendations. This will run parallel with the Duty of Candour guidelines and where appropriate support or advocacy or help with language needs provided. For all new SIs, the Head of Risk and Clinical Governance will write to the patients/next of kin with an initial apology and offer for them to be involved in the investigation if they feel that would be beneficial

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Incident Management Table (Table 1)

Type of investigation	Description	Grading	Incident investigated by	Report received and approved by	Actioned and monitored by	Timescale for investigation and report
Informal	No' or 'low harm' incidents' Those with a higher actual or potential harm may also only require an informal investigation but this decision must be made by the Matron/Head of Department. These may include incidents where responsibility for the incident mainly rests outside the Trust or the cause is obvious.	No or low harm- Actual or near miss	Investigations are carried out by line/ward managers on RADAR. These are recorded on RADAR for reporting to Clinical Service Unit (CSUs) and inclusion in reporting data for the appropriate Governance Committees.	CSU	CSU	14 calendar days from incident reported date
Concise RCA	Moderate harm' or multiple 'no or low harm' incidents (that are NOT SIs)	Moderate or a group of no or low harm – actual or near miss	These must be commissioned by a Matron, Clinical Director, Head of Department level or above. They should be carried out by one or more persons of Matron or Departmental Manager level, one of whom have had RCA training. A structured investigation should be carried out involving some RCA tools, which may be found on the Trust Intranet, if a patient is directly affected, they/relative/carer should be involved where/if appropriate. The report should include plans for shared learning in addition to the RADAR form and the RCA should be attached to the RADAR web incident reporting form as evidence of investigation.	CSU (where appropriate)	CSU	21 calendar days from incident reported date

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Comprehensive RCA	Actual or potential 'severe harm or catastrophic incidents	Major or catastrophic – actual or near miss	This should be commissioned by the Head of Risk and Clinical Governance/Executive Team. The investigation will also be overseen and approved by the CSU Lead. The lead investigator and or expert advisor should be trained in RCA. A multidisciplinary team should be involved, including a consultant (for a patient safety incident) or senior manager and any other expert advisor (such as the Head of Risk and Clinical Governance) as required. To ensure independence, there should be participation from a senior individual from another division/CSU where possible. The patient /relative/ carer should be included (if/where appropriate) and they should be offered links to independent representation or advocacy services. The investigation should be conducted to a high level of detail to enable a thorough and credible investigation. The RCA should be attached to the RADAR incident reporting form as evidence of investigation.	CSU, SIRG Quality and Clinical Risk Committee (overview) Minutes of the Risk and Quality Committee to the Management Board	CSU Management Board	Initial summary report within 72hr working hours of incident being reported. Final Draft 20 working days from incident for presentation at SIRG Submission within 45 working days from SI being declared. Where not an SI complete RCA within 45 working days of incident being reported
Serious Incident or 'Never Event' (level 2)		Major or catastrophic – actual or near miss	Overseen and Lead chosen by Executive Director. Team to include Consultant or senior manager	Report to SIRG and the Quality and Clinical Risk Committee	Management Board Trust Board Joint SI Review Group	3 days from incident 72-hour report to be submitted to NHSMK, Risk Management & Medical Director, Director of Patient Care/Chief Nurse 20 days from incident draft report & action plan submission to SIRG. Final report and action plan to be signed/ approved by SIRG and the Executive Lead within 45 days

A crucial part of the investigatory process is to ensure that it is carried out in an objective and supportive way and that staff affected by and involved in the incident feel supported and listened to. Investigation of an untoward incident should not be about apportioning blame. The occurrence of an incident or an error in itself, however serious the outcome, is not evidence of neglect, carelessness, or dereliction of duty. The disciplinary process should only be involved in cases of repeated poor performance or in cases of deliberate offence. The Root Cause Analysis and management processes must be kept separate

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4.4 Investigations across organisational boundaries/multiple agencies

Where there are multiple services involved the CCG will agree how best to manage SI investigations. In all cases a RASCI (Responsible, Accountable, Supporting, Consulted, Informed) model will be used to ensure clear commissioner responsibility for leading the investigation, where the accountability sits and who should be kept consulted/informed. Wherever possible all organisations should work collaboratively to undertake a single investigation although in some circumstances and in complex circumstances separate investigations may need to be completed organisations **must** consider cross boundary issues when determining root causes and drafting action plans.

4.5 Reporting to external agencies

Depending on the nature and severity of the incident, there may be a need for the findings of an incident to be reported to relevant external bodies. The Trust has a duty to comply with external reporting systems.

The following table outlines the process, responsibilities, and timescales for the external reporting systems most frequently used. This is a non-exhaustive list.

External Body	Process	Responsible	Timescale	Data reviewed by
NRLS	All patient safety incidents are reported anonymously to the NPSA using the National Reporting and Learning System. Incidents are uploaded on a weekly basis once the investigation has been approved. Serious Incidents are uploaded on NRLS when they are reported on STEIS and then re-uploaded once the incident is closed by MKCCG.	Risk Management Team	Within two weeks	Clinical Quality Board and Quality and Clinical Risk Committee
NCL and/or NHS London	The Trust reports all relevant serious incidents to NCL and NHS London via the STEIS system.	Risk Management Team	Within 3 working days of becoming aware of the SI approved by SIRG/CEO	Quality and Clinical Risk Committee
MHRA (voluntary reporting)	Incidents which involve equipment failure or user error are reviewed by the Head of Risk and Clinical Governance and Biomedical engineering.	Risk Management Team	Within 1 month of incident being logged on RADAR	Health & Safety Committee
	The Risk & Systems Manager/Risk and Safety Coordinator reports incidents to the MHRA regarding Equipment or Medication via the website or by phone. Staff should provide details of confirmation of reporting if reported locally to the Risk Management Team. This can accompany an incident form or be used in place of an incident form providing all relevant details are included	All staff	Within 5 days of incident occurring.	Health &Safety Committee
SHOT/SABRE	Blood Transfusion is informed of all incidents involving the transfusion of blood components and relevant incidents are then reported SABRE and/or SHOT in line with legal requirements.	Specialist Practitioner of Transfusion/ the Chief Biomedical Scientist in Blood Transfusion	Within 1 week of being notified of incident.	Clinical Quality Board and Quality and Clinical Risk Committee
CARE QUALITY COMMISION	All unintended radiation exposures are reported via the incident reporting system. The Radiation Protection Advisor and the Radiation Protection	Radiology Chair	Within 1 week of being	Clinical Quality Board and

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	Advisor are notified. The person reporting the incident and the Radiation Protection Advisor investigate and identify recommendations. The incident is reported to the Care and Quality Commission in line with Ionising Radiation (Medical Exposure) Regulations (IRMER).		notified.	Quality and Clinical Risk Committee

External Body	Process	Responsible	Timescale	Data reviewed by
HEALTH AND SAFETY EXECUTIVE	All incidents are reported via the incident reporting system. The incident form requires the person completing it to specify whether the staff member has been off for more than six days. Incidents are reviewed upon receipt and reported in line with RIDDOR requirements	Health and Safety Advisor	Within 10 days of incident	Clinical Quality Board and Quality and Clinical Risk Committee
COMMISSIONERS INFORMATION COMMISSIONER	By direct contact re any serious untoward incidents (Grade 4 & 5) including data loss incidents.	Chief Finance Officer	Within 1 working day of becoming aware of the incident	Clinical Quality Board and Quality and Clinical Risk Committee

Where the external body does not specify a timescale for reporting the Trust aims to report any relevant incident within seven days of the incident occurring unless otherwise specified.

4.6 Stop clock guidance

A stop clock request can be made to the CCG where there are circumstances that make a timely completion of the RCA investigation within the set time frame per the commissioning contract difficult or not possible to comply with.

Please see appendix 15

4.7 Learning from Incidents

When things go wrong in the delivery of care or services to patients, the Trust, and its staff, has a duty and a responsibility to actively learn and prevent such failings happening again. At the same time staff have a responsibility to seek information and implement learning from incidents. This is a fundamental principle of providing safe and harm free care for every patient (refer to Trust's Learning Compact and Framework)

It is recognised that staff need to be informed about incidents, claims and complaints from which they can learn to ensure there is Trustwide shared learning and feedback. A variety of forums and methods are used including:

- Messages in the weekly CEO newsletter
- Ward Meetings/Departmental Meetings
- Maternity Weekly Risk Meetings
- Directorate CSU meetings.
- Quality and Clinical Risk Committee, Management Board, and Trust Board.
- Multidisciplinary Audit half days
- Risk management newsletters
- Trust Serious Incident Review Group (SIRG)

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- Joint Serious Incident Review Group with PCT
- Health Economy Serious Incident Group with PCT
- National Patient Safety Agency NRLS reports
- Contact with other groups such as the Ambulance Trust and Campbell Centre (Mental Health)
- MK CCG

Staff will receive feedback on completion of incidents reported on RADAR once the investigation has been completed. To receive feedback staff must include an NHS e-mail account when reporting the incident. This should be in addition to the investigator discussing the incident with the reporter.

Where lessons learned from either incidents, complaints or claims, including aggregated analysis of these (see also the Complaints Policy and the Litigation Policy) that require changes in organisational practice or culture, then the recommendations/action plans will be submitted to the Quality and Clinical Risk Committee for discussion and approval as part of the quarterly risk reports.

Following the completion of an RCA it may be that there are lessons learned which can be shared with the wider healthcare community. The Trust will identify opportunities to share learning from incidents, complaints, and claims (or the aggregation of these) on an anonymised basis and will engage with other Trusts/Agencies who seek to share learning in this way and feedback to the MK Health Economy Wide SI review meeting. Front line staff need to have an understanding of the learning, outcomes of investigations, and the actions implemented, and the Trust requires assurance that this is embedded and evidenced across the organisation. Learning from incidents is incorporated into the Trust's Quality and Safety report discussed at the Quality and Clinical Risk Committee, which in turn is presented to the Board.

Where multi-incidents and investigations occur for recurring problems of a similar nature e.g. falls in a similar setting or amongst similar groups it may be more appropriate to arrange a 'deep dive' in order to provide more detailed analysis and to identify common problems that **one** comprehensive action plan is developed and monitored to help move the focus from repeated investigation to learning and improvement.

All action plans from RCA are owned by the relevant CSU and it is their responsibility to ensure actions are implemented and monitored and appropriate evidence disseminated to the Risk Management Team

4.8 Aggregated investigation & analysis of Incidents, Complaints & Claims

To avoid duplicate investigations the Complaints and PALS and Risk Management Teams will work collaboratively to ensure the right information is given in compliance with both SI and complaint processes and to ensure the concerns and questions of the patients/next of kin involved are fully met.

In order to support learning and identify early trends which may need action or further investigation, the data from incidents, complaints, and claims, including root cause analysis data, will be used to learn lessons and improve and/or make changes to practice following aggregated analysis. This supports a proactive approach to risk management to use previous learning to mitigate the risk of similar situations occurring in the future.

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A weekly summary report to the Executive Team from the Risk Management, Complaints and Governance Teams, details incidents, claims and inquests that arise.

4.9 Training

Training on incident reporting is given at Trust Induction and 3 yearly thereafter in line with the Trust's mandatory risk management training. Additional training on RADAR can be arranged with the Risk & Systems Manager.

In the event of a staff member being called to attend as a witness, the Trust solicitor's Legal team will hold a pre-event meeting and will provide advice. More detailed information is available in the Trust's Litigation and Inquests Policy

http://portal.mkhospital.nhs.uk/Guidelines/Non%20Clinical%20Documentation/Risk%20Management/Risk%20Management%20Polices%20and%20Guidelines/Litigation%20and%20Inquests%20Policy.doc

4.10 Immediate/Ongoing Support

Support includes the encouragement, sponsorship and resources provided by the Organisation, Managers and Colleagues. Staff experiencing difficulties associated with a traumatic/stressful incident will be offered support by their line Manager in the first instance and given the opportunity to discuss their concerns and where necessary, offering confidential in-house counselling services or advice through the Staff Health & Wellbeing Department. Staff can also approach Staff Health & Wellbeing who will be able to offer information about internal/external agencies that can offer support e.g. Independent Complaints Advocacy Service (ICAS)

Staff involved in a Root Cause Analysis should be given the opportunity to see the report before it is widely circulated. While they may have the chance to correct factual inaccuracies, they do not have a right of veto.

4.11 Legal Advice

This will be provided through the Litigation Office, who will involve legal professionals where it is deemed appropriate. As such, advice will be reviewed and shared as relevant.

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5.0 Statement of Evidence and References

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2) National Patient Safety Agency (2004) *Seven steps to patient safety: the full reference guide*. [Online]. London: NPSA. Available from: https://webarchive.nationalarchives.gov.uk/20171030131217/http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=59971&type=full&servicetype=Attachment [Accessed 16 April 2019]

3) NHS England (2015) *Serious incident framework.* [Online]. London: NHS England. Available from: https://improvement.nhs.uk/documents/920/serious-incidnt-framwrk.pdf [Accessed 15 April 2019]

4) *The Care Quality Commission (Registration) Regulations 2009.* SI 2009/3112. [Online]. Available from: http://www.legislation.gov.uk/uksi/2009/3112/contents/made [Accessed 16 April 2019]

5) Care Quality Commission (2015) *Regulation 20: Duty of candour: information for all providers: NHS bodies, adult social care, primary medical and dental care, and independent healthcare.* [Online]. Available from: https://www.cqc.org.uk/sites/default/files/20150327_duty_of_candour_guidance_final.pdf [Accessed 16 April 2019]

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7) *Mental Health Act 2007*. (c. 12). [Online]. Available from: http://www.legislation.gov.uk/ukpga/2007/12/contents [Accessed 15 April 2019]

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9) NHS Improvement (2018) *A just culture guide.* https://improvement.nhs.uk/resources/just-culture-guide/

10) NHS Improvement [2018] *Root cause analysis using five whys.* https://improvement.nhs.uk/documents/2156/root-cause-analysis-five-whys.pdf

11) NHS Improvement (2018) *The future of NHS patient safety investigation.* https://improvement.nhs.uk/documents/2525/The_future_of_NHS_patient_safety_investigations_for_publication_proofed_5.pdf

12) NHS Improvement (2018) *A just culture guide: supporting consistent, constructive and fair evaluation of the actions of staff involved in patient safety incidents.* [Online]. Available from: https://improvement.nhs.uk/documents/2490/NHS_0690_IC_A5_web_version.pdf [Accessed 16 April 2019]

13) NHS Improvement (2018) *Never Events policy and framework*. [Online]. Available from: https://improvement.nhs.uk/resources/never-events-policy-and-framework/ [Accessed 15 April 2019]

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15) NHS Improvement (2018) *Never Events list 2018*. [Online]. London: NHS Improvement. Available from: https://improvement.nhs.uk/documents/2899/Never_Events_list_2018_FINAL_v6.pdf [Accessed 15 April 2019]

16) NHS Improvement (2016) *Patient safety incident reporting and responding to Patient Safety Alerts.* [NHS/PSA/RE/2016/003].https://improvement.nhs.uk/documents/47/Patient_Safety_Alert_Stage_2_-_Patient_Safety_transfer_to_NHS_Improvement.pdf

17) NHS Improvement (2018) *Learning from patient safety incidents.* [Online]. Available from: https://improvement.nhs.uk/resources/learning-from-patient-safety-incidents/ [Accessed 16 April 2019]

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21) *Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).* [Online]. Available from: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=uriserv:OJ.L_.2016.119.01.0001.01.ENG [Accessed 16 April 2019]

6.0 Overall responsibility for the document

The Trust Head of Risk and Clinical Governance has overall responsibility for the review and maintenance of this policy.

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7.0 Supporting Policies

1. Risk Management Strategy
2. Whistle blowing
3. Health and Safety Control of substances hazardous to Health (COSHH)
4. Working with Asbestos
5. Health and Safety (Display screen equipment)
6. Bullying and Harassment
7. Safer Manual Handling of People and Loads Policy
8. Security of People & Premises
9. Infection Prevention and Control Manual
10. Fire Safety Policy
11. Managing Unacceptable Behaviour, Abuse, Harassment and Discrimination from Patients/Public Policy
12. Waste Disposal Policy
13. Restricted Smoking Policy
14. Equipment Asset Management Policy
15. Safe Working with Electricity Policy
16. Management of Medical Gas Pipeline Systems
17. Health and Safety (First Aid) Regulations
18. Latex Policy for Employees
19. Missing Patients Policy
20. Bed Rails Policy
21. Health & Safety Policy
22. Litigation and Inquests Policy
23. Being Open Policy

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8.0 Governance

8.1 Document review history

Version	Date	Author	Reason
5	June 2008		To update document
5.1	November 2008	N/A	Addition of Appendix 16
6.0	January 2009		Update to Appendix 4 due to Medical Devices Alert MDA/2009/001
6.1	January 2009		Updated to comply with NHSLA and NPSA requirements
6.2	May 2009		Updated to meet NHSLA & GMC 'apologies' information section 2.1
6.3	June 2009		Chairman's approval to minor amendment Appendix 2.0 section 2.1 GMC comments
V7.0 Draft 1	September 2010		To update document due to governance changes, NPSA & NHSLA requirements
V7.0 Draft 2	February 2011		To update document with comments from the Trust Documentation Committee and to meet current Trust Policy template.
V7.0 Draft 3	August 2011		Fully updated to included further recommendations and new SI Investigation Template (change to document reference from ORG-GL-9 to Risk Management reference)
7.1	November 2011		Minor amendment to Section 6.0
7.2	January 2013		Review against NHSLA standards
8	June 2014		Revised to include duty of candour guidelines & stop the clock guidance
9	March 2015		Revised to reflect new NHS England SI and Never Event guidelines and internal investigation process changes
10	April 2015		Reference made to responsibility of Incident Reporting moving from NHS England to NHS Improvement from 1st April 2016 in appendices 15 and 16
11	January 2018		New falls and pressure ulcer summits and new Never Event guidance
12	April 2019		Policy review date review
13	February 2021		Policy review with minor amendments
13	March 2023		Minor amendments changed Datix to RADAR

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8.2 Consultation History

Stakeholders Name/Board	Area of Expertise	Date Sent	Date Received	Comments	Endorsed Yes/No
	Risk Manager	Sept 9th	Sept 9th	Inclusion of SI process	Yes
	Clinical Governance	Sept 9th	Sep 12	Format	Yes
	Various	Sept 23rd	Sept 26th	No comments	No
	Chief Compliance Officer	Jan 2013			
	Medical Director	Jan 2013			
	Director of Patient Care/Chief Nurse	Jan 2013			
	Deputy Chief Nurse/head of Quality	Jan 2013			
	RADAR Manager	Jan 2013			
	Senior Pharmacist	Jan 2013	Jan 2013	Minor changes to medication incident reporting form	Yes
	Head of Research & Development	Jan 2013	Jan 2013	No	
	Governance Lead - Women's Health CSU	Jan 2013		Process clarification & additional information	Yes (majority)
	Equipment Library and Training Manager	Jan 2013	Jan 2013	No	
	Patient Safety Lead CCG	Jan 2013	February 2013	Process clarification & additional information	Yes (majority)
	Nursing	Jan 2013			
	Chair SIRG	Jan 2013			
	Divisional Director Core Clinical Services	Jan 2013			
	Divisional Director Surgery	Jan 2013			
	Divisional Director	Jan 2013			

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	Medicine				
	Chair Quality Committee	Jan 2013			
	Risk Midwife	Jan 2013			
	Medical Director	June 2014			
	Cross representation	August 2014		Addition of IG specific breaches & feedback process to staff	Yes
Clinical Board General Managers Senior Nurses Risk Management Team Pharmacy R&D Team Medical Equipment and Training Manager	Cross representation	June 2015			
Management Board	Cross representation	June 2015			
Medical Director Associate Medical Directors SIRG Risk Management Team	Cross representation	March 2017			
Medical Director Associate Medical Directors SIRG General Managers Senior Nurses Risk Management Team Pharmacy R&D Team Medical Equipment and Training Manager	Cross representation	May 2019		None	
Medical Director Associate Medical Directors SIRG General Managers Senior Nurses Risk Management Team Pharmacy R&D Team Medical Equipment and Training Manager	Cross representation	February 2021			

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8.3 Audit and monitoring

An annual Internal Audit Statement will be presented to the Audit Committee. The Audit Committee will review the internal audit reports. The Quality and Clinical Risk Committee and any other relevant committees or groups will take appropriate action according to the recommendations of the internal audit reports.

The monitoring of a document is a separate process from reviewing a document with separate aims. Monitoring is an ongoing process throughout the life of a document to determine and improve its effectiveness and implementation. Reviews are centred on the aims of the document based on regulation and corporate need. Please complete the table below to detail how you intend to monitor the process/processes within this document.

The duties within this policy will be reviewed every two years as part of the policy review process.

Audit/Monitoring Criteria	Tool	Audit Lead	Frequency of Audit	Responsible Committee/Board
Compliance with SI reporting timescales and submission of RCAs and subsequent evidence	Assurance report Trust and CSU dashboards	Head of Risk and Clinical Governance	Monthly Bimonthly Quarterly	SIRG Clinical Quality Board Quality and Clinical Risk Committee
Compliance with Duty of Candour	Assurance report Trust and CSU dashboards	Head of Risk and Clinical Governance	Monthly Bimonthly Quarterly	SIRG Clinical Quality Board Quality and Clinical Risk Committee
Triangulation of claims, Incidents, SIs, and complaints	Assurance report	Head of Risk and Clinical Governance	Quarterly	Quality Board and Quality and Clinical Risk Committee
Learning from incidents/SIs in relation to recurrence of similar incident/SI types	Assurance report	Head of Risk and Clinical Governance	Quarterly	Clinical Quality Board and Quality and Clinical Risk Committee

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8.4 Equality Impact Assessment

As part of its development, this Guideline and its impact on equality has been reviewed. The purpose of the assessment is to minimise and if possible, remove any disproportionate impact on the grounds of race, gender, disability, age, sexual orientation, religion or belief, pregnancy and maternity, gender reassignment or marriage and civil partnership. No detriment was identified. Equality Impact assessments will show any future actions required to overcome any identified barriers or discriminatory practice.

Equality Impact Assessment			
Division	Corporate	Department	Risk Management
Person completing the EqIA		Contact No.	01908 995099
Others involved:		Date of assessment:	03/02/2021
Existing policy/service	Yes	New policy/service	

Will patients, carers, the public or staff be affected by the policy/service?	Yes
If staff, how many/which groups will be affected?	*All staff*

Protected characteristic	Any impact?	Comments
Age	No	Positive impact as the policy aims to recognise diversity, promote inclusion, and fair treatment for patients and staff
Disability	No	
Gender reassignment	No	
Marriage and civil partnership	No	
Pregnancy and maternity	No	
Race	No	
Religion or belief	No	
Sex	No	
Sexual orientation	No	

What consultation method(s) have you carried out?			
Policy sent to various committees, ward managers/matrons and other relevant staff			
How are the changes/amendments to the policies/services communicated?			
Email			
What future actions need to be taken to overcome any barriers or discrimination?			
What?	Who will lead this?	Date of completion	Resources needed
Review date of EqIA	March 2024 – on policy review		

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Appendix 1: Incident investigation procedure

The main purpose of this is to identify the cause of an incident and ways to stop recurrence.

3 main stages

- Establishing the facts
- Identifying the causes
- Determining and carrying out practical proactive measures

Decide on level of investigation (Section 5.0 for details**)**

a) Informal
b) Concise Root Cause Analysis
c) Comprehensive Root Cause Analysis

Informal investigations will use the following stages but to a more limited degree.
Concise and Comprehensive RCA's will need to follow all steps as recommended.
Root Cause Analysis training is available from the Risk Management Team and useful tools and information is on the Risk Management Team's website.

Trust terms of reference - "To identify the root causes and key learning from the incident. To use this information to significantly reduce the likelihood of future harm to patients and to try and prevent such an incident happening again" to be complied with

Prepare

- Allocate time.
- Timetable when you need to have the report by
- Make sure the incident description is kept objective.
- Scope incident – think how far back you will need to go. This might be from the events leading up to the incident, or from the patient admission, however if they were discharged from hospital recently you might need to look further back.
- Gather as much information as possible a useful way to think of this is people, paper, parts, place.
    - People – e.g. Statements, interviews, discussion from relevant people
    - Paper – e.g. medical records, policies, guidelines, training, training records, staffing levels/rotas, product information.
    - Parts – e.g. equipment, structures
    - Place – if you have not been to the places the incident occurred it is useful to visit them – it can help you see things that may be relevant to the investigation.
- Statements should be obtained as soon as possible after the event for accuracy.
- Keep all your evidence together.
- The patient and/or relatives/carers account of any incident that resulted in moderate or serious harm must be fed into the investigation and consent should be sought from them to disclose information beyond the clinicians involved in the treating the patient. (See sections – 4.1/2; 5.1, 5.5 – 'Being Open').

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Map the Information

- Use a simple timeline to break down the incident step by step. The more you breakdown the events the easier it will be.
- The timeline needs to be factual with clarification in layman's terms of complex medical terminology to enable comprehension by patients/next of kin.
- Abbreviations must be written in full the first time used.
- Reports must be anonymous with staff referred to by title not by name.
- Place each event in chronological order.
    - 09:15 Admitted to ward.
    - 09:20 Seen by staff nurse. Respiration rate 22, Pulse rate 120, Blood Pressure 90/60. Patient short of breath. Doctor asked to see patient immediately.
    - 09:30 Seen by Foundation Year 1 doctor. 5-day history of productive cough. Examined.....Plan: chest x-ray, antibiotics.
    - 09:45 IV antibiotics prescribed according to BTS protocol; Chest x-ray ordered.
    - 10:00 Antibiotics given. Patient taken for x-ray.
- It is useful to make sure that if a test has been asked for, check that that test has been done and the results acted on if necessary.
- It is useful to have all the information before you start, but if this is not possible then information can be added when it becomes available.

A tabular timeline may be useful to use in helping you gain the information.

Analyse

- Look at Care and Service Delivery Problems.
- Care Delivery Problems (CDP) relates to the process of care and is usually acts or omissions by staff.
- Service Delivery Problems (SDP) are acts or omissions but not associated with direct provision of care.
- When looking at these be precise e.g. 'allergies not documented' is vague, 'allergy to penicillin not documented on drug chart' is much more precise. This will make it much easier to look at contributory factors which led to the CDP or SDP.
- For each CDP and SDP look at, what the factors were which could lead to this occurring are – these are contributory factors.
- There are often more than one CDP or SDP. Prioritise these into order, with those that are considered the most important first.
- Look at the systems or barriers that are already in place to prevent error occurring e.g. computer system alerts you before you delete a file. See if the barriers worked or failed.
- You can then make recommendations that should fix the contributory factors.

The RCA tools

Incidents requiring a Concise or Comprehensive Root Cause Analysis should employ techniques and tools including but not limited to concise or Comprehensive Root Cause Analysis use fishbone, 5 whys, Post Incident Control Analysis) which are available on the Risk Management page of the intranet.

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Five Whys Technique - best suited to simple non-complex problems or as a means of identifying second and third level contributory factors from primary problems.

(E.g. Temporary loss of specimens may identify a number of factors including who handled the specimens etc; no knowledge of what has been lost and issues of security. Each of these three secondary factors can analysed separately using '5 Whys' to identify the final root cause or causes)

Contributory factors or Human Factors Framework provides a paradigm for is the identification of the influencing and causal factors that contributed to the incident and is fundamental to a Root Cause Analysis Investigation The relative significance of a causal factor will be variable to the specific chain of events under investigation or more commonly present within the working environment. (Further details and guidance can be obtained from the Risk Management Department's web site on the Trust intranet or by contacting the Risk Manager).

a) Individual Factors - brought by individuals involved in the incident that are unique to them including but not limited to psychological, home, factors, work relationship.
b) Team and social factors (includes role definitions, leadership, support, and cultural factors).
c) Communication factors (including verbal, written and non-verbal between individuals, teams and/or organisations)
d) Task factors (includes work guidelines / procedures / policies, availability of decision-making aids)
e) Education and training factors (e.g. availability of and attendance at training)
f) Equipment and resource factors (e.g. clear machine display, poor working order, size, placement, ease of use)
g) Work and environment factors (e.g. poor/excess administration, physical environment, workload and hours of work, time pressures)
h) Organisation and strategic factors (e.g. organisational structure, contractor / agency use, culture)
i) Patient factors (e.g. clinical condition, social / physical / psychological factors, relationships)

Verification of Causal/ Contributory Factors

The investigator/ panel/team should only select those issues that contributed or helped shape the incident under investigation. Care should be taken that issues which may have influenced similar types of problems or are known but did not help shape this incident are not considered as part of the analysis. The inclusion of other unrelated factors will reduce the validity of the analysis and lead to a focus on an improvement strategy that does not address the fundamental causes of the incident.

Identify the Root Cause

- Look at each contributory factor and see if this had not occurred would the incident still have happened.
- There may be occasions when nothing could have prevented the incident and no root cause(s) are identified.
- You may have more than one root cause.

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Lessons learnt

- There are always lessons to learn and key safer practice issues may be identified which did not materially contribute to the incident.
- Lessons learned from the incident and the investigation should be identified, numbered, and addressed by the recommendations, alongside any root causes.
- From this you can look at solutions to stop or reduce recurrence

Recommendations

- These should be designed to address the root cause and any key learning points.
- Keep these precise
- Consider the most effective ways to reduce the likelihood of the incident happening again.
- Produce recommendations/action plan with SMART objectives.

Preparing a report and dissemination

The report should be clear, free of jargon, acronyms and names and using plain English. Where technical terms are necessary a glossary may be required and full wordings for all abbreviations must be used first time.

Use the report format and guidance available from the Risk Management Website

It is important to note that unless there are specific exceptions, the patient or family of a patient have a right to the full investigation report under the provisions of the current Data Protection Act 2018.

Feedback to staff involved

- Individual staff member reporting incident
- CSU meetings
- Departmental/Ward meetings
- Patient/next of kin (in line with Duty of Candour requirements)

Trust wide sharing of learning as appropriate (refer to Trust's Learning compact and Framework)

- Trust audit plenary sessions
- CEO newsletter
- Specialty newsletters
- Cross specialty presentations at Clinical Improvement Groups (CIGS)
- Monitored and facilitated by SI

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Appendix 2: Medication Incident Procedure

Scope:
This medication incident procedure applies to all staff that dispense, prescribe, or administer drugs, whatever the route. It is important that medication incidents are reported, in order that clinical risk is kept to a minimum. The aim of this policy is not to be punitive but to encourage staff to think about the incident, therefore identify what went wrong and to learn from the mistake so that it does not recur.

Definition:
A drug error is defined as: 'Any drug which has been prescribed or dispensed incorrectly, or the wrong drug or the wrong dose has been administered, or the drug has been administered at the wrong time or to the wrong patient or failed to be administered when prescribed (unless this is at the request of the doctor or patient).

Procedure:
If a medication error has occurred and this has not been administered to the patient, follow point (3) onwards.

If a medication incident has occurred, the following actions should be taken:

1. **All** medication incidents must be notified **immediately** to:
    (a) The line manager, whether it is the nurse-in-charge of the ward, the Consultant, the ward Pharmacist, etc.
    (b) The doctor.
    (c) The Matron/Divisional bleep holder or Duty Nurse Manager
2. Following medical assessment of the patient, the doctor will decide what medical action will be taken and if it is appropriate that the patient and/or relatives are to be informed of the error.
3. An online incident report must be made ensuring that the Medication Incident section is completed **at the time** by the person responsible for the Medication Incident.
4. A full investigation will be undertaken by the Head of Department/Consultant or Matron and recommendations/action to prevent a recurrence clearly outlined on the Medication Incident.
5. If the medication incident is seen as potentially serious (i.e. result in serious harm, death or a never event), statements will be required from all staff concerned.
6. The Director of Patient Care/Chief Nurse, Medication Safety Officer and Chief Pharmacist will receive a copy of all Medication Incidents, review the information, and decide if further action needs to be taken.
7. The reason for this approach is to help us learn reasons for medication incidents. However, in the event that a medication incident is deemed to be of a very serious nature, or the same person has committed a series of medication incidents over a short period of time, it may be necessary to invoke the Trust's disciplinary procedure. This will be at the discretion of the relevant line manager.
8. Monthly Medication Incident Report will be produced by the Risk Management Department for the Prescribing & Medicines Governance Committee - staff and patient names will not be included within the report.

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Appendix 3: Missing Drugs Procedure

1. Inform the Directorate Matron/Duty Nurse Manager immediately

2. Together with the Directorate Clinical Nurse Manager/Duty Nurse Manager, re-check the Medication stock cupboards and Medication carts against all documentation, e.g. patient's medication chart etc.

3. Inform the ward pharmacist (in hours) and place a request for resupply of drugs with pharmacy.

4. Out of pharmacy hours, the incident will be reported by the Duty Nurse Manager via email to the Chief Pharmacist, Medication Safety Officer and Director of Patient Care/Chief Nurse as soon as possible. To avoid missed or delayed doses, obtain any urgent medication for the patient by accessing the Pharmacy Emergency Cupboard (PEC) through the Duty Nurse Manager or contacting the On-Call Pharmacist.

5. Report the incident via the online incident system, ensuring completion of the medication incident section. An appropriate level of investigation will be undertaken as per section 5.

6. If the missing medication is a Controlled Drug (CD) the following additional steps should be followed:

a) Refer to the Controlled Drugs SOPs (section 6.6.3 Anomalies and Discrepancies).

b) If the CD discrepancy is not resolved**, Statements should be received from all registered nurses working in the previous 24 hours since the CDs were last checked**.

c) Red ink pen should be used to write in the CD Record Book (CDRB) on the relevant page for the medication, form and strength stating:

"missing CD identified, Trust procedure carried out. New drug balance =……". "Incident Report reference number: ……..".
This entry must be signed by the Nurse in charge of the ward and Matron/Duty Nurse Manager. The Duty Hospital Manager will decide if the police should be informed.
d) Refer to the Controlled Drug Standard Operating Procedure for full details.

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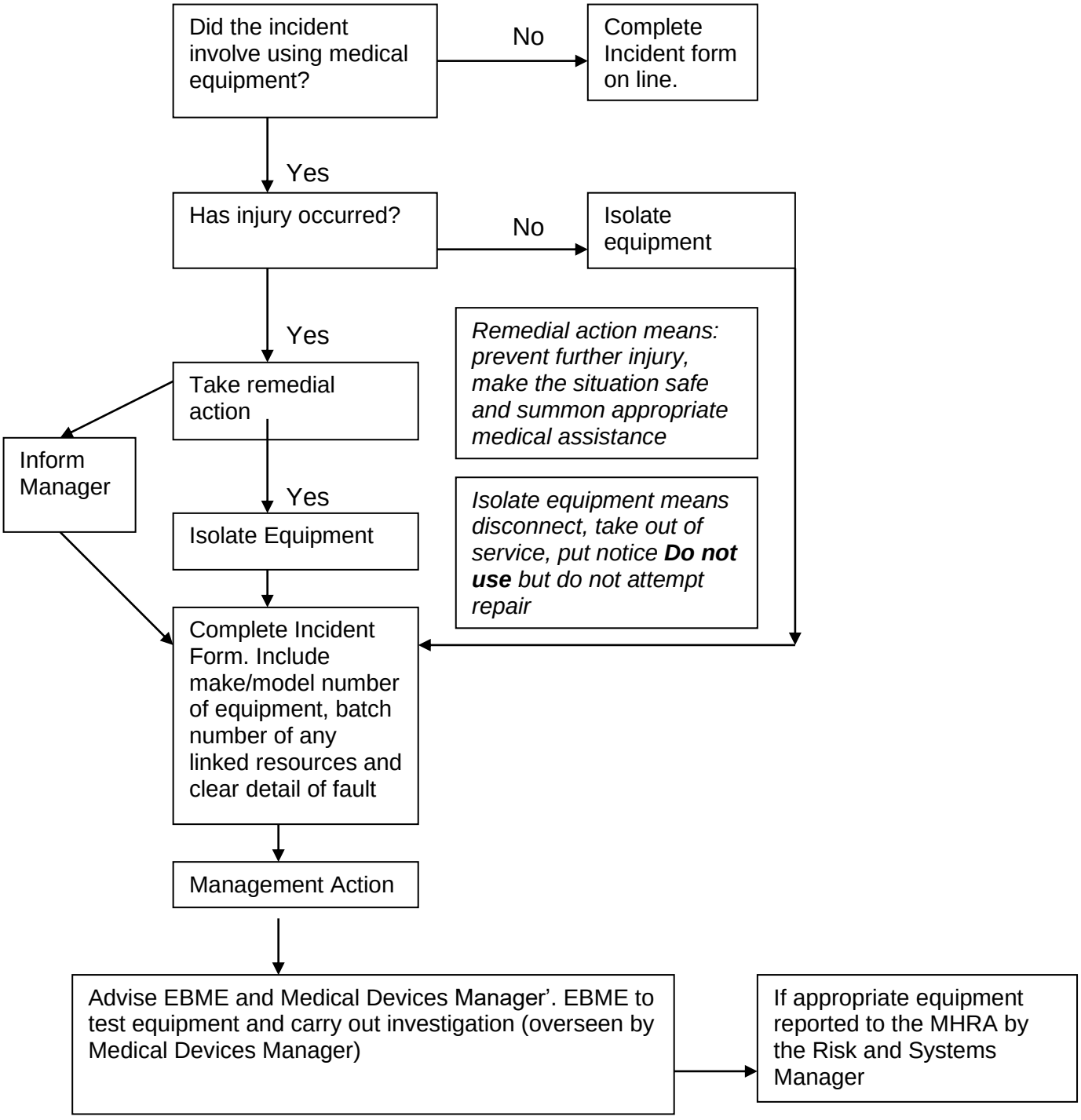
Appendix 4: Medical Equipment Procedure Flowchart



NB – Do not contact manufacturer, do not permit the manufacturer to remove/repair item without approval from a senior manager

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Appendix 5: Serious Incident Process (this includes Never Events)

NHS Improvement Never Events Policy and Framework (January 2018)

Definition Serious Incident – In broad terms, 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 extend beyond incidents which affect patients directly and include incidents which may indirectly impact patient safety or an organisation's ability to deliver ongoing healthcare.

Examples include serious injury/death due to violence or medical mishap, unexpected neonatal or child death, serious theft or fraud, serious infection outbreak, damage to the building or equipment by fire or other that may be a significant threat to service provision.

Definition Never Event

- Never Events are patient safety incidents that are wholly preventable where guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and have been implemented by healthcare providers.
- Each never event type **has the potential to cause serious patient harm or death**. However harm/death is not required to happen as a result of a specific incident occurrence to be categorised as an SI.
- There is evidence that the category of Never Event **has occurred in the past** e.g. through reports to the National Reporting and Learning System (NRLS) and a risk of recurrence remains.
- **Occurrence of the Never Event is easily recognised and clearly defined** – this requirement helps minimise disputes around classification and ensures a focus on learning and improving.

See appendix 18 for details of all never events and SI that **must be reported** in line with the NHS England Policy and Framework**.** In addition, the Trust is able to request internal investigation of any serious incidents or near misses deemed to be requiring comprehensive investigation.

Never Events may highlight potential weaknesses in how an organisation manages fundamental safety processes and

Prevented Never Event - provide vital warning signs to Provider organisations that the potential for actual never events exists in their organisation and are defined as incidents that may have been Never Events had action not been taken to avoid an incident meeting the Never Events criteria and where such action is not part of the specified preventative action detailed in the relevant associated guidance or safety recommendations. Prevented never events should be reported to the organisation's leadership and externally to the Commissioner (although they should not be labelled as Never Events on the NRLS or STEIS systems) and should be investigated through a comprehensive RCA process.

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Never events are clearly defined as serious incidents requiring reporting and therefore must be reported to the Care Quality Commission (CQC) and Monitor. Failure to report a never event, is an extremely serious failing on the part of the staff involved as well as the organisation. It is likely to constitute a breach of CQC regulation requirements (Regulation 16 and 18 of the Care Quality Commission (Registration) Regulations 2009).

It also breaches NHS Standard Contract Section E Clause 25, which requires the appropriate reporting of serious incidents and patient safety incidents to the Commissioner and CQC. Commissioners should seek to withhold payment for the cost of the episode of care in which a Never Event has occurred and any subsequent costs involved in treating the consequence of the Never Event. Commissioners are able to waiver these contractual terms depending on the individual circumstance.

Where a Never Event is discovered by the organisation but appears to be the responsibility of another the 'discovering' organisation should inform the originating organisation and is not required to report the incident as their own.

The seven key principles in the management of Serious Incidents

1. Open and transparent – Duty of Candour
2. Preventative – identification of weaknesses in the system and analysis to prevent similar incidents occurring again.
3. Collaborative – working in partnership with other organisations/teams.
4. Proportionate – focusing of investigation and resources appropriately to scale of SI.
5. Systems based – use of appropriate investigation methodology (NPSA RCA) by appropriately trained staff.
6. Timely and responsive – reported within 28 working hours of SI occurring/being brought to staff attention.
7. Objective – investigation completed by staff **not** involved in the direct care of the patient affected or working in the same team to ensure appropriate critical analysis.

Assessment and reporting

1) Internal reporting procedure

If the line manager/supervisor making the assessment identifies the incident as possibly being a Serious Incident (see definitions above) then this should be reported immediately as below:

In hours:
To the Head of Risk and Clinical Governance who will ensure the relevant Executive Director (as below) is advised and also ensure that the Divisional Manager is informed:

- patient related incidents: Director of Patient Care/Chief Nurse and/or Medical Director
- Incidents involving building or equipment or violence and aggression incidents: Deputy Director of Facilities
- Incidents involving financial matters e.g. fraud: Director of Finance.
- Information governance: Deputy CEO

If from the initial RADAR incident report it is unclear if the incident is definitely an SI a 72-hour report will be required within three working days to allow an informed decision by the Executive Team

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The Head of Risk and Clinical Governance in consultation with the relevant Executive and specialty/department will be responsible for ensuring an immediate assessment of the situation to:

- Put in place immediate processes to reduce or limit further harm.
- Depending on the nature of the SI advise the CEO or deputy and involve other Executive Directors with key responsibilities as appropriate – HR (communication) Facilities (help line and hotel, estate services), Finance (IT) Operations (adjustments to service provision), Director of Patient Care/Chief Nurse
- Advise the Trust Communications Manager and Serious Incident Lead of the CCG, (01908 278 681) (Monday to Friday 0900 – 1700 hours) and the CCG Duty Director on Call (out of hours) verbally within 24 hours.
- Ensure completion of the Strategic Executive Information System (STEIS) electronic form within working 48 hrs.
- Advise other stakeholders and external agencies as appropriate, e.g. Police, Child Protection, CCG, Coroner (see below for list of stakeholders).
- Within 48 working hours of incident determine which level of RCA is appropriate, appoint an Investigating Officer, agree remit, and confirm timescale for investigation according to the Trust Incident Policy and follow trust processes including involving patients and their relatives/carers. Identify witnesses and request statements of facts from their involvement in the incident.

Out of hours:
The line manager/supervisor being advised of a potential serious incident should immediately advise the Manager on Call.
The Manager on Call is responsible for briefing the Executive on Call who will confirm whether the event qualifies as a serious incident. If confirmed the Executive Director will be responsible for ensuring an immediate assessment of the situation to:

- Put in place processes to reduce or limit further harm.
- Advise the Trust out of hour's communications team and CCG Duty Director on Call verbally within 24 hours.

The next working day the Executive Director is responsible for:

- Advising the CEO or deputy and involve other Executive Directors with key responsibilities as appropriate – HR (communication) Facilities (help line and hotel, estate services), Finance (IT) Operations (adjustments to service provision), Director of Patient Care/Chief Nurse (Patient Safety).
- Ensuring completion of the electronic form within 48 working hrs.
- Advising other stakeholders and external agencies as appropriate, e.g. Police, Child Protection, CCG, HM Coroner (see below for list of stakeholders).
- Within 48 working hours of incident determining which level of RCA is appropriate, appointing an Investigating Officer, agreeing the remit, confirming timescales for investigation according to the Trust Incident Policy and following trust processes including involving patients and their relatives/carers.

2) Clinical Commissioning Group (CCG) and other Stakeholders

- The Serious Incident Lead of the CCG (in hours) and CCG Director on call (out of hours) will be informed by telephone at the earliest opportunity and by using the electronic form. This will normally be the next working day, but dependent on the severity of the incident, the on-call press officer may need advising.

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- If events cause media interest or have the potential to cause media interest but do not meet with the Serious Incident definition, then the Trust need only report the incident via the Trust Communications team to the CCG Communications team. In this case a STEIS does not need to be submitted but Monitor/CQC may need to be informed.

- The CCG Communications Team will make the judgement as to whether the Serious Incident is likely to attract significant media interest i.e. regional TV.

- External stakeholders, dependent on the incident, will need to be kept advised of the ongoing processes. The responsibility for this lies with the Director of Human Resources and the lead Executive Director/Director and CEO. Out of hours this responsibility will lie with the Executive Director on Call, working with the Manager on call, and liaison with the Duty Hospital Manager, and, if a patient safety incident the Speciality Consultant.

- The SHA will support the investigation of 'Never Events' through the Patient Safety Action Team.

3) Media and Communication

- In liaison with the lead Executive Director/Director and CEO, the Trust Secretary and Trust Communications Manager will have the responsibility for dealing with all press releases and media enquiries. No new information will be provided to the media without ensuring that patients/relatives and involved staff have been informed. Out of hours this responsibility will lie with the manager on call in liaison with the executive on call. All information provided to the media should be documented.

- A brief communication should be sent to the patient's GP before discharge, explaining what happened where relevant.

Helpline – dependent on the incident help lines may need to be set up and this will be the dependant on the nature of the SI and be in liaison with the lead Executive Director/Director the same or next working day. It should be recognised that the help line may be provided internally or externally dependent on the nature of the incident. The lead Executive Director/Director should assess the likely need for a help line, and the number of likely callers.

- Patient s incidents will be manned by qualified clinical staff from the directorate involved, other incidents by staff from that division. Help line staff will be fully briefed by the Lead Executive Director or designated deputy prior to taking up the role and each member of staff will be provided with a Call Log Form (Appendix 10). A detailed log of all calls received, and the information/advice given will be recorded on paper records.

4) Documentation and Investigation

- Recording of the incident must commence at the time of reporting the incident and that includes ensuring an electronic form within 48 hours of the event. In incidents involving patients, medical records should be completed and up to date and all documents that may be linked to the incident should be preserved and kept safe. In

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rare cases and specific circumstances, documents may pass to an external body by decision of the CCG.

- The investigation of a Serious Incident must follow the guidance set out in Trust processes. Documents produced as part of the investigatory process should be retained by the lead Executive officer. It should be noted that all documents can be requested by interested third parties, and therefore copies should be provided at the earliest time to the manager responsible for legal issues in all but the most sensitive issues. This manager will also be responsible for the safe keeping and copying of medical records where appropriate.

- The final draft report and Action Plan will go to the Head of Risk and Clinical Governance for approval at the Trust's Serious Incident Review Group. There may be a requirement to provide the investigatory report to appropriate external bodies. It should be noted that this report, like all other documents, may be disclosable to other interested parties on request.

- Once the Trust has approved the Investigation Report. The Risk Management Team Head will email to the CCG and update STEIS and RADAR to reflect submission.

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Appendix 6: Incident Report Form

Datix

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Please enter as much information as possible – The Incident Reporter section MUST be completed.

Incident Reporting Form

(This form is only to be used when RADAR is unavailable

Incident Reporter

First names: **Surname:**

Job Role: **Extension/Bleep:**

Role:

NHS Email Address:

(NHS email is required if you would like to receive feedback on this incident)

Do you wish to receive feedback?

Staff Group:

Division Reporting the Incident:

Specialty Reporting the incident:

Incident Details

Is this a Potential SI?

Incident Type:

Date of Incident:

Time of Incident:

Location of Incident:

Description of Incident:

Is this a Potential RIDDOR?

Immediate Action Taken:

Who did you notify?

Equipment Details

Serial Number:

Batch Number:

Description of Device:

Accessories Kept?

(Ensure all accessories are kept for testing (Excluding Controlled Drugs)

Has the Equipment Been Isolated?

Current Location:

Description of the Defect:

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Medication Incident

Stage of Medication Error:

Drug Administered:

Correct Drug:

Dose & Strength Administered:

Correct Dose & Strength:

Quantity Missing:

Miss Drug Recovered?

Name of Pharmacist Informed:

Comments:

Violence & Abuse

Was this a Code Victor?

Restraining Techniques Required?

Police Called?

Time Police Called:

Police Attended?

Time Police Attended:

Action Taken by Police:

Crime Number:

Severity & Outcome

Outcome of Incident:

Actual Severity of Incident:

None	No injury, no treatment required. No days off work.
Low	Extra observation/minor treatment, verbal abuse, minor damage, 1-3 days off work.
Moderate	Needs extra treatment. Recovery 1 week to 6 months. Moderate damage. 4-14 days off work.
Major	Permanent or long-term harm. 6 months+. Serious damage. Closure of some service
Catastrophic	Death caused by incident. Harm to 50+ people. Complete shutdown.

Patient Fall Incidents:

Which Bed/Bay/Toilet did fall occur:

Was the Fall Witnessed:

What Post Fall Review Undertaken:

Previously fall this admission:

Was the Call Bell within reach:

What Type of Mobility Aid Used:

What Footwear was patient wearing?

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Pressure Ulcer Incidents

Hospital Acquired: **Grade:**

If Nursing Home acquired which one:

Security Incidents

Was this a Code Victor: **Were Restraint Techniques Used?**

Were Police Called: **Time Police Called:**

Police Attended: **Time Police Attended:**

Action Taken by Police: **Police Crime Reference Number:**

What were the Aggravating Factors: **Type of Security Incident?**

Was Trust Property Stolen:

Type of Damage/Loss:

If other, please specify:

Were Items Repaired: **Were Items Replaced:**

Were items Written Off: **Were items Sold:**

Were items Decommissioned: **Residual value at time of loss:**

Additional Information:

Additional Security Incidents Details

Was the staff member working alone?

Did individual become unconscious:

Did individual need resuscitation:

Hospitalised for more than 24 hours:

Patient Factors:

Was any contact made:

Was any physical Injury caused?

Was personal Discomfort caused:

Was there public disorder:

Harassment/Malicious Behaviour:

Individual want police to pursue:

Property lost/damaged/stolen:

If Yes, give details including value:

Person involved 1

Forename: **Surname:**

Contact Role: **Job Title (staff only):**

MRN (patients only): **NHS/Lab Number (patients only):**

Was patient informed: **Were Next of Kin Informed:**

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Person involved 2	
Forename:	**Surname:**
Contact Role:	**Job Title (staff only):**
MRN (patients only):	**NHS/Lab Number (patients only):**
Was patient informed:	**Were Next of Kin Informed:**

Person involved 3	
Forename:	**Surname:**
Contact Role:	**Job Title (staff only):**
MRN (patients only):	**NHS/Lab Number (patients only):**
Was patient informed:	**Were Next of Kin Informed:**

Witness 1	
Forename:	**Surname:**
Contact Role:	**Job Title (staff only):**
MRN (patients only):	**NHS/Lab Number (patients only):**
Was patient informed:	**Were Next of Kin Informed:**

Witness 2	
Forename:	**Surname:**
Contact Role:	**Job Title (staff only):**
MRN (patients only):	**NHS/Lab Number (patients only):**
Was patient informed:	**Were Next of Kin Informed:**

Witness 3	
Forename:	**Surname:**
Contact Role:	**Job Title (staff only):**
MRN (patients only):	**NHS/Lab Number (patients only):**
Was patient informed:	**Were Next of Kin Informed:**

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Appendix 7: Internal Helpline Log Form [for use following SIs if required]

Incident Title……..

Incident Date……...

Date of Call……. Time of Call……

Caller Name……. Hosp. No……..
Date of Birth……
Address……

Detail of Query raised:

Advice given:

Further Action/Response Required: YES NO (ring appropriate)

Logger Name……. Date……

Signature……

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Appendix 8: Guidance for Reporting Adverse Events in Clinical Trials

1. Introduction

This document provides links to further information on good practice and how to comply with the recording and processing of adverse events in clinical trials that assess the efficacy or safety of medicinal products at Milton Keynes University Hospital NHS Foundation Trust. The principles may also be applied to trials of other forms of intervention, and applies to all investigators and trial staff, working with trial patients.

2. Background

The EU Clinical Trials Directive (2001/20/EC) was published on the 4th April 2001. The Medicines for Human Use (Clinical Trials) Regulations 2004/1031 transposed this EU Directive into UK law on 1st May 2004. The Medicines for Human Use (Clinical Trials) Amendment Regulations (SI 2006/1928) came into force on 29 August 2006. The Amendment Regulations principally implement EU Directive 2005/28/EC (the Good Clinical Practice (GCP) Directive) by amending the 2004 Regulations.

These Regulations set out the legal requirements for pharmacovigilance in clinical trials involving UK participants that evaluate medicines.

3. Reporting research related Adverse Events

3.1 Recording and reporting of Adverse Events (including Adverse Reactions, Serious Adverse Events, Serious Adverse Reactions and Suspected Unexpected Serious Adverse Reactions) must be managed in line with the reporting policy of the sponsor of the research study.

3.2 For research patients involved in incidents, the Milton Keynes University Hospital NHS Foundation Trust Incident Reporting Policy and Procedures will apply.

3.2 Where no sponsor policy exists, or where the minimum reporting requirements laid out within the Milton Keynes University Hospital NHS Foundation Trust Guidance for reporting Adverse Events in Clinical Trials are not met, the Milton Keynes University Hospital NHS Foundation Trust Incident Reporting Policy and Procedures must be followed as a minimum.

3.3 Please note that Milton Keynes University Hospital NHS Foundation Trust will not act as Sponsor for clinical trials of medicinal products under the Research Governance Framework unless a Clinical Trials Unit is appointed to assist with the conduct and monitoring of the clinical trial.

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4. Definitions

Term	Definition
Adverse Event (AE)	Any untoward medical occurrence in a patient or clinical trial subject administered a medicinal product and which does not necessarily have a causal relationship with this treatment. Comment: An adverse event can be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease in any subject in a clinical trial (including those in an untreated control group), whether or not considered related to the investigational medicinal product.
Adverse Reaction (AR)	Any untoward and unintended responses to an investigational medicinal product related to any dose administered. Comment: All adverse events judged by either the reporting investigator or the sponsor as having a reasonable causal relationship to a medicinal product qualify as adverse reactions. The expression "reasonable causal relationship" means to convey, in general, that there is evidence or argument to suggest a causal relationship.
Unexpected Adverse Reaction (UAR)	An adverse reaction, the nature or severity of which is not consistent with the applicable product information (e.g. Investigator's Brochure (IB) for an unapproved investigational product or Summary of Product Characteristics (SmPC) for an authorised product) Comment: When the outcome of the adverse reaction is not consistent with the applicable product information, this adverse reaction should be considered as unexpected.
Definition of Seriousness: Serious Adverse Event (SAE), Serious Adverse Reaction (SAR) or Suspected Unexpected Serious Adverse Reaction (SUSAR)	Any AE, AR or UAR that at any dose: • results in death. • is life-threatening* • requires hospitalisation or prolongation of existing. • hospitalisation • results in persistent or significant disability or incapacity. • consists of a congenital anomaly or birth defect. Comment: Medical judgement should be exercised in deciding whether an adverse event/reaction should be classified as serious in other situations. Important adverse events/reactions that are not immediately life-threatening or do not result in death or hospitalisation but may jeopardise the subject or may require intervention to prevent one of the other outcomes listed in the definition above, should also be considered serious. *Life-threatening in the definition of a serious adverse event or serious adverse reaction refers to an event in which the subject was at risk of death at the time of the event. It does not refer to an event which hypothetically might have caused death if it were more severe. The definition of seriousness above reflects the definition used in the EU Directive, and from EudraCT guidance. "Other important medical condition" is taken from ICH E2A and can also be used to define an SAE.

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5. Guidance

The full guidance on pharmacovigilance is available at:

Medicines and Healthcare products Regulatory Agency (2014) *Good pharmacovigilance practice (GPvP) [guidance]*. [Online]. Last updated 28 January 2019. Available from: https://www.gov.uk/guidance/good-pharmacovigilance-practice-gpvp [Accessed 17 April 2019]

National Institute for Health Research [2019] *Clinical trials toolkit*. [Online]. Available from: http://www.ct-toolkit.ac.uk/ [Accessed 17 April 2019]

The Toolkit covers the following subjects:

- Definitions
- General Considerations
- Assessment of Adverse Events concerning Seriousness, Causality and Expectedness
- Assessment of Adverse Events - Responsibilities
- Assessment of Adverse Events in Blinded Trials
- Adverse Events - Sponsor Responsibilities and reporting arrangements.
- Informing Investigators
- Reporting of Safety Issues Following Completion of the Clinical Trial in the
- European Community
- Clinical Trials in Third Countries
- Role of the DMC
- Patient Safety Incidents
- Notifying NHS Trusts – Investigator Responsibilities
- Reporting to the National Patient Safety Agency (NPSA) - Trust Responsibilities

6. Overall responsibility for this guidance

Guidance for reporting Adverse Events in Clinical Trials will be regularly reviewed by the Research and Development Manager in conjunction with other key stakeholders, including research personnel. It will be made available on the Intranet and on request from the Research & Development Department.

7. Other Associated Documents

The Medicines for Human Use (Clinical Trials) Regulations 2004 and The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006

The Medicines for Human Use (Clinical Trials) Regulations 2004. SI 2004/1031. [Online]. Available from: http://www.legislation.gov.uk/uksi/2004/1031/contents/made [Accessed 17 April 2019]

The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006. SI 2006/1928. [Online]. Available from: http://www.legislation.gov.uk/uksi/2006/1928/contents/made [Accessed 17 April 2019]

Also note:
The Medicines for Human Use (Clinical Trials) Amendment (No.2) Regulations 2006. SI 2006/2984. [Online]. Available from: http://www.legislation.gov.uk/uksi/2006/2984/contents/made [Accessed 17 April 2019]

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The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality (Amendment) Regulations 2008. SI 2008/941. [Online]. Available from: http://www.legislation.gov.uk/uksi/2008/941/contents/made [Accessed 17 April 2019]

The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019. SI 2019/744. [Online]. Available from: http://www.legislation.gov.uk/uksi/2019/744/contents/made [Accessed 17 April 2019]

The Medicines for Human Use (Clinical Trials) Regulations 2004 and subsequent amendment require the sponsor to ensure that the investigators responsible for the conduct of a trial are kept informed of any SUSARs that occur in relation to any Investigational Medicinal Product in that trial. If a significant new safety concern is identified, either upon receipt of an individual case report or upon review of aggregate data, then this should be done immediately.

In the case of blinded trials data, a decision could be made to present all SUSARs, regardless of the medication administered (including those allocated placebo or no active drug) in order to avoid the risk of inadvertently informing the investigators of the identity of a patient's treatment.

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Appendix 9: MKHFT Serious Incident Investigation process flowchart

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Appendix 10: NHS England January 2018 Never Event list

The following Never Event List is the list that all organisations providing NHS care should use and is applicable for all incidents that occur on or after 1 February 2018.

Wrong site surgery
Wrong implant/prosthesis
Retained foreign object post procedure
Mis-selection of a strong potassium containing solution
Wrong route administration of medication
Overdose of insulin due to abbreviations or incorrect device
Overdose of Methotrexate for non-cancer treatment
Mis-selection of high strength Midazolam during conscious sedation
Failure to install functional collapsible shower or curtain rails
Falls from poorly restricted windows
Chest or neck entrapment in bedrails
Transfusion or transplantation of ABO incompatible blood components or organs
Misplaced naso- or oro-gastric tubes
Scalding of patients
Unintentional connection of a patient requiring oxygen to an Air Flowmeter
Undetected oesophageal intubation (temporarily suspended as a Never Event)

Full guidance can be obtained from:

NHS Improvement (2018) *Never Events list 2018*. [Online]. London: NHS Improvement. Available from: https://improvement.nhs.uk/documents/2899/Never_Events_list_2018_FINAL_v6.pdf [Accessed 15 April 2019]

Note: Policies issued after the 1st April 2016 were led by NHS Improvement

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Appendix 11: MKHFT Duty of Candour guidelines

NHS Standard Contract – Service condition 35 (Duty of Candour for serious incidents – SI)

NHS England (2019) *NHS Standard Contract 2019/20 Service conditions (full length).* [Online]. v2 March 2019. Available from: https://www.england.nhs.uk/publication/nhs-standard-contract-2019-20-service-conditions-full-length/ [Accessed 17 April 2019]

If a reportable patient safety serious incident occurs or is suspected to have occurred staff must:

- Report the incident on the RADAR system.
- Instigate & conduct a full investigation in line with the Trust Incident Reporting policy (20-day internal deadline & 45 days submission deadline to the CCG)
- Notify the patient/next of kin that the incident has occurred & provide a **step-by-step explanation** of what happened in plain English & an **appropriate apology**. This must include a sincere expression of sorrow or regret for the harm caused. However this does not require fault to have been demonstrated & **expressing regret is not the same as admitting liability** & the risk of potential litigation should not prevent an apology. This can be verbally with the offer of subsequent written notification & must be within 10 working days after the incident occurred or came to light. Patients/next of kin should be offered the opportunity to be involved in the investigation.
- Document patient/next of kin communications in the medical/nursing notes including they decline any further involvement or updates.
- Offer the patient/next of kin a copy of the SI investigation report or appropriate feedback dependant on their involvement to date.
- Provide evidence that the patient/next of kin have been offered a copy of the SI investigation report when submitting the final SI report or appropriate rationale where not appropriate. This can be a duty of candour letter; outpatient follow up consultation notes etc.

Each failure to notify the patient/next of kin of a suspected or actual reportable patient incident will result in a financial penalty in the recovery of the cost of the episode of care or **£10,000** if the cost of the episode of care is unknown or indeterminate.

NHS Standard Contract – Service condition (Duty of Candour for patient safety incidents (non-SI) where there is moderate or significant harm

If a reportable patient safety incident occurs or is suspected to have occurred where there is moderate or significant harm (NPSA definitions) staff must:

- Report the incident on the RADAR system.
- Instigate & conduct a full investigation in line with the Trust Incident Reporting policy (14 days informal, 21 days for concise RCA or 30 days for comprehensive RCA)
- Notify the patient/next of kin that the incident has occurred & provide a **step-by-step explanation** of what happened in plain English & an appropriate apology. This must include a sincere expression of sorrow or regret for the harm caused. However this does not require fault to have been demonstrated & **expressing regret is not the same as admitting liability** & the risk of potential litigation should not prevent an apology. This can be verbally with the offer of subsequent written notification & must be within 10 working days after the incident occurred or came to light. Patients/next of kin should be offered the opportunity to be involved in the investigation.

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- Document patient/next of kin communications in the medical/nursing notes including they decline any further involvement or updates.
- Offer the patient/next of kin within 10 working days of the investigation being completed a copy of the investigation report or appropriate feedback.

Duty of candour **does not relate to low or no harm incidents** from a contractual perspective however, it is best practice to inform patients/next of kin if appropriate.

Note: Policies issued after the 1st April 2016 were led by NHS Improvement

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Appendix 12: Stop the Clock Guidance

It is acknowledged that whilst every effort should be made to ensure that all SI investigations are completed in a timely manner there are instances when this is impossible due to circumstances which are beyond the immediate control of the reporting organisation. This guidance sets out the options available to providers when there is a threat to the completion of SI timescales. The guidance builds on the information within Milton Keynes Clinical Commissioning Group's Serious Incident Policy and is intended to establish a working definition on the term 'Stop the Clock'.

If the reporting organisation faces unavoidable delays in its investigation of a SI then MKCCG should be notified of the reason for the delay, the anticipated delay period and a new reporting timescale will be negotiated on a case-by-case basis. Such delays may be caused by, but are not limited to:

- Awaiting outcomes of court proceedings.
- Awaiting Coroner Inquests.
- Awaiting forensic post-mortem findings.
- Awaiting Toxicology results.
- Awaiting completion of an external review.
- In direct response to a Police request under Memorandum of Understanding.
- Third Party investigations

It is the decision of the MKCCG whether or not a SI meets the criteria for a 'stop the clock'. Once a 'stop the clock' rule has been applied MKCCG will add an entry to the comments section in STEIS to explain the rationale for the delay. The reporting organisation must inform MKCCG of when they will be able to restart their investigation so that the RCA deadline can be recalculated. At the point when the clock restarts, the reporting organisation will have the remainder of the SI timeframe to complete the investigation e.g. if the clock is stopped on a SI at day 20, the reporting organisation will have 25 days left once the clock restarts; the CCG will confirm the new deadline.

When the 'stop the clock' is granted a review date will be set. The reporting organisation must provide the CCG with an update on or before this date regarding when the investigation can restart. If an update is not provided by this time the clock will restart. In this event the reporting organisation may re-apply for 'stop the clock' if required however those investigation days will have been lost.

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Appendix 13: CQC Regulation 20 Duty of Candour

Care Quality Commission (2015) *Regulation 20: Duty of candour: information for all providers: NHS bodies, adult social care, primary medical and dental care, and independent healthcare.* [Online]. Available from: https://www.cqc.org.uk/sites/default/files/20150327_duty_of_candour_guidance_final.pdf [Accessed 17 April 2019]

Care Quality Commission (2017) *Regulation 20: Duty of candour: Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20.* [Online]. Page last updated 08 June 2017. Available from: https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-20-duty-candour [Accessed 17 April 2019]

The intention of this regulation is to ensure that providers are open and transparent with people who use services and other 'relevant persons' (people acting lawfully on their behalf) in general in relation to care and treatment. It also sets out some specific requirements that providers must follow when things go wrong with care and treatment, including informing people about the incident, providing reasonable support, providing truthful information and an apology when things go wrong.

Trusts are required to evidence compliance with this standard as part of the regulatory control and to meet the requirements of the regulation, a provider has to:

Ensure that patients/relevant persons are made aware of any notifiable safety incidents through the following processes:

Must do first notification

- Inform the patient/relevant person as soon as is reasonably practicable (10 working days)
- Be given in person.
- Provide a true account of all the facts as known at that time.
- Advise what further enquiries are appropriate.
- Be recorded in writing.

Must do second notification

- Follow the first notification.
- Written notification to be provided that includes.
  - A true account of the facts
  - Details of enquiries as per CQC guidance
  - Results of further enquiries.
  - An apology

Notifiable safety incident means **unintended or unexpected** incident that occurred in respect of the service user during the provision of a **regulated activity** and that in the reasonable opinion of the health care professional could result in/appears to have resulted in:

- Death of service user where the death relates **directly to the incident** rather than course of illness or underlying condition or
- Severe harm, moderate harm, or psychological harm to the service user

An apology means "expression of sorrow or regret in respect of the notifiable safety incident".

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Relevant person means the service user or in certain circumstances a person acting lawfully on their behalf:

- Death of service user
- Service user is under 16 and not competent to make decision.
- Service user is 16 or over and lacks capacity in relation to the matter.

Moderate harm means harm that requires a moderate increase in treatment (unplanned return to surgery, unplanned re-admission, prolonged episode of care, extra time in hospital or as an outpatient, cancellation of treatment or transfer to another area e.g. DoCC

Severe harm means permanent lessening of bodily, sensory, motor, physiological or intellectual functions, including removal of wrong limb, or organ or brain damage that is related directly to the incident and not to the natural course of the service user's illness or underlying condition.

Psychological harm means psychological harm which the service user has experienced for a continuous period of at least 28 days.

Prolonged pain means pain which the service user has experienced or is likely to experience for a continuous period of at least 28 days.

Failure to comply is a criminal offence and failure to comply with CQC standard 20 will also result in action in line with their Judgement and Enforcement Policy

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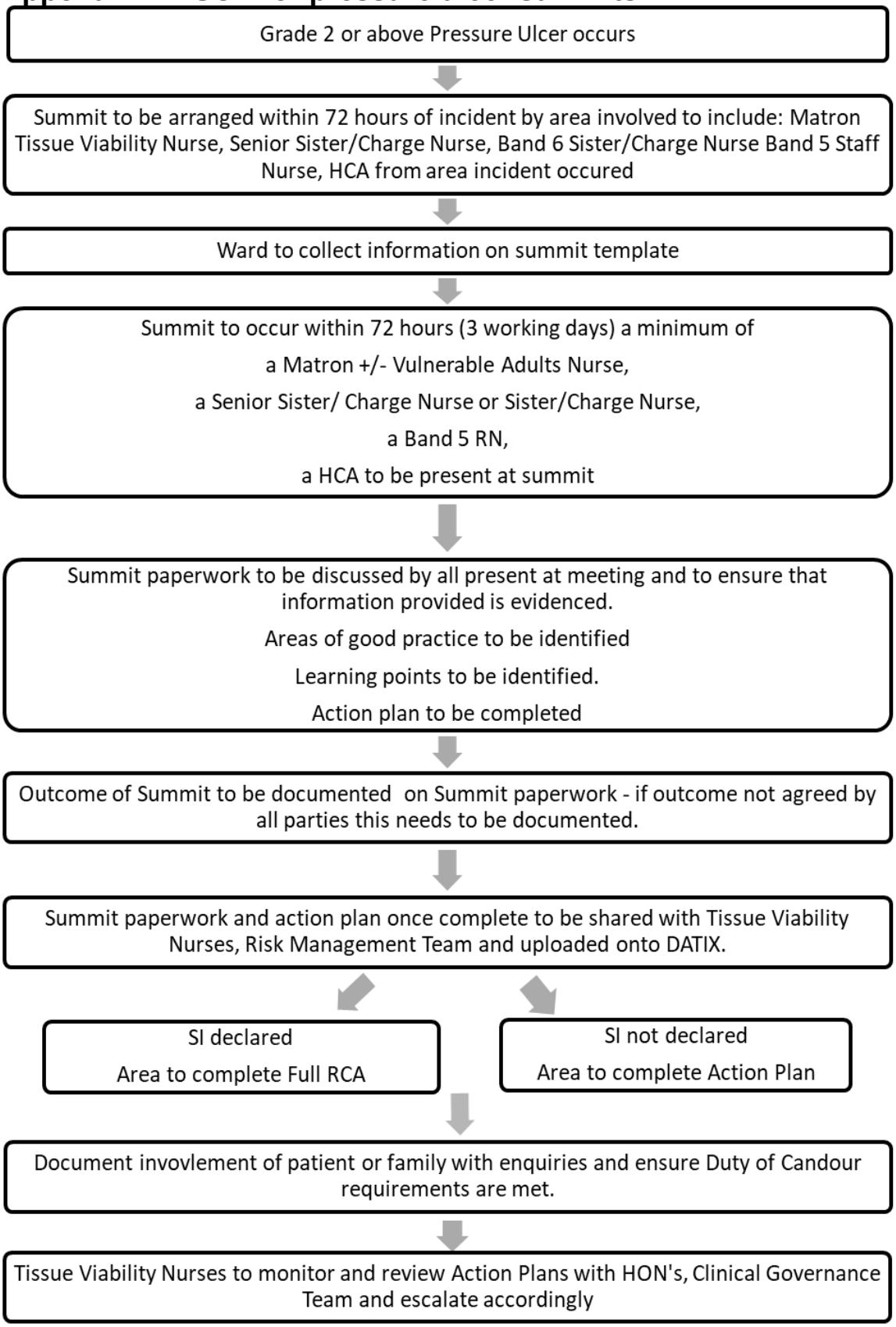
Appendix 14: SOP for pressure ulcer summits



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Appendix 15: Pressure ulcer summit template

PU Summit Template.docx

PU RCA Template .doc

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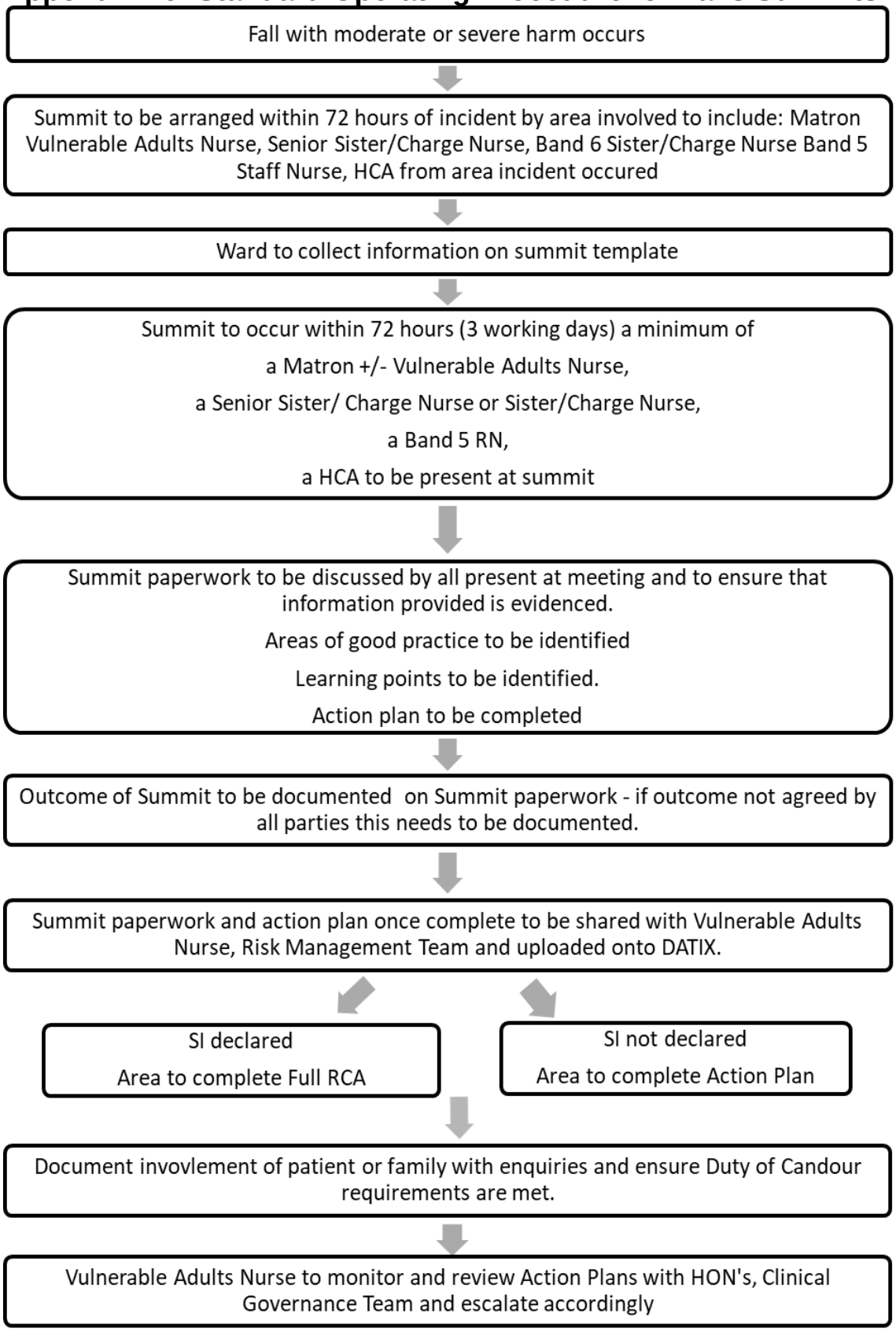
Appendix 16: Standard Operating Procedure for Falls Summits



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Appendix 20: Falls Summit template

Falls Summit Template.xlsx