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Table of Revisions

Date	Section	Revision	Author
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Jan 2010	All	Information Governance updates Committee structure updates, GOLD form information, reference to examples of Serious Incidents related to HCAI, contributory factors framework	S. Ross
Mar 2011	All	PCT harmonization	D Wells, A Yuill, S Golding, J Todd
Jan 2012	All	Review of Policy	D Wells
Feb 2012	All	Minor Changes	D Wells
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May 2013	All	Amendments to show clarity of the process and investigation links with complaints and claims	D Wells
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February 2014	All	Minor change Definitions for Grading Actual Impact of Incidents matrix and to NHS England Screening Programmes	D Wells
June 2015	All	Changes made to reflect the new national Serious Incident Framework and Never Event List 2015/16	D Wells
December 2015	All	Changes made to reflect the changes related to serious incident process and action plan monitoring	D Wells L Stainsby S Mole

Contents

1. Introduction

Risk is inherent in all that we do, good risk management and incident reporting is key to effective governance in the organisation.

Incident reporting is a fundamental tool of risk management, the aim of which is to collect information about adverse incidents, including near misses, ill health and hazards, which will help to facilitate wider organisational learning. If incidents are not properly managed, they may result in a loss of public confidence in the organisation and a loss of assets.

The incident reporting system is the route by which accidents and incidents are reported to the appropriate persons so that appropriate action can be taken to prevent recurrence of the accident/incident and that lessons can be learnt and shared to reduce future risk.

This policy outlines the process to be followed in relation to clinical and non-clinical incidents.

Risk Management is the term applied to a logical and systematic method of establishing the context, identifying, analysing, evaluation, treating, monitoring and communicating risks associated with any activity, function or process in a way that will enable organisations to minimise losses and maximise opportunities.

Risk Management is having in place a corporate and systematic process for evaluating and addressing the impact of risk in a cost effective way and having staff with the appropriate skills to identify and assess the potential for risk to arise.

There is a legal obligation for employers to make provisions for the reporting of accidents at work. There is also a requirement for the Trust to report Serious Incidents (SI's) to Commissioners and all clinical incidents to the National Reporting and Learning System (NRLS). The Trust uploads all clinical incidents to the NRLS system so national learning and sharing can take place. Standard Operating Procedures (SOPs) are in place. A Root Cause Analysis (RCA) will be carried out for all SIs and moderate/orange graded incidents.

As an organisation the Trust also has a legal duty to comply with the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) 1995. These regulations require the reporting of certain categories of injuries, diseases etc. to the Health & Safety Executive (HSE).

2. Aims

The aims of this policy are to:

- Define the general objectives for reporting incidents/near misses involving staff, patients and others including reporting to external agencies.
- To clarify roles and responsibilities.
- Describe the principles of incident reporting.
- To describe the principle of incident risk grading and investigation.
- To describe the mechanisms through which lessons are learnt from incidents
- To describe the duty of candour process

Compliance with the policy will make sure that any incident, near miss or SI is properly recorded and that appropriate action is taken to minimise the risk of a recurrence. With feedback to patient and next of kin illustrated to ensure transparency.

3. General Principles

These are:

- To contribute to the Trust's ability to deliver high quality harm free care to patients.
- To contribute to the health and safety of staff, patients, visitors and other persons.
- To safeguard the Trust's assets and estate.
- The Trust Board is committed to the promotion of a learning and just culture/fair blame in which staff feel able to report all incidents.
- The Trust believes that incident investigation and reporting should only trigger or contribute to any disciplinary procedure where there is a criminal act or where a member of staff has wilfully, and/or negligently, exceeded their professional boundaries.
- Investigations carried out under this policy are conducted for the purposes of learning to prevent recurrence not for inquiries into how a person died (where applicable) as this is a matter for Coroners. Neither are they conducted to hold any individual or organisation to account as other processes exist for that purpose including: criminal or civil proceedings, disciplinary procedures, employment law and systems of service and professional regulation, such as the Care Quality Commission and the Nursing and Midwifery Council, the Health and Care Professions Council, and the General Medical Council. In circumstances where the actions of other agencies are required then those agencies must be appropriately informed and relevant protocols, outside the scope of this policy must be followed.

In order to achieve this, an effective system of identifying, recording and managing risks is fundamental to the risk management process.

The Trust recognises the need for a simple, effective and efficient system of incident reporting not as a means of apportioning blame, but as a mechanism for identifying risks and learning from mistakes. The Trust supports and encourages a just blame culture in that incident reporting is outside the disciplinary procedures unless the incidents are malicious, criminal or repeated by the individual. This Trust has a Safeguard electronic system for reporting incidents.

The Trust recognises that an individual's career should not suffer as a result of that person reporting incidents or reporting breaches of this policy and associated policies and procedures. This principle is reinforced in the Raising Concerns (Whistleblowing) Policy which can be accessed on the Trust Intranet (Workforce).

Confidentiality will be maintained at all times and patient, staff and visitors details should be limited only to those who need to know.

There are 14 'Never Events' identified by the Department of Health (DoH) www.dh.gov.uk; (See Appendix 1). The new never event list was published March 2015. These are care issues that should never occur.

All areas within the organisation have reviewed their processes and controls to give assurance; mitigation is in place to prevent a 'Never Event' occurring within the organisation. If a 'Never Event' is reported the Executive Lead for Safety will be informed immediately and a Serious Incident (SI) review will commence.

4. Purpose of Incident Reporting

Incident Reporting achieves a number of objectives:

- To set out the arrangements for a systematic and practical approach to the reporting and management of all incidents, including Serious Incidents and Moderate harm Incidents where an RCA may have taken place.
- To record events that have caused injuries so that they can be investigated and fully documented to prevent recurrence and to ensure that Trust management are aware of the nature, extent, type and frequency of events taking place and lessons learnt shared with stakeholders.
- To record 'near-misses' so that steps can be taken to prevent recurrences that would eventually lead to an incident.
- To ensure that Trust management is aware of the hazards, actual and potential, inherent in its activities, so that they can be evaluated and suitable precautions can be taken or to be considered for inclusion on the risk register.
- To ensure that all staff that are involved in the investigation process are aware of the training required to undertake this role.
- To ensure that the regulatory authorities are notified of any incidents (e.g. Health & Safety Executive under RIDDOR and the NPSA).

Organisations have short memories and an effective incident reporting system can serve to act as a memory so that lessons are learnt from previous incidents.

5. Definitions

Serious Incident

An accident or incident involving any person on Trust premises who suffers injury or unexpected death, or the risk of such whilst on Trust premises, or where the actions of health service staff are likely to cause significant public concern or attract the attention of the media if appropriate actions had not been taken to prevent an untoward incident. In broad terms, a serious incident is an event 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 on-going health care.
A Never Event – all Never Events are defined as serious incidents although not all Never Events necessarily result in serious harm or death. (Never Events arise from failure of strong systemic protective barriers which can be defined as successful, reliable and comprehensive safeguards or remedies e.g. a uniquely designed connector to prevent administration of medicine via the incorrect route – for which the importance rational and good practice use should be known to, fully understood by, and robustly sustained throughout the system from suppliers, procurers, requisitions, training units and front line staff alike.
See Never Event Policy and Framework available online at:
http://www.england.nhs.uk/ourwork/patient safety/never-events/

Unexpected or avoidable death of one or more people. This includes suicides/self-inflicted death and homicide by a person in receipt of mental health care within the recent past.
Unexpected or avoidable injury to one or more people that has resulted in serious harm
Unexpected or avoidable injury to one or more people that requires further treatment by a healthcare professional in order to prevent:-
The death of the service user;
Or serious harm
A domestic homicide is a serious incident.

Actual or alleged abuse; sexual abuse, physical or psychological ill treatment, or acts of omission which constitute neglect, exploitation, financial or material abuse, discriminative and organisational abuse, self-neglect, domestic abuse, human trafficking and modern day slavery where:
Health care did not take appropriate actions/intervention to safeguard against such abuse occurring or where abuse occurred during the provision of NHS funded care.
An incident or serious of incidents that prevent, or threaten to prevent, an organisations ability to continue to deliver an acceptable quality of health care services.

Other Incidents

An accident or incident where any person suffers injury results in the person being off work, suffering from ill health or co-morbidities, unexpected death or is placed at unnecessary risk. Other incidents which should be reported for the purpose of this policy include near misses, property loss and damage to Trust property.

Near Misses

A situation in which an event or omission, or a sequence of events or omissions, fails to develop further, whether or not as a result of compensating action, thus preventing injury to a patient, visitor or member of staff.

Never Events

The DoH has identified 14 incidents that should never occur (See Appendix 1).

Hazard

A hazard is anything with the potential to cause harm, such as chemicals, electricity, working from ladders, an open drawer etc.

Risk

Risk is the chance, high or low, that somebody could be harmed by these and other hazards, together with an indication of how serious the harm could be. This also encompasses all risks which include finance and Organisational reputation.

Likelihood

The probability or chance of the event occurring.

Harm

An injury (physical or psychological), disease, suffering, disability or death. In most instances, harm can be considered to be *unexpected* if it is not related to the natural course of the patient's illness or underlying condition, or the natural course of events if harm occurs to persons other than a patient.

Grade

A position on a scale of intensity or amount or quality.

Investigation

The process of using inquiry and examination to gather facts and information in order to solve a problem or resolve an issue.

Risk reduction

Application of Risk Management principles to reduce the Likelihood or Consequences of an Event, or both.

Casual factors

The conditions and events that influence outcomes.

6. Roles and Responsibility (Duties)

The requirement to report all incidents applies to every member of staff (clinical and non clinical) irrespective of grade or place of work. However, additional responsibilities and accountabilities of staff under the policy are related to their managerial position within the Trust.

Chief Executive

The Chief Executive is accountable and responsible to the Board for ensuring that within the constraints of the budget setting process, resources, policies and procedures are in place to ensure the effective reporting, recording, investigation and treatment of incidents. In practice the Chief Executive may delegate the day-to-day responsibility for this duty to Heads of Department and Care Group Leads.

Nominated Director(s)

The Trust will ensure that an Executive Director(s) is accountable and responsible for:

- Ensuring risk management systems and process are developed and utilised within the Trust.
- Ensuring systems are in place to enable effective utilisation of the NHSLA Risk Management Standards.
- Ensuring that all associated reports relating to SI's are reported to our Commissioners following agreed processes.
- Ensuring that a system is in place to ensure effective day to day management of risk within the Trust.
- Ensuring systems are in place to ensure timely reporting under RIDDOR.

Care Group Leads and Senior Managers

Are responsible and accountable for:

- Ensuring there is a process in place for reporting incidents.
- Ensuring that the induction process for new staff to the Care Group/Department includes training in incident reporting and grading.
- Ensuring that all incidents are graded, investigated and actions taken, to the level commensurate with the incident risk grading and that the investigation is documented.
- Ensuring that where action to prevent a recurrence is required, the relevant action is taken. This may include maintenance/engineering modifications, training issues, modification or development of local policy and procedure, referral of staff to occupational health, review of risk assessments, removing equipment from service, ensuring statements are completed.
- Ensuring that day to day systems are in place to ensure that staff are supported as necessary following an incident with immediate and on-going actions identified.

- Ensuring that the results of incident investigation, modification to local policy and procedure are brought to the attention of their staff and any information, instruction or training required is given.
- Ensuring that incidents which may have an impact across the Trust are brought to the attention of other Care Groups and Senior Managers via Safety Committee or Safety Forum.
- Ensuring that risk assessments and the departmental Local Health & Safety Policy are reviewed as necessary. Liaising with the Risk Manager and Health & Safety Managers for notification of problems and obtaining specialist advice when necessary.

Executive Director of Nursing

The Executive Director of Nursing is the lead for safety.

Medical Director

The Medical Director is accountable and responsible to the Trust Board regarding medical staff and will take the lead when the memorandum of understanding is required.

Consultants

The consultant is responsible for:

- The continuing clinical care of the patient.
- Informing the Clinical Director and the Medical Director of the incident.
- Providing general advice on the clinical implications of the incident to the Medical Director.
- Ultimately it is the responsibility of the Consultant to ensure that the patient and/or relatives have been informed of the incident and to discuss any further treatments required as a result of the incident and ensure that the Being Open policy is being followed. If appropriate, the advice of the Medical Director should be sought.
- Providing advice for press statements.
- Ensuring the coroner has been informed if appropriate.
- Ensuring any risks/incidents have been reported to the appropriate Trust systems.

Risk Managers/Patient Safety Managers

The Risk Managers/Patient Safety Managers (Clinical and Non-Clinical) are responsible and accountable for:

- Ensuring the effective application of the incident management policy and associated policies and procedures.
- Ensuring where necessary that statutory bodies have been notified within the appropriate timescales.
- Analysing incidents and producing relevant reports to ensure appropriate action is taken to reduce the risk.
- Provide evidence of incident report forms, Root Cause Analysis and SIs to the Legal Services Manager and Patient Experience Manager when requested on receipt of a claim or complaint/PALs enquiry.
- Notify complaints and claims manager of any potential claims and complaints arising from incident reports.
- Identification of corporate training needs, developing training criteria and training programmes and delivery of training programmes as appropriate.
- Non-Clinical Risk Management will notify the HSE, of any RIDDOR reportable incidents.

- Non-Clinical Risk Management and Patient Safety Managers will re-grade incidents after investigation as necessary.
- Ensure where appropriate occupational health are notified of occupational incidents or health related incidents or industrial disease.
- Notify Human Resources Governance & Quality of any incidents related to doctors in training to ensure additional support and inclusion in training revalidation documentation.

Patient Experience

- The Patient Experience Team is responsible for ensuring that all complaints and PALs issues are investigated thoroughly, appropriately and promptly, in line with relevant Trust Policies.

Legal Services

- Legal Services are responsible for ensuring that all claims are investigated thoroughly, appropriately and promptly, in line with relevant Trust Policies.
- Legal Services are responsible for providing documents following unexpected deaths for Coroners' inquests.

Line Manager

Line Managers are responsible and accountable for:

- Ensuring staff report all accidents and incidents using the Trust's web based incident reporting systems following the Safeguard Reporting Incident Policy.
- Ensuring availability of incident reporting forms for all staff in their area in the event of the electronic system being unavailable. These forms are to be faxed to Patient Safety to enable timely reporting to take place.
- Ensuring that the local induction process for new staff to the Care Group/Department includes information on incident reporting, grading and management appropriate to their job description.
- Ensuring that all incidents are graded, investigated and actions taken, to the level commensurate with the incident risk grading and that the investigation is documented.
- Ensuring that where action to prevent a recurrence is required, the relevant action is taken. This may include maintenance/engineering modifications, training issues, modification or development of local policy and procedure, referral of staff to occupational health, review of risk assessments, removing equipment from service, ensuring statements are completed, etc.
- Ensuring that the results of incident investigation, modification to local policy and procedure are brought to the attention of their staff and any information, instruction or training required is given.
- Access root cause analysis training to ensure effective incident management takes place.
- Ensure that provision of immediate and on-going support following an incident is given to any member of staff following the Supporting Staff Policy.
- Ensuring that incidents which may have an impact across the Trust are brought to the attention of other Care Groups and Senior Managers via the safety committee.
- Ensure that they follow the "Being Open" Policy as appropriate.
- Ensure all controls to prevent 'Never Events' are monitored e.g. WHO Checklist compliance audits/monitoring etc.

Supervisors of Midwives

Supervisors must undertake investigation in accordance with Local Supervising Authority (LSA) guidance and use their decision making tools to identify appropriate investigation

National screening programmes – all harm incidents will have a RCA, example shown below with specific screening leads linking with regional leads and Public Health England. Management of these incidents must follow the Managing Safety Incidents in National Screening Programmes. The Screening Quality Assurance Service is also responsible for surveillance and trend analysis of all screening incidents. It will ensure that the lessons identified from incidents are collated nationally and disseminated. Where appropriate these will be used to inform changes to national screening programme policy and education/training strategies for screening staff.

Hospital Based Programme Coordinator for Cervical Screening (HBPC)

Any potential programme failure within the cervical Screening Programme at the Trust should be brought to the attention of HBPC immediately. This may involve Cytology, Histology, GUM and Gynaecology/Colposcopy at any site across the Trust.

They are responsible and accountable for:

- Ensuring that the implications of any such incident are brought to the attention Chief Executive Officer/Medical Director.
- Ensuring that key personnel across the Trust in other directorates are informed of the incident.
- Ensuring that the Quality Assurance Reference Centre (QARC) and the NHSCSP are made aware of the incident and kept up to date as any evidence becomes available.
- Ensuring that the local Director of Public Health is made aware of an impending problem with the Screening Programme and what the implications may be.
- Ensuring that they are an integral part of the incident team convened to deal with such an incident.

All other Staff

There is a requirement for employees to bring to the notice of their employers any workplace health and safety risks or clinical risks/incidents or near misses. There is also a requirement for employees to co-operate with their employer to enable their employer to comply with their statutory duties.

Any member of staff who has detailed knowledge of a particular incident or event must complete an incident report form including the grading section and report on Safeguard Risk Management system.

Any member of staff involved in an incident and requiring support must identify their needs to their Line Managers.

Any employee who witnesses an incident must take all relevant steps to ensure that the incident is reported and the process must ensure relevant stakeholders/external agencies are informed as appropriate to the incident type. List of Stakeholders (Appendix 2)

Others (visitors, contractors, PFI)

Any incident involving non Trust employees should be reported as per Trust policy to ensure that an accurate record of the incident is maintained and that the Trust can take remedial action where required. Therefore, a Trust employee should report the incident.

Trust Board

The Trust Board, collectively, is responsible to ensure systems are in place for reporting, recording, investigation and treating of all incidents identified via the Incident Report to Quality & Healthcare Governance Committee.

Quality & Healthcare Governance Committee

The Quality & Healthcare Governance Committee will receive the minutes from the Safety Committee on a monthly basis as the Safety Report contains all incidents and actions after analysis on a monthly basis.

The Patient Safety Lead, Patient Experience Lead, Legal Services Manager are jointly responsible for providing information for the CLIPS report which will be reviewed by the Quality and Healthcare Governance Committee. This provides a co-ordinated approach to the aggregation of incidents, complaints and claims on a quarterly basis. The content of the CLIPS report provides qualitative and quantitative analysis of incidents, complaints and claims. The aim is to highlight any themes or concerns so the Care Groups/Board can put in place actions to mitigate or prevent similar issues reoccurring.

Safety Committee

The Safety Committee forms part of the risk management accountability arrangements of the organisation to ensure the appropriate management of all clinical and non clinical risks.

The Committee leads the continuous development of improved patient safety through monitoring of all elements of patient safety and proactive risk management, identifying lessons and embedding solutions across the organisation.

A report highlighting all incidents will be discussed at the Safety Committee on a monthly basis.

Safety Forum

Since October 2014 a safety forum is in place to discuss serious/moderate harm incidents to give assurance that their management is appropriate and aid discussion on learning and actions are being completed as stated in RCA action plans. Monitoring of duty of candour and identifying any incident where feedback is delayed or issues identified takes place at this meeting.

Risk Management Committee

The Risk Management Committee has responsibility to review the Trust's Care Groups/Departments risk registers and to manage the Trust's Corporate Risk Register. The Group will meet bi monthly and review the Care Groups/Departments risk registers, detailing current risk status and actions taken.

The Risk Management Committee will analyse and re-grade risks if appropriate, on the basis of the whole Trust priorities. Items that remain extreme after this regarding exercise will be entered on to the Trust Corporate Risk Register. The Risk Register Group will feed back non-compliance where registers have not been received and on any alterations to scores to the Care Groups/Departments (refer to Risk Register Procedure).

The Trust Secretary will take updates of the Corporate Risk Register and minutes to the Executive Directors' Group on a two monthly basis the Risk Management Committee.

The Trust Board will receive the Corporate Risk Register in a seminar every 6 months.

7. Process

Web based Reporting – Safeguard System

Reporting can be accessed by staff opening the intranet on a Trust computer. On the home page is a link direct to incident reporting. The form is then displayed for employees to complete on line; this is then received within risk management and then placed on the risk management incident reporting system (see Safeguard Policy on intranet). If required there is an e-learning training guide on how to complete an incident.

Anonymous reporting is possible as the organisation needs to be aware of all incidents that occur in the organisation.

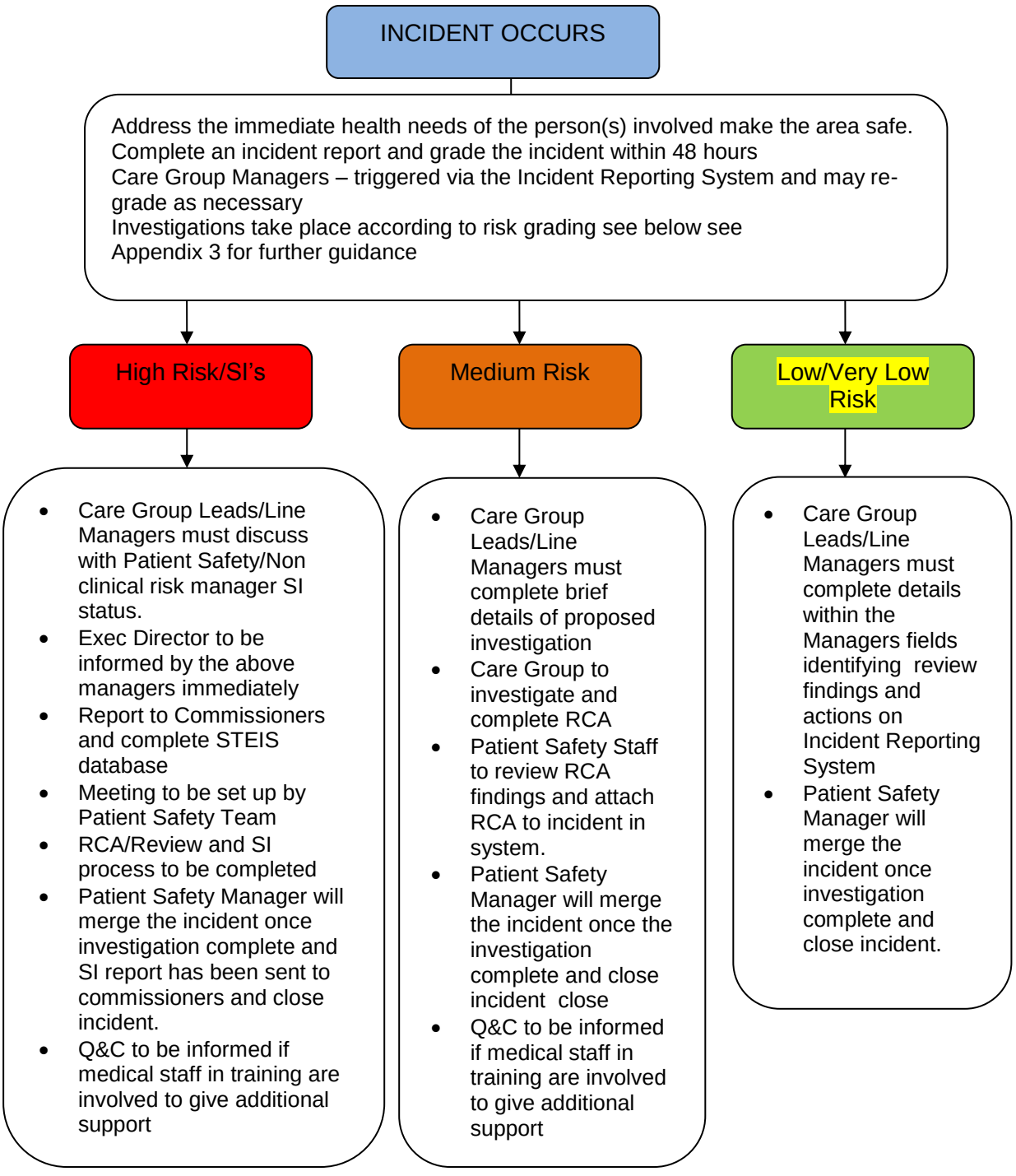
The system triggers the appropriate line managers to commence investigation of any incidents reported. A number of Safeguard triggers have been created to inform specific people when different types of incidents are reported examples below:

Blood Transfusion Incidents – Blood Transfusion Team
Medical Devices/Equipment incidents – Clinical Engineering
Medication Dispensing Incidents – Pharmacy
Needle stick/sharps injuries – Occupational Health/Non Clinical Risk Management
Possible SI's and Moderate/Orange Incident – Patient Safety Lead
RIDDORs – Non-Clinical Risk Management
Pressure sores occurring within the hospital – Tissue Viability Team
Information Governance incidents – The Information Governance Manager
Radiation Incidents – The Radiation Protection Advisor, etc.

Managers investigate the incident and actions are identified to mitigate further similar incidents which should take place within seven days of incident being placed on the system. These are then reviewed by the relevant Patient Safety/Health & Safety Managers. A report is produced for Care Group/Specialties on a monthly basis and monthly report to Safety Committee on all incidents reported with investigation findings.

A tool kit for staff is available on the intranet with different templates related to specific types of incidents, e.g. information governance, pressures sores, falls and SI's. This can be accessed via Trust intranet on Patient Safety website.

Process for the Reporting all incidents/near misses involving staff, patients and others.



Incident Risk Grading

Incidents need to be prioritised so that the appropriate action can be taken and so that some continuity in investigating is ensured. Incidents are risk graded according to the process outlined below by the staff completing the form.

For any incident the actual outcome of the incident should be determined using Table 1.

Table 1

1. An actual outcome of the incidents, complaints and claims (e.g. near miss = 'insignificant')

None	Minor	Moderate	Major	Death

A near miss on the Safeguard system is graded 'no harm'.

A second process linked to grading takes into account the current controls in place and is undertaken using table 2. This shows the severity and likelihood of reoccurrence.

Table 2 Risk scoring = consequence x likelihood (C x L)

	Likelihood				
Likelihood score	**1**	**2**	**3**	**4**	**5**
	Rare	**Unlikely**	**Possible**	**Likely**	**Almost certain**
5 Catastrophic	5	10	15	20	25
4 Major	4	8	12	16	20
3 Moderate	3	6	9	12	15
2 Minor	2	4	6	8	10
1 Negligible	1	2	3	4	5

For grading risk, the scores obtained from the risk matrix are assigned grades as follows

1 - 3	Low risk
4 - 6	Moderate risk
8 - 12	High risk
15 - 25	Extreme risk

Investigation of the incident

The degree of investigation/action required for a particular incident, complaint is dependent upon its grading. See Appendix 4 that illustrates the classification and investigation for complaints. Green/Yellow as minor harm only requires completion of Managers fields on the Safeguard incident management system to indicate review and findings, with actions to prevent in future. All orange and above incidents must be considered for a Root Cause Analysis. Themes of low grade incidents may also require further in-depth analysis to put in place further controls to mitigate the incident occurring again. Medication errors have a specific framework to give consistency across the organisation related to level of investigation (Appendix 5). Discussion at Safety Committee will take place on themes from low grade incidents and actions required by the Care Groups often following aggregation of CLIPS or Safety Committee data. Examples of incidents that require reporting are in Appendix 6. Special arrangements are in place for radiation incidents in order to ensure appropriate notification to an enforcing authority in keeping with current best practice.

Serious Incidents (Black/Red)

Not all deaths reported are patient safety incidents and therefore are not a reportable incident to the NRLS following investigation but will be on the Safeguard risk management system.

All red incidents are reported as Serious Incidents (SI's) to the Commissioners. Other graded incidents from green to red could be a SI and require reporting discussion with safety leads and line managers must take place to agree investigation process (Appendix 7). All incidents must be considered on a case-by-case basis. Inevitably there will be borderline cases that rely on the judgement of the people involved the rationale for stating it is an SI or not must be documented in the patient's notes.

Staff members who identify a potential SI must notify their line manager/or duty manager immediately whatever time of day they occur. All other incidents must be reported within 48 hours. This is to ensure that reports to external agencies can be made within the appropriate timescales.

If an incident is related to Information Governance ensure the Information Governance Procedure is adhered to as personal information and data loss can lead to identity fraud and significantly impact on individuals and should be considered as serious.

72 Hour Report

For all incidents identified as moderate harm and above a 72 hour report should be considered as this will aid decision making and if the incident is to be reported externally to the organisation. The template is available on the patient safety web site all staff should populate the report and sent it to the patient safety team for attachment to the incident with clear rational if incident considered a serious incident, downgrading has occurred and not considered a moderate harm incident when all information obtained, or if an RCA needs to take place as a moderate harm is considered to have taken place.

All SI's a 72 hour report must be completed this is considered a process that will enable staff to make a decision 'is this a serious incident or not?' with a clear rationale why based on facts identified.

An RCA can take place on any graded incident if staff consider there is beneficial learning possible, related to one incident or a cluster in the organisation.

Moderate Incidents (Orange)

The Care Group will nominate a lead to investigate moderate incidents with support from Non Clinical Risk Management and Patient Safety team as appropriate. Findings and recommendations will be reviewed at the Safety Committee. A Root Cause Analysis will be considered for all Orange or above incidents.

Low/Very Low Incidents or Near Misses (Yellow/Green)

Heads of Department will be responsible for taking appropriate action in these cases. In the majority of these incidents, action plans are not required as remedial action will have been taken and evidence will be in the 'additional information aspect' of the Incident Management System. Trends arising from these incidents will be discussed at the Safety Committee and Health and Safety Committee for non-clinical incidents. Care Groups will review these incidents in the appropriate Care Group clinical governance forum. Most radiation incidents will fall into this category although they are "specific" incidents and all must be reported to the Radiation Protection Advisor, who will advise as necessary (See Appendix 8 for full details relating to radiation incidents).

Never Event near miss incidents must have an RCA to identify any weaknesses within a system.

Within the national Serious Incident Framework a near miss could be considered an SI if the likelihood of the incident occurring again if current systems/process remains unchanged and the potential for harm to staff, patients, and the organisation should the incident occur again. This does not mean that every 'near miss' should be reported as an serious incident but, where there is a significant existing risk or system failure and serious harm, could occur the serious incident process i.e. RCA should take place to understand and mitigate the risk.
All prisoner deaths in our care should have an RCA and will be reported by the prison service often these are no harm (ill health issues).

Any patient in our care who is being detained under the Mental Health Act (1983) must be reported to the CQC without delay. However providers are also responsible for ensuring that there is an appropriate investigation into the death of a patient detained under the Mental Health Act (1982 (or where the Mental Capacity Act (2005 applies) often the Mental Health Trust will lead this investigation but we as a provider will interface with the investigation and share information.

Investigation - The Process

Following an incident there are many issues to consider.

- Coping with the immediate problems
- Investigation of the incident – consider utilisation of the patient safety incident decision tree (Appendix 9)
- Communication with appropriate stakeholders
- Reporting information and action taken
- Monitoring of action plans
- Support for staff involved
- Supporting and being transparent with patient or next of kin

The purpose of an investigation is following an incident is to determine:

- What happened?
- How did it happen?
- Why did it happen?
- Who was involved?
- Where did it happen?
- What are the factors that contributed to the incident?

Timescales for completion of investigations:

- All SI's should be reported within 48 hours on STEIS from being identified as a serious incident.
- All SI's should be completed within 60 days and reports with our commissioners unless there is a rationale why this cannot occur, for example awaiting pathology or post-mortem following a child death any anticipated delays must be discussed with our commissioners and these must be very exceptional cases.
- All incidents must be reported to improve the quality of care and service delivery in the organisation.
- All incidents reported on the Safeguard system must be reviewed within 7 days by the manager, and the majority of incidents closed as soon as possible following the appropriate investigation, which must be documented with key learning and changes to mitigate and prevent the incident reoccurring documented in the Safeguard system.

The list of contributory factors may be substantial and root causes or fundamental issues to prevent incidents reoccurring must make up the actions in the action plans. Action Plans must be realistic and achievable and will be monitored by the Safety Committee and Quality & Healthcare Governance Committee.

Patient Experience and Legal Services policies outline the investigation process they undertake. All incidents are investigated according to their grade, all moderate harm and above incidents must be considered for a root cause analysis investigation.

All claims will be investigated by the Legal Services Department in accordance with the guidance issued by the NHS Litigation Authority and the Pre-Action protocol for the Resolution of Clinical Disputes. If a claim highlights a serious clinical risk issue the Head of Clinical Risk is informed so she can assist in deciding whether a Root Cause Analysis should take place.

Patient Experience will investigate all complaints and PALs issues according to the complexity of the complaint/PALs. This grading classification will be used to determine the level of the investigation. (Appendix 4)

Links between the management of investigation of incidents, complaints and claims takes place at the CLIPs meetings and quarterly reports are provided to the Trust Board to give assurance that all lessons are identified following investigation.

Coping with the immediate problem

The person who witnesses, discovers or is involved in the incident is responsible for ensuring the safety of patients, relatives and other members of staff. This may involve seeking advice from other specialist staff, e.g. the Health and Safety Manager, Fire Officer.

Although serious incidents can be distressing for members of staff involved it is important that they are reported. Staff should be aware that all incidents will be investigated in a fair way. Where there has been no intention to cause harm to the patient this will be taken into account during the investigation process.

Use of the Incident Decision Tree Tool gives consistency to the investigation to aid identification of deliberate harm (Appendix 9).

Further information is also available from the “Supporting Staff Policy” to ensure our staff are signposted to appropriate support for the individual.

A statement may be requested by investigating lead. Instructions on how to write a statement are in Appendix 10.

Communication with appropriate stakeholders and external agencies

The Trust is committed to learning from incidents and accidents. For this the ‘Trust ‘Being Open’ policy will be followed. The responsibilities for informing patients and where appropriate their relatives are as outlined in the above policy. The Duty of Candour legislation must be followed all patients must have an verbal apology as soon as incident identified and a letter of apology for all moderate harm and above incidents with patient and families asked if they have any questions to be answered during the investigation process. An individual must be identified to link with the patient or family during the investigation process (RCA) to ensure support is available.

It is important that the patient (and relatives, where appropriate) should be kept informed of the progress of the investigation as well as the incident itself. Depending on the specific

incident stakeholders/external agencies as appropriate will be informed, and invited to the RCA, a copy of the root cause analysis with action plan shared with them (reference Appendix 2).

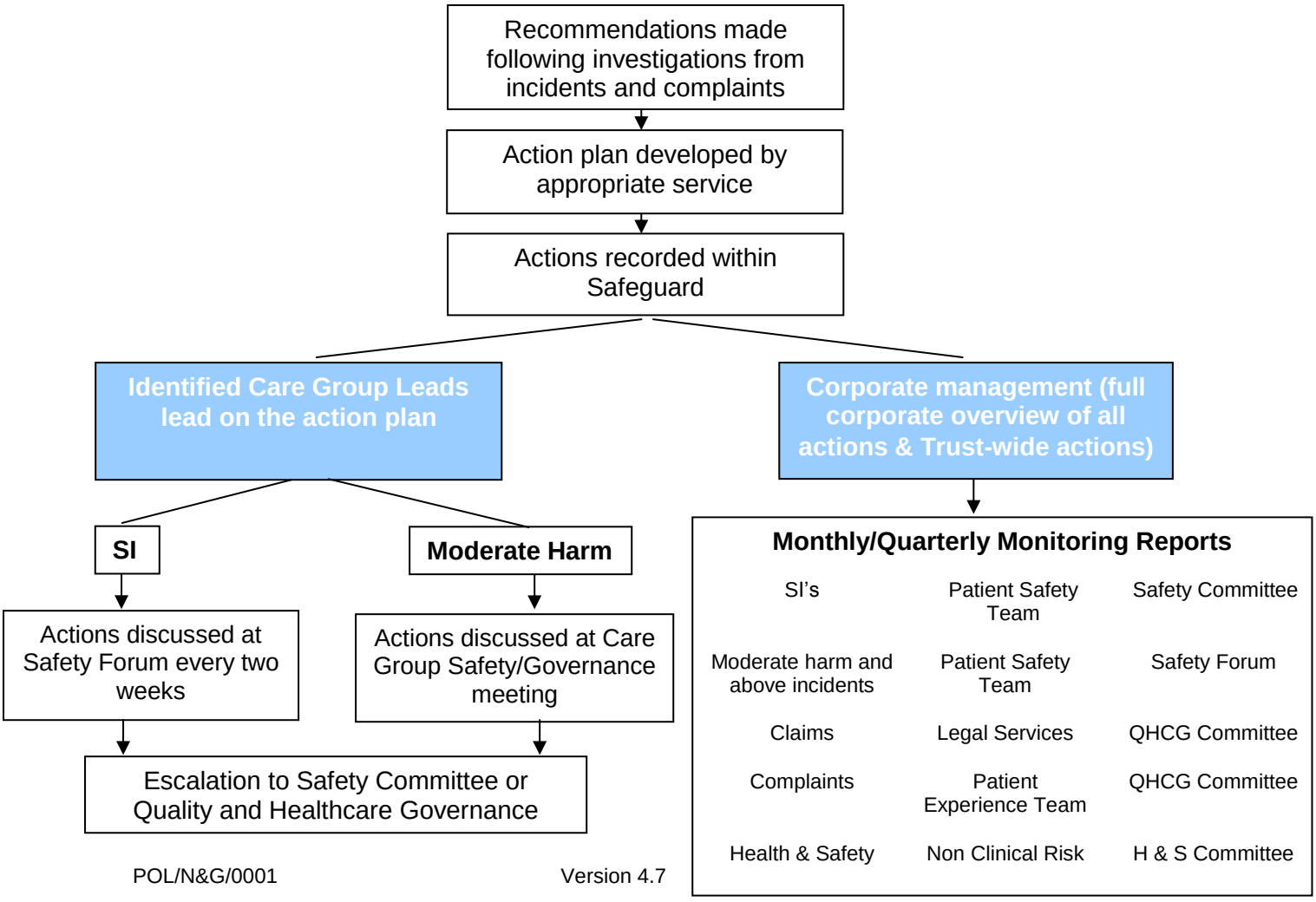
Lessons Learnt from incidents

All incidents will be discussed at the appropriate governance meetings or Health and Safety Meetings. Members of each meeting will be provided with a summary of all incidents reported appropriate to specific Care Groups. The Patient Safety Team prepare the monthly incident report for Safety Committee where action plans are identified and agreed to identify controls to prevent further incidents. Action Plans must be completed within timeframe stated; monitoring will take place within the Care Groups and within Governance Department to ensure embedding and completion is undertaken.

Where appropriate a review of the Trust's handling of the incident will be initiated by the Chief Executive or the appropriate Director to ensure the continued efficiency of the process.

Monitoring Action Plans

Action plans will be agreed by the Care Group and an individual within the Care Group will be identified to ensure the actions are completed within the agreed timeframe following individual incidents examples from root cause analysis investigations for moderate harm and above. The Action Plan must be SMART (Specific, Measurable, Attainable, Relevant and Timely). Governance will seek assurance that the actions have been completed at the fortnightly Safety Forum and monitoring of action plans will take place at the monthly Care Group meetings and at the Trust wide Safety Committee and at Quality and Healthcare Governance committee on a quarterly basis via Care Group Integrated Governance Report.



Support for the staff Involved

The Trust recognises that being involved in a serious incident can be traumatic for members of staff. The Trust will support staff that might be traumatised by the effects of involvement in an adverse incident. Any staff requiring support/counselling should make an approach to their Line Manager and be aware that the Trust can also offer an Occupational Health Service that can facilitate counselling services, support leaflets are available and can be accessed via the Trust intranet.

Further information on roles and responsibilities and types of support available can be found in guidelines for supporting staff involved in potentially traumatic or stressful work related incidents. Supporting Staff Involved in Potentially Traumatic or Stressful Work Related Incident Policy can be found the Trust Intranet.

Support for medical staff in training will be provided by their educational/training supervisors once individual are identified and information given to Quality and Governance Department in Human Resources. This will aid documentation completion for the Deanery and aid revalidation for medical staff.

Consultants involved in incidents will be identified and the Medical Director informed to ensure support is given. This also aids documentation being available for revalidation.

External Investigation

The Trust, Police and Health & Safety Executives (HSE) have a responsibility to investigate incidents, which fall into the categories to discharge their specific duties.

Serious patient incidents, defined as an unexpected death or incidents involving serious untoward harm to patients should be assessed as it may be required that they are investigated by the Police or HSE.

Patient safety incidents displaying one or more of the following characteristics may require the police to investigate:

- Evidence of or suspicion that the actions leading to harm were intended.
- Evidence of or suspicion that adverse consequences were intended.
- Evidence of or suspicion of gross negligence and/or recklessness as a result of failure to follow safe practice, procedure or agreed protocol.

Following the DOH Memorandum of Understanding document, liaison with the police and other external agencies, will be clearly defined at the onset of any investigation.

Patient incidents required to be reported to the HSE are contained in the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR).

The decision to report an incident to the Police or HSE should be made by the Chief Executive or an Executive Director.

Once the Police or HSE have been notified they may request the Trust to establish an Incident Co-ordination Group to be set up to enable the investigation to take place.

In certain circumstances the Police and HSE jointly may investigate the incident, the responsibility of who takes the lead will depend on the nature of the incident.

How the organisation reports incidents to external agencies can be found in Appendix 11.

Record Keeping

The member of staff who witnesses, discovers or is involved in the incident must:

- Complete an incident form.
- Record a factual summary of the incident in the appropriate health record including the remedial actions taken, personnel informed etc. All entries should be factual with no expression of opinion
- Complete supplementary statements relating to their part in the incident if necessary. The Care Group leads or Head of Department will provide support in writing statements as will the legal services manager or risk managers. All statements must be legible and signed with the date and time of completion.
- Mark "RETAIN" on all supporting documentation related to the incident which must be retained in the medical record e.g. fluid balance charts, observation charts, turning charts etc.
- Mark any medical device relevant to the incident and remove from circulation. The serial number of the device should be quoted on statements where appropriate.
- Maternity CTG documents must be identified if they require copying.

All entries in the health record should be in keeping with the Trust policy on Record Keeping and Medical Records requirements. In particular records should be written in black ink, with the time, date and signature of the author clearly visible. Where health records are required for on-going treatment they should be copied and the copies retained in the serious incident file. All hard copy notes must be sent for electronic processing so our ECDM processes are followed, notes must not be kept on wards due to an incident occurring, they must be available on the electronic system as soon as possible.

The Care Group Leads and the Clinical Director are responsible for ensuring that all information released to the public or staff is clearly documented and recorded as part of the incident investigation.

Informing patients, relatives and staff

In cases where patients have been seriously harmed as a result of a patient safety incident, please refer to the Trust 'Being Open' Policy and ensure the key elements of the Duty of Candour process is followed, a verbal apology given, letter written apologising for the incident occurring and full documentation in the patients notes, with clear identification of the individual identified as the link with the patient or family.

Staff, patients and/or their relatives must, whenever possible, be informed ***before*** the media becomes involved. This may not be possible where an affected patient, or their relatives, choose to communicate with the media, but it is important that the Trust does not aggravate the situation by communicating with the media before attending to the affected patients, or their relatives. All available methods of communication should be considered. Failure to manage communication well with those affected may lead to successful claims for post-traumatic stress by patients and relatives.

It is essential that as soon as a serious incident is identified, or there is the possibility of multiple enquiries, an appropriate person is charged with informing patients, or their relatives. Who that appropriate person should be will be dependent upon the type of incident. For example, it may be the Care Group Lead in which the incident arose, or the Consultant in charge of the patient's care. The important issue is that this person is identified without delay.

Apologies

Good practice indicates it is natural and desirable for those involved in treatment which produces an adverse outcome, for whatever reason, staff should sympathise with the patient or the patient's relatives and to express sorrow or regret at that outcome. Such expressions of regret would not normally constitute an admission of liability, either in part of full, and it is not the policy of the NHSLA to prohibit them, nor to dispute any payment, under any scheme, solely on the grounds of such an expression of regret. Therefore an apology should be made, and reinforce the Trust 'Being Open' procedures.

Press / Media Enquiries

All media enquiries will be handled from the Chief Executive's office.

Press statements will be coordinated, when appropriate, with the Associate Director of Marketing & Communications. In the event of a serious criminal incident where the police are informed, any press statement will be prepared with the police press officer. Any statement relating to a prisoner will be handled by the Prison Authority.

The media will not be given any information with regard to personal injury or information until the patient; their relatives or staff injured have been informed. No information will be given without prior agreement of the individuals involved. There will be due regard for patient confidentiality when drafting press statements. Including cases where there is potential for a claim to be brought against the Trust, the NHS Litigation Authority will need to be involved in the preparation of any press statements.

Information given to the media will concentrate on the fact of the incident and where possible its potential consequences, but personal speculation about the cause of the incident will be avoided.

In the event of large numbers of patients being involved, a help line may be required.

Help lines for Multiple Enquiries

In some incidents, such as problems with screening results, it can be anticipated that there will be multiple enquiries from the public or other stakeholders.

In the event that a large number of patients or relatives are likely to make telephone enquiries the Trust will consider establishing a "help line". The Chief Executive or nominated executive director will authorise the establishment of a help line under the leadership of a nominated coordinator. The relevant senior managers and clinicians will agree the information to be given and the number of staff required. Usually senior nursing staff will be required to staff the phone lines, although this may need to be revised according to the nature of the incident. All staff answering calls to the helpline will receive a full briefing on the incident, Trust response and information required to be documented prior to taking any calls. Consideration will be given to use of an external body that have expertise in this area. In some cases elements of the major incident policy may be implemented.

A press release stating the help line number will be drafted and issued via the Communications Department. Help lines will be set up on appropriate Trust sites. A written record of the calls received will be made including a summary of the advice given.

If it is necessary to contact a large number of patients by post, a team led by the coordinating Executive Director must agree:

- The content of the letter to be sent
- To whom the letter should be sent
- Who should sign the letter
- The timing of the letter, including who will liaise with the post room about the volume and timing of the mail
- The timing of any media release
- The timing of the opening of a telephone “hot line”

The coordinator will review the number of calls made to the help line and based on the information the Chief Executive and appropriate directors will declare “stand down” at an appropriate time. Before stand down is declared arrangements will be made for the receipt of any further calls relating to the incident and switchboard will be informed of these arrangements.

8. Training

So that all staff can understand the importance of the Incident reporting system the Trust will ensure that staff are trained to the appropriate level.

Trust Board members and senior managers attend training appropriate to their identified needs on a yearly basis.

All managers or staff involved in investigating incidents must undergo training on root cause analysis incident investigation techniques and risk grading. This training consists of a 1 day programme based on the Root Cause Analysis methodology and refresher must be undertaken every three years. The objectives of the course are to:

- Increase the understanding of the theory underpinning RCA
- Provide candidates with an overview of the RCA process
- Provide skills in some RCA Tools
- Demonstrate the advantages of using a system based approach to patient safety incidents.
- Train staff on complaints and claims processes and how they interface with incident management.

Non clinical risk managers/patient safety managers will receive appropriate specialist training as identified in personal development plans.

All other staff groups will receive information on the risk management processes and how to report incidents on the Trust induction day.

Additional training can be provided to departments/care groups by contacting the relevant risk manager (Patient Safety Team or Non-Clinical Risk).

Attendance at Essential Training is recorded by People & Organisational Development and entered onto the Trust Training Management System, OLM. Monitoring of non-attendance will be in line with the Training Needs Analysis, Monitoring and Evaluation Policy and carried out by People & Organisational Development. Please refer to this policy for detailed information.

9. Policy Review and Monitoring

This policy will be reviewed on a 3 yearly basis unless national, regional or professional bodies require an earlier update.

Monitoring Criterion	Response
Who will perform the monitoring?	Patient Safety Lead /Head of Non-Clinical Risk Management
What are you monitoring?	Monitoring the process of the incident management policy • All the incidents raised across the organisation will be reviewed monthly and analysis broken down into the individual Care Groups so themes/concerns can be identified with the development of action plans from the individual Care Group areas. • Monitoring of involvement of other stakeholders and external agencies will take place. • Monitoring of the reporting, investigation and analysis of incidents when the development of an action plan has been identified and this will be monitored by the Safety Committee. • All serious incidents will be discussed at Safety Committee and review of action plans to consider if robust to prevent similar incident reoccurring. • Audit from Safeguard incidents on a monthly basis. Monitoring the aggregated data from claims, patient experience (complaints/PALS issues) and incidents • Number of claims • Number of complaints • Number of incidents • The CLIPS report prepared quarterly will aggregate the incidents/claims/patient experience concerns to give a comprehensive overview of all identified risks. • Discussion at Health and Safety, Security and Safety Committee of all incidents reported and graded to identify themes and concerns across the Trust. From this monitoring action plans and remedial work to mitigate and prevent incidents will take place.
When will the monitoring be performed?	Incident management – monthly CLIPS – quarterly Policy audit – annual
How are you going to monitor?	Audit of incident management process annually including external agency involvement Monthly Safety Report Monitoring trends across care groups and the organisation From the CLIPS report on a quarterly basis deeper analysis with aggregated data from Complaints, Litigation, Incidents and PALs.
What will happen if any shortfalls are identified?	Raise with appropriate staff to agree action plans/controls to mitigate and reduce incidents. Raised at Quality & Healthcare Governance for discussion and sign-off.
Where will the results of the monitoring be reported?	Safety Committee and Quality & Healthcare Governance Committee. Safety Forum
Where will the resulting action plan be progressed and monitored?	Safety Committee and Quality & Healthcare Governance Committee.
How will learning take place?	Sharing outcomes with relevant departments, stakeholders and external agencies. Patient Safety website, one liners, bulletins.

In addition to the monitoring outlined in the table attendance at Essential Training is recorded by People & Organisational Development and entered onto the Trust Training Management

System, OLM. Monitoring of non-attendance will be in line with the Training Needs Analysis, Monitoring and Evaluation Policy and carried out by People & Organisational Development. Please refer to this policy for detailed information.

10. References

1. NHSLA 'Risk Management Standards for Acute Trusts" April 2007.
2. Department of Health 2001 "Building a Safer NHS for Patients" HMSO London.
3. Department of Health 2000 "An Organisation with a Memory" HMSO London. Available at
4. ALARM/UCL 1999 "A Protocol for the Investigation and Analysis of Clinical Incidents" ALARM, London.
5. National Patient Safety Agency (NPSA) Seven Steps to Patient Safety. The full reference guide.
6. Health and Safety Executive (HSE) The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR), HSE Books.
7. Connecting for Health, Information Governance Toolkit
8. National Patient Safety Agency's *National Framework for Reporting and Learning from Serious Incidents Requiring Investigation*
9. Serious Incident Frame work NHS England (March 2015)
10. Never Event list 2015/16 (March 2015)

11. Associated Documentation

Risk Management Strategy
Risk Management Operational Policy
Health and Safety Policy
Radiation Protection Policy
Violence and Abuse Policy
Complaints Policy
Medical Devices Policy
Infection Control Manual and Policies
Security Policy
Major Incident Plan
Claims Policy
Raising Concerns (Whistleblowing) Policy
Being Open Policy
Supporting staff Guidelines
Falls Policy
Security Incident Management Policy (POL/HIG/0010)
SafeGuard IT Policy
Risk Register Procedure
Training Analysis, Monitoring and Evaluation Policy

Induction Policy
Clinical Audit Policy
Policy for Policies
Consent Tool Kit
Blood Borne Virus Policy
Policy for Production of Patient
Learning from Experience Policy
Safeguarding Adults Policy
Safeguarding Children Policy

Appendix 1

Definition of a Serious Incident requiring investigation

A serious incident requiring investigation is defined as an incident that occurred in relation to NHS funded services and care resulting in one of the following:

Serious incidents at a glance:-
Serious incidents in health care are adverse events, where the consequences to patients, families and carers, staff or organisations re so significant or the potential for learning is so great, that a heightened level of response is justified. This for learning is so great that a heightened level of response is justified. Serious incidents must be identified correctly, investigated thoroughly and, most importantly learning from to prevent the likelihood of similar incidents happening again. Rationales for downgrading or identification of why it is a serious incident must be documented and discussion with patient or families when this takes place must be documented.

Serious incidents include acts or omissions in care that result in unexpected or avoidable death, unexpected or avoidable injury resulting in serious harm including those where the injury required treatment to prevent death or serious harm, abuse, Never Events, incidents that prevent (or threaten to prevent) an organisations ability to continue to deliver an acceptable quality of healthcare services and incidents that cause widespread public concern resulting in a loss of confidence in health care services.

Patients and their families/carers and victims 'families must be involved and supported throughout the investigation process.

Examples

- Serious harm to one of more patients, staff, visitors or members of the public or where the outcome requires life-saving intervention, major surgical/medical intervention, permanent harm or will shorten life expectancy as a result in prolonged pain or psychological harm (this includes incident graded under the NPSA definition of severe harm).
- Severe harm (patient safety incident that appears to have resulted in permanent harm to one or more person receiving NHS funded care.)
- Chronic pain (continuous, long term pain of more than 12 weeks or after the time that healing would have been thought to have occurred in pain after trauma or surgery) or
- Psychological harm, impairment to sensory, motor or intellectual function or impairment to normal working or personal life which is not likely to be temporary (i.e. has lasted, or is likely to last for a continuous period of a t least 28 days).
- A scenario that prevents or threatens to prevent a provider organisation's ability to continue to deliver healthcare services for example, actual or potential loss of personal/organisational information, damage to property, reputation or the environment, or IT failure.

- Dangerous Occurrences as identified under the RIDDOR Regulations.

- Adverse media coverage or public concern about the organisation or the wider NHS

- A Never Event.(New guidance from March 2015)

The full ‘never events’ list for reference is:

1. Wrong site surgery
2. Wrong implant/prosthesis
3. Retained foreign object post-procedure
4. Mis-selection of a strong potassium containing solution
5. Wrong route administration of medication
6. Overdose of Insulin due to abbreviations or incorrect device
7. Overdose of methotrexate for non-cancer treatment
8. Mis–selection of high strength midazolam during conscious sedation
   MENTAL HEALTH
9. Failure to install functional collapsible shower or curtain rails
   GENERAL
10. Falls from poorly restricted windows
11. Chest or neck entrapment in bedrails
12. Transfusion or transplantation of ABO incompatible bloods components or organs
13. Misplaced naso or oro gastric tubes
14. Scalding of patients

Appendix 2

List of Stakeholders

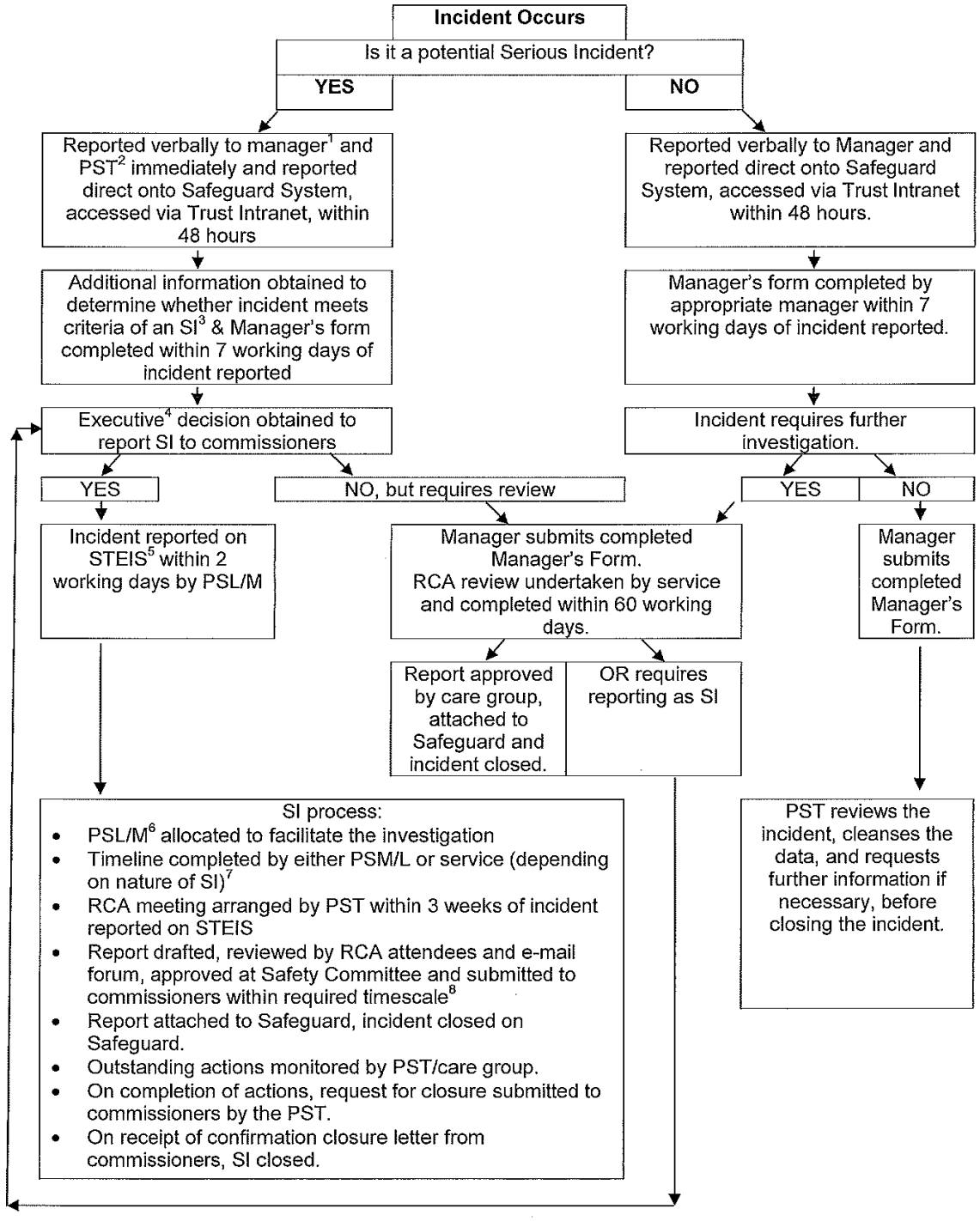
The stakeholders listed below may need to be informed of a serious incident. They should be informed after discussion with the Executive Director of Nursing and Executive lead for Patient Safety.

- Local General Practitioners (particularly if the incident involves many patients)
  - Department of Health, Public Health and Adult Social Care
  - Monitor
  - Commissioners
  - Care Quality Commission
  - Primary Care Trusts
  - Other NHS Trusts
  - Patients' Forum i.e. Health Watch
  - Litigation Authority (NHSLA)
  - Public Health England
  - Police
  - Coroner
  - Social Services
  - Safeguarding children or adult services leads
  - Medicines and Healthcare products Regulatory Authority (MHRA)
  - Health and Safety Executive (HSE)
  - Serious Hazards of Transfusion (SHOT)
  - Radiation Protection Advisor
  - Area Child Protection Committee
  - Child death lead and rapid response senior nurse
  - Public Health department
  - Trust's legal advisors
  - NHS Estates
  - Food Standards Agency
  - Media
  - Politicians
  - Mental Health Commission
  - Home Office
  - PALS
  - Local Supervising Authorities for Maternal Deaths – LSA officer
  - Confidential Enquiries Lead

This list is not exhaustive.

Appendix 3

INCIDENT REPORTING & INVESTIGATION PROCESS



[1] "Manager refers to either line/ward/team/service/duty manager as appropriate.
[2] PST refers to Patient Safety Team
[3] SI refers to Serious Incident (see policy for criteria).
[4] Executive refers to Director of Nursing/Medical Director or designated deputy
[5] STEIS refers to the Commissioner's electronic reporting system for reporting SIs
[6] PSL/M refers to Patient Safety Lead/Patient Safety Manager
[7] Pressure sores, fractured neck of femur, IG incidents, maternity incidents and potential failure to rescue incidents - timeline provided by service.
[8] Timescale: Level 1 SI: 45 working days. Level 2 SI: 6 months (see policy for criteria)

Appendix 4

CLASSIFICATION OF COMPLAINTS: COMPLEXITY AND LEVEL OF INVESTIGATION

CLASS	COMPLEXITY	LEVEL OF INVESTIGATION	Correspondence	RESPONSE TIMESCALE
LOW	**May be simple, non-complex issues:** **example** • delayed, cancelled appointments • event resulting in minor harm i.e. cut/strain • loss of property • lack of cleanliness • transport problems • single failure to meet care needs • medical records missing	**Low level investigation:** • Enquiries to relevant staff /departments and information obtained recorded on IT Safeguard System • Investigated by ward/department manager if concern or Investigating Officer if formal complaint • Complainant choice regarding processing as formal complaint or concern	If managed as concern, liaise with ward manager. If investigated as a formal complaint, send initial letter of complaint and agreed timescales for completion to: Investigating Officer, Care Group Manager, Associate Chief Operating Officer, Director Nursing and PA, Associate Director Nursing and PA, Patient Experience Manager. If complaint involves a patient with learning disability, send to LD Lead, If complaint involves named medical staff send to Associate Director Corporate Medical Services, Revalidation Officer and People & OD Manager. If complaint identifies a patient safety issue send to Patient Safety Manager to oversee completion of Incident Report	If concern – within 5 working days. If complaint – timescale to be agreed with complainant

MODERATE	**Several issues relating to short episode of care service:** • event resulting in moderate harm i.e. fracture, • delayed discharge • miscommunication/misinformation • medical errors • incorrect treatment • staff attitude or communication • failure to meet care needs	**Moderate level investigation:** • Enquiries to relevant staff /departments and information obtained recorded on IT Safeguard System • Investigated by Investigating Officer if formal complaint. • Complainant choice regarding processing as formal complaint or concern • Consider local resolution meeting	As above	Timescale to be agreed with the complainant.
HIGH	**Multiple issues relating to a longer period of care, often involving more than one organisation or individual.** see moderate list • event resulting in serious harm i.e. damage to internal organ	**High level investigation:** • Enquiries to relevant staff /departments and information obtained recorded on IT Safeguard System • Investigated by Investigating Officer. Obtain reports from staff involved as appropriate on specific issues identified (particularly where possible negligence and serious harm) • Consider local resolution meeting	As above	Timescale to be agreed with the complainant.
EXTREME	**Multiple issues relating to serious failure, causing serious harm:** Events resulting in serious harm or death Gross professional misconduct	**Extreme level investigation** Serious Incidents (SI) will be investigated by a SI Panel with the final report shared with the patient/complainant as appropriate.	As above	Agree with complainant in consideration of the SI timescales and the date of the Coroner's Inquest.

	Abuse or neglect Criminal offence (e.g. assault)	Any outstanding issues following the report may be investigated within the complaints framework if requested by the complainant Where the issues are subject to a Coroner's Inquest the report will be shared with the patient/complainant as appropriate via Patient Safety Team. Any outstanding issues may be investigated within the complaints/claims framework. All extreme cases are reported to the Trust Board		

Guidance to Support the Management of Medication Related Incidents

1. Introduction

A prescribed medicine is the most frequent treatment provided within the NHS and medication incidents are among the highest categories of incidents reported within County Durham and Darlington NHS Foundation Trust. Reporting and analysis of medication incidents is an opportunity to share learning and improve medication systems and is an important way for staff to contribute to improving safety for patients. Research[1] has shown that where rates of incident reporting are high there is more likely to be a better culture of safety and risk management and therefore staff are encouraged to report incidents and to share the learning that is gained from such events.

Patient safety is of paramount importance and County Durham and Darlington NHS Foundation Trust wish to manage medication related incidents in such a way that supports patient safety, manages risk and ensures that lessons are learned and practice improved at individual, team and organisational level, when a medication related incident occurs.

2. Purpose

All incidents must be managed according to the principles which are outlined in the CDDFT Incident Management Policy (POL/NQ/0001). The purpose of this guidance document is to offer additional information to support the management of medication related incidents.

3. Definitions

Medication errors are patient safety incidents involving medicines in which there has been an error in the process of prescribing, dispensing, preparing, administering, monitoring, or providing medicine advice, regardless of whether any harm occurred (National Prescribing Centre 2010). The majority of medication incidents report clinical outcomes of no harm or low harm; however there is important learning to gain from reviewing all medication incident reports.

A medication error may occur at any stage of the medicines process and may be at one point in the process or be a combination of events. The following are examples of possible errors at different stages of the medicines process, but this does not provide a definitive list of possible errors:

Prescribing Errors

- Medication not prescribed
- Patient prescribed the wrong medication/dose/route/rate
- Medication prescribed to the wrong patient
- Transcription errors
- Prescribing without taking into account the patients clinical condition
- Prescribing without taking into account the patient's clinical parameters e.g. weight or renal function
- Prescription not signed
- Deviation from CDDFT policy and procedures

Dispensing Errors

- Incorrect medication/dose/route dispensed
- Medication dispensed to the wrong patient
- Out of date medication dispensed
- Medication labelled incorrectly
- Deviation from CDDFT policy and procedure

Storage Errors

- Interruption of cold chain storage
- Incorrect storage of Patients' Own medication
- Deviation from CDDFT policy and procedure

Supply, Preparation and Administration Errors

- Patient administered the wrong medication/dose/route
- Patient administered out of date medication
- Medication administered to the wrong patient
- Medication omitted without clinical rationale
- Medication incorrectly prepared
- Incorrect medication supplied
- Incorrect infusion rate
- Medication administered late/early where there is potential for a detrimental effect on the patient
- Deviation from CDDFT policy and procedure

Monitoring Errors

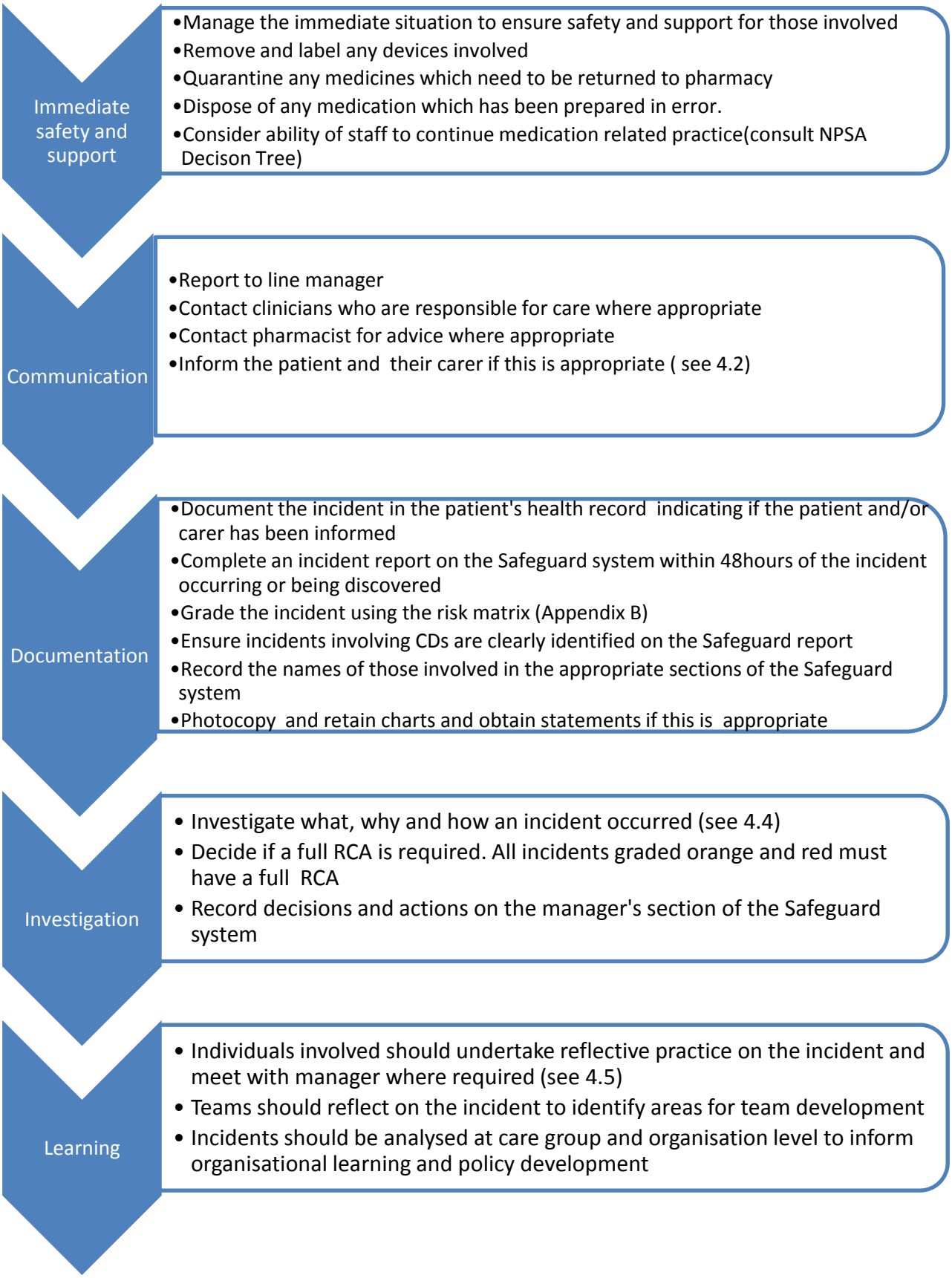
- Patient allergic to the medication but the medication was prescribed and/or dispensed and/or administered
- Failure to ensure on-going monitoring e.g. warfarin
- Failure to provide the patient with correct information regarding their medication e.g. what the medication is for, when to take it, side effects.
- Failure to communicate on-going care on transfer of care or discharge.

4. Guidelines for Managing Medication Errors

The management of a medication error is outlined below in terms of the decision making and actions required to minimise harm and promote patient safety and learning from the incident.

Details of the steps involved are outlined in section 4 and a summary of the process is available on page 3.

Managing a Medication Error



4.1 IMMEDIATE SAFETY AND SUPPORT

Ensure the patient is safe

- The person involved in the incident, or the person reporting the incident, must ensure the patient's safety by assessing the situation and taking any required action to stabilise the patient.

- Any devices which were involved in the incident should be labelled and removed from use.

- Any medicines which need to be returned to pharmacy should be quarantined and an alternative supply arranged where necessary

Provision of immediate support for members of staff

- Once the patient's safety has been managed, support should be offered to staff involved in the incident. The vast majority of medication incidents are unintentional. Staff will need to be offered support following an incident and consideration should be given to the way the member of staff feels about continuing with medication related practice.

- An immediate decision must be made about the ability of the member of staff to continue with medication related practice. In most cases there will be no need to suspend practice.

- Where deliberate harm, reckless behaviour or serious lack of fundamental knowledge is judged to be involved then a decision must be made about how this will be managed (the NPSA Decision Tree may be of use to support this decision making Appendix A).

  Possible decisions on action may include:
  - No action required
  - A period of supervised practice
  - Suspension from one particular aspect of practice until a full investigation is complete.

4.2 COMMUNICATION

- Medication incidents must be reported immediately to the line manager (or most senior team member for the service area at that time) who must manage the incident in line with the Trust Incident Management Policy.

- It may be appropriate to contact clinicians who are responsible for the medical care of the patient to inform them of the incident.

- It may also be appropriate to contact a pharmacist for advice regarding the possible outcome of a medication incident and to consider any further action to be taken.

- Patients or their carers should be informed of every incident which has an impact upon them and in line with the Being Open Policy (POL/NQ/0009) must be informed of all incidents graded moderate (orange) and above.

- Where a medication incident involves a Controlled Drug (CD), the Trust Chief Pharmacist must be informed; completion of the appropriate section of the Safeguard

report will ensure that the Trust Chief Pharmacist and appropriate managers are automatically informed of such incidents.

- In the case of a potential dispensing error it may be appropriate to inform the relevant pharmacy department of the potential incident (in community settings this may be the community pharmacy).

4.3 DOCUMENTATION

- Ensure the incident is documented in the patient's health record. Most incidents will require a specific entry in the medical or nursing record.
- An incident report on the Safeguard system should be completed within 48 hours of the incident occurring or being discovered.
- The incident must be graded using the risk matrix identified in the Incident Management Policy; a more detailed grading of medication incidents can be found in Appendix B.
- To support individual learning the names of the person/s involved in the incident should be recorded as part of the Safeguard report.
- Photocopies of charts should be made if required; any original charts which should be retained in the health record should be marked 'RETAIN' (see Incident Management Policy)
- Statements should be obtained from those involved in the incident where it is appropriate.

4.4 INVESTIGATION

The nature and context of the medication incident will guide the type of investigation which is required. As a minimum the following should occur for all incidents:

- Report via Safeguard
- Decision making and immediate action in relation to patient safety
- Decision making about any action required to support staff
- Decision making about management of the incident
- Investigation (not necessarily full RCA) which identifies what, why and how an incident occurred
- Record of actions taken on the Managers section of the Safeguard report
- Reflection by those members of staff involved in the incident. This should support identification of learning needs.
- All incidents graded orange and red must have a full Root Cause Analysis (RCA) investigation

Managers should monitor incidents to identify trends and re-occurrence of similar incidents. Those Incidents which are graded green or yellow should be investigated if trends are identified by managers and teams, or if individual members of staff make repeated errors. In these situations it would be appropriate to conduct an RCA.

4.5 LEARNING

Learning from an incident is a valuable way of reducing risks and improving practice for the future and should take place at three levels following an incident:

Individual
Individuals who have made a medication error should undertake reflective practice to analyse their personal practice and take measures which will improve personal knowledge, skills, performance or awareness of risk.

The tools in Appendix C and D should be used to guide appropriate reflective practice and a framework to support competency in administration of medicines can be found on the pharmacy website:

- Appendix C outlines a generic reflective model which can be used to guide reflection.

- Appendix D is a document to record any meetings between a staff member and manager/ supervisor/mentor. While such a meeting would be useful for all staff they are essential for students and those taking part in a programme of education which involves placement in practice and evidence of performance in practice. Copies of completed reflective tools should be filed in personal files.

- The Administration of Medicines Practice Reflection and Learning Framework can be found on the Pharmacy website E. This framework may assist reflection where incidents involve administration of medicines.

Team
Learning from incidents should be part of team meetings and clinical supervision. These meetings should also facilitate wider reflection on team practice and processes to identify areas for improvement.

Organisation:
Incidents should be analysed at Care Group and organisational level to identify themes and trends to review systems and procedures contributing to incidents.

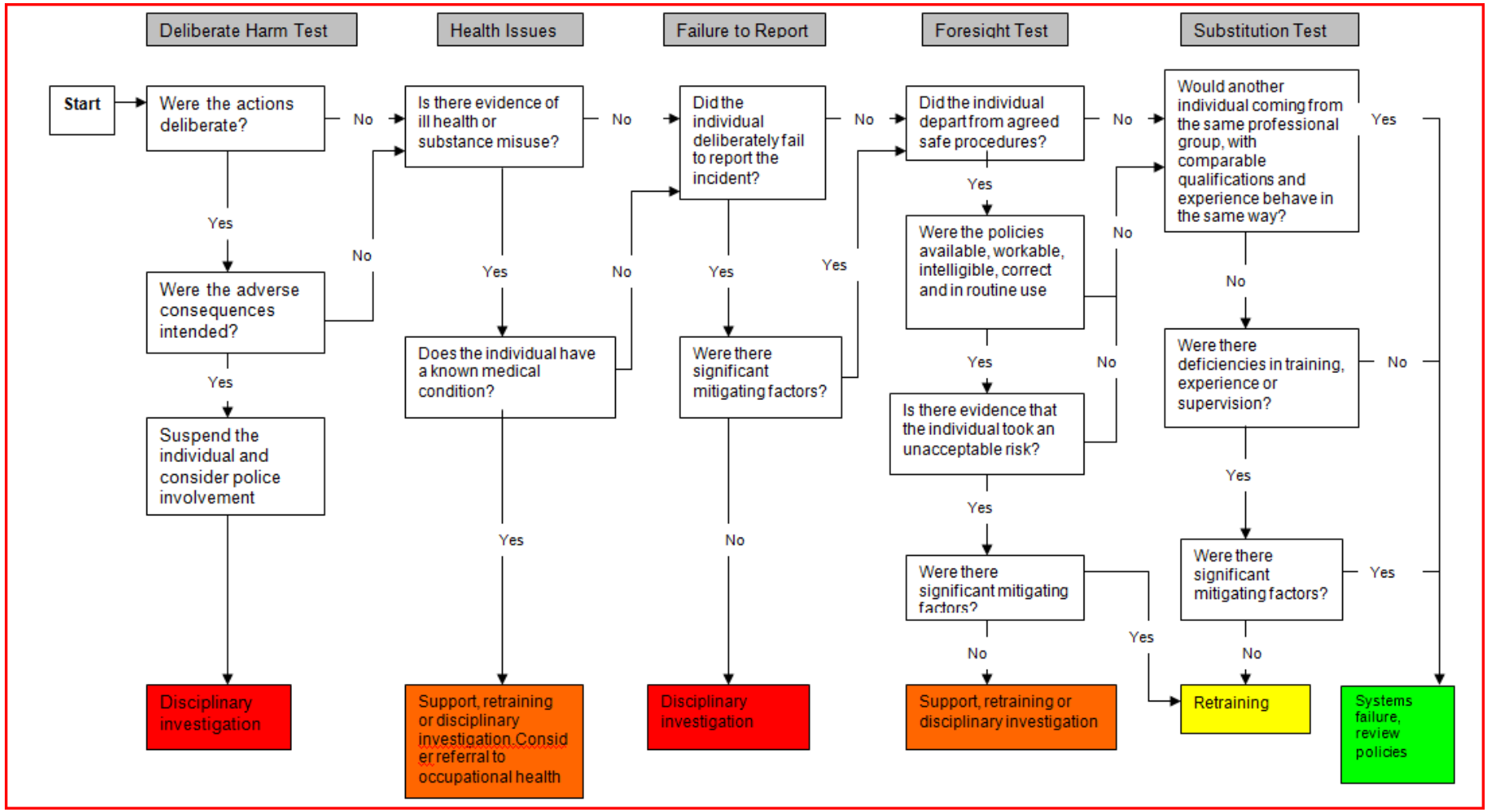
5. References

1. NHS Confed NPSA briefing: Five actions to improve patient safety reporting Reference 1095 Issue date June 2008
2. NPSA
3. Gibbs, G. (1988) Learning by Doing: a guide to teaching and learning methods
4. National Patient Safety Agency (2003). The Incident Decision Tree Information and advice on use

Associated Documentation

5. Incident Management Policy
6. Medical Devices Policy
7. Being Open Policy

Appendix A Medication Error Tree



Appendix B Definitions for Grading Actual Impact of Incidents (based on National Patient Safety Agency guidance)

Actual Impact	Colour	Definition
Near miss	Green	Any patient safety incident that had the potential to cause harm but was prevented and so no harm was caused to the patient.
No harm	Green	Any patient safety incident that occurred but no harm was caused to the patient.
Minor harm	Yellow	Any patient safety incident that required extra observation or minor treatment of the patient (e.g. first aid, additional medication).
Moderate harm	Orange	Any patient safety incident that resulted in a moderate increase in treatment (e.g. return to surgery, unplanned re-admission, prolonged episode of care, transfer to another area such as ITU) and that caused significant but not permanent harm to the patient).
Severe harm	Red	Any patient safety incident that appears to have resulted in permanent harm to the patient (e.g. permanent lessening of bodily functions, sensory, motor, physiological or intellectual, including removal of the wrong limb or organ, or brain damage).
Death	Black	Any patient safety incident that directly resulted in the death of the patient (the death must be related to the incident rather than the patient's illness or underlying condition).

Appendix C Gibbs' (1988) Reflective Cycle

Gibbs' (1988) 6 stage reflective cycle is a popular model for reflection and can be a useful tool to guide reflection following and incident. Reflection should acknowledge good practice and focus on learning from incidents to improve practice for the future.

Adapted from Gibbs, G. (1988) Learning by Doing: a guide to teaching and learning methods.

Phase of Gibb's Cycle	Possible questions to guide reflection
1.Description	What happened? Briefly describe the event as objectively, accurately and concisely as you can. Who was involved? Where did it happen? Do you intend to focus on the structure, process or outcomes of care?
2.Feelings and Thoughts	What were your feelings and thoughts: At the time? Afterwards?
3.Evaluation	How well did things go? Were things satisfactorily resolved?
4.Analyse	What were the factors that affected the outcome? What helped and what hindered? Can you explain the event? Why did it happen? How did it happen?
5. Conclusion	What might have been some alternative actions or approaches? What might you have done differently (even when things went well)? Could negative events be avoided? Could positive events be made more effective?
6. Action Plan	What will you do if you encounter this kind of situation again? What will you do in the future to increase the likelihood of similar positive outcomes and minimise the likelihood of similar negative outcomes? What do you need to learn? How might you learn this?

Appendix D

Reflective Practice Meeting

Action following medication related incident
(Incident Number)

Date	Areas identified for reflection	Action required to support reflective learning	Date action required by

Learning identified from reflection:
Comments from Manager/Mentor/Supervisor:
Record participants of meeting below

Name	Signature	Date

Appendix 6

Examples of what to report:

- All incidents/accidents resulting in staff being absent from work
- All dangerous occurrences including near misses
- All Visitor accidents/incidents
- Any occurrence which effects a patient, member of staff or visitor while he or she is undergoing treatment or is on hospital premises, which could have or actually has caused harm or could lead to a complaint or claim. (including slips, trips and falls) See Falls Policy
- All defects or failures from medical devices
- All radiation incidents
- Fires including false alarms
- Near misses
- Property loss/damage
- Ill Health or Industrial Diseases
- Violence/Abuse
- Environmental issues
- Clinical Incidents
- Data Quality issues
- Control of Infection issues
- Staffing shortfalls

This list is not exhaustive

Appendix 7

Protocol for Investigation and Review of Serious Incidents/Any Harm incidents

Introduction

This protocol is a framework to facilitate in-depth analysis of and learning from events where there has been significant harm to or death of a patient.

Aim / Purpose

- To ensure in-depth analysis of the incident that can then assist in responding to a claim or complaint.
- To ensure appropriate experience and expertise is fully applied to the review process
- To ensure that (in addition to the immediately obvious cause) **all** the events leading up to the adverse outcome are considered
- To ensure a structured and systematic approach is applied to the review aiding mapping of the events, a comprehensive investigation and production of a formal report
- To ensure a consistent (and documented) approach is used to all incidents, therefore, increasing openness for staff, reducing fear of unknown and creating a less threatening approach
- To facilitate a climate of openness and a blame free approach
- To ensure that learning takes place, reducing subsequent / similar risks
- To ensure that the findings are applied at all relevant levels

Scope

Any incident, claim or complaint which has been categorised as red during the investigation should be reviewed using this protocol. The protocol may also be used for other incidents, claims or complaints where the executive team feel that there may be significant lessons for the organisation.

Initiation

The Chief Executive or any member of the executive team can request a review of an incident, claim or complaint.

This decision is taken after considering the incident report, claim or complaint file, the advice of the appropriate Risk Manager, Complaints or Legal Services Manager, initial discussion with lead consultants and / or nursing and Allied Health Professionals.

Who should investigate?

There needs to be a degree of objectivity and independence in the review and for this reason, in the case of a clinical event, the lead consultant and clinical staff actively involved in the case may not be involved in conducting the investigation.

The appropriate Risk Manager and Complaints Manager will be actively involved in the review process with the support of either the care group lead, matron for the ward or the Clinical Director or appropriate staff in the case of a non-clinical incident.

The appropriate Director will advise who will be the lead reviewer and who will assist.

Roles and responsibilities (Duties)

The lead reviewer conducts all interviews and prepares a report for the appropriate Director.

The second reviewer supports the lead at reviewer interviews taking notes and clarifying points made where necessary.

The lead reviewer is responsible for ensuring that the relevant external agencies have been notified and where appropriate either consulted or involved in the investigation process.

Disciplinary Issues

The purpose of the review is to learn lessons and, rather than seek to blame individuals, consider the wider general organisational issues.

The occurrence of an event is not in itself evidence of neglect, carelessness or dereliction of duty. Only if evidence of repeated poor performance emerges despite adequate training / retraining will disciplinary action be considered.

If this becomes evident then advice should be sought from the Personnel Department. The Trust's policy on discipline gives more detail on this point.

Report

A report of the investigation and findings will be produced by the review team. The report will describe the chronology of events, map the events and put them into context i.e. (environmental factor, statutory requirements, care management problems, clinical context and factors, specific and general contributory factors).

The report should include the following:

- Statement of what happened
- The review team
- The nature of the investigation
- The findings
- The root causes
- Recommendations (with timescales)
- Lessons learned
- Any audit findings

Follow Up

Once completed the report should be presented to the appropriate director and reviewed according to the Trust process. The original incident form will be re-graded as appropriate by the appropriate Manager. Lessons learned will be shared at the Safety Committee, Quality and Health Care Governance Committee and appropriate Care Groups.

Appendix 8

Procedure in the Event of a Radiation Incident arising from Medical Exposure

All radiation incidents must be reported to the Radiation Protection Adviser (RPA) by the department in which the radiation exposure occurred. A brief description of the incident, root cause (if known) and radiation exposure information must be supplied.

When should a radiation incident be notified to an enforcing authority?

A radiation incident that has resulted in a radiation dose "much greater than intended" must be notified to the appropriate enforcing authority. The RPA has been authorised by the trust to advise when an incident is required to be notified to an enforcing authority in accordance with current guidance.

How will I know what my role is with regard to radiation incidents?

The process that must be followed once a radiation incident is known to have occurred is outlined in the flow chart in Appendix 1. Responsibilities against specific actions are allocated in this flow chart. Those needing to undertake an investigation of the incident must produce a "notifiable radiation incident report" (see Appendix 2) and forward this to the RPA & Patient Safety team.

Who is responsible for making a notification of a radiation dose much greater than intended?

A manager within the department in which the radiation exposure occurred must make the initial notification (see Radiation Protection Policy). This may be a superintendent radiographer who also has Radiation Protection Supervisor (RPS) responsibilities or another with management responsibility. The Patient Safety team will submit the full and final report of the incident to the relevant enforcing authority once agreed by the Safety Committee.

How can I make a notification to the Care Quality Commission (CQC)?

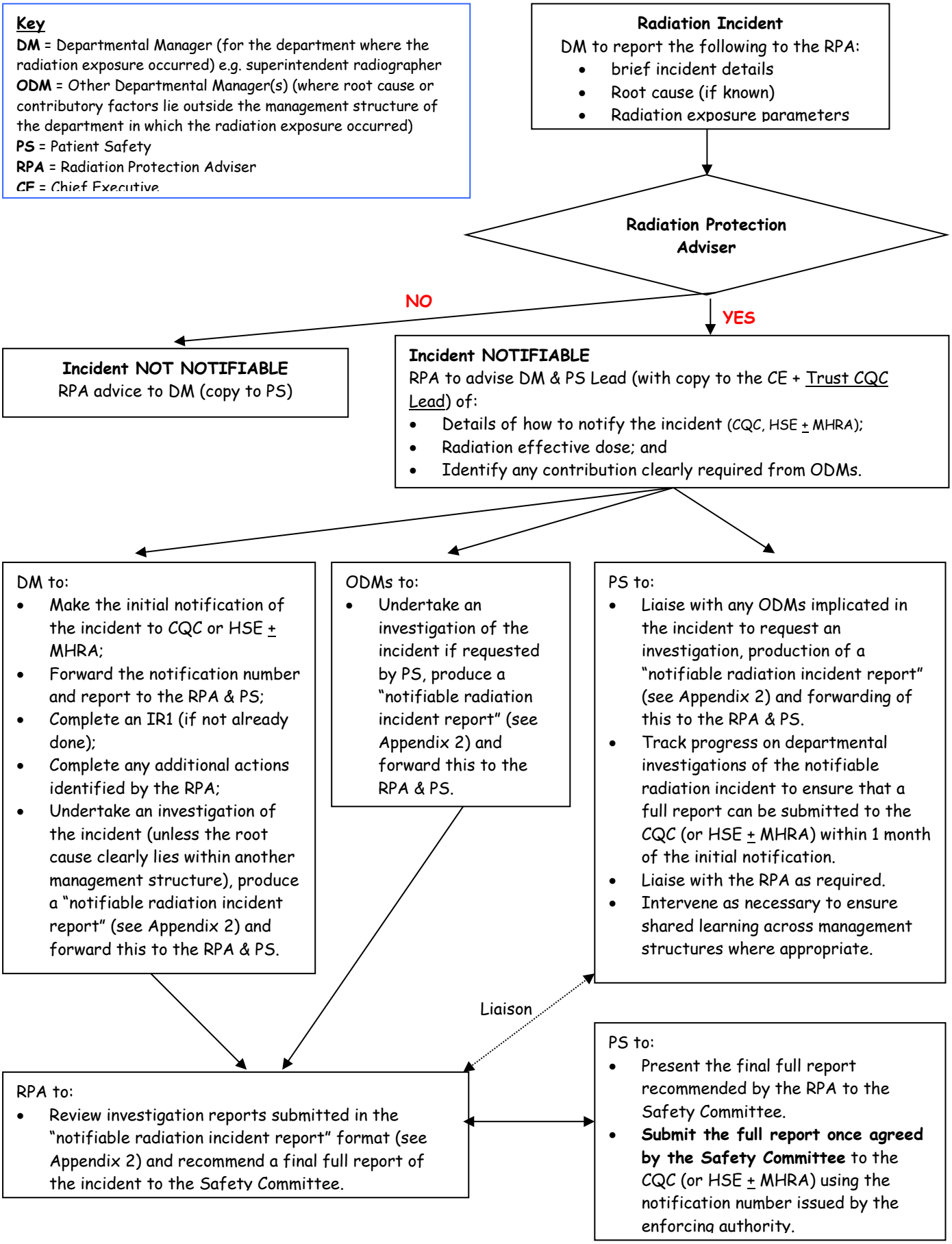
Incidents resulting in radiation exposure "much greater than intended" must be notified to the CQC if the incident arose as a consequence of human error. The report must be made as soon as possible once it is clear that notification is required. A radiation effective dose estimate (available from the RPA) will be required when making the notification. Notifications can be made on-line using the following link:
http://www.cqc.org.uk/organisations-we-regulate/special-reviews-and-inspection-programmes/ionising-radiation/reporting-inc

How can I make a notification to the Health and Safety Executive (HSE)?

Incidents resulting in radiation exposure "much greater than intended" must be notified to the HSE if the incident arose as a consequence of radiation equipment failure. The report must be made as soon as possible once it is clear that notification is required. A radiation effective dose estimate (available from the RPA) will be required when making the notification. The incident should be reported to the HSE by e-mailing irrnot@hse.gsi.gov.uk (if this e-mail does not work check the website at http://www.hse.gov.uk/radiation/ionising/notification.htm)
The notification is made under IRR99 regulation 32(6) not RIDDOR.

The RPA may also advise you to report the incident to the Medicines and Healthcare products Regulatory Agency (MHRA). Notifications can be made on-line using the following link:

http://www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/Devices/index.ht



Responsible managers undertaking an investigation into a notifiable radiation incident must supply information under the **headings** below (*guidance in italics*). When complete the report should be submitted to both the RPA and Patient Safety team.

Notification number allocated by the enforcing authority (if known)**:**

Incident date:
Date of birth (*of affected patient*)**:**
Medical exposure/investigation:
Radiation Effective Dose (*provided by the RPA*)**:**

Chronology of events: *Simply list events leading up to the notifiable radiation incident in chronological order. This should be factual lists of events, detailed without analysis or judgement regarding root cause etc.*

Root cause of the incident: *Seek to identify the root cause of the incident here.*

Contributory factors to the incident: *Seek to identify any other contributory factors to the incident.*

Conclusions: *Bullet points the key conclusions from your investigation.*

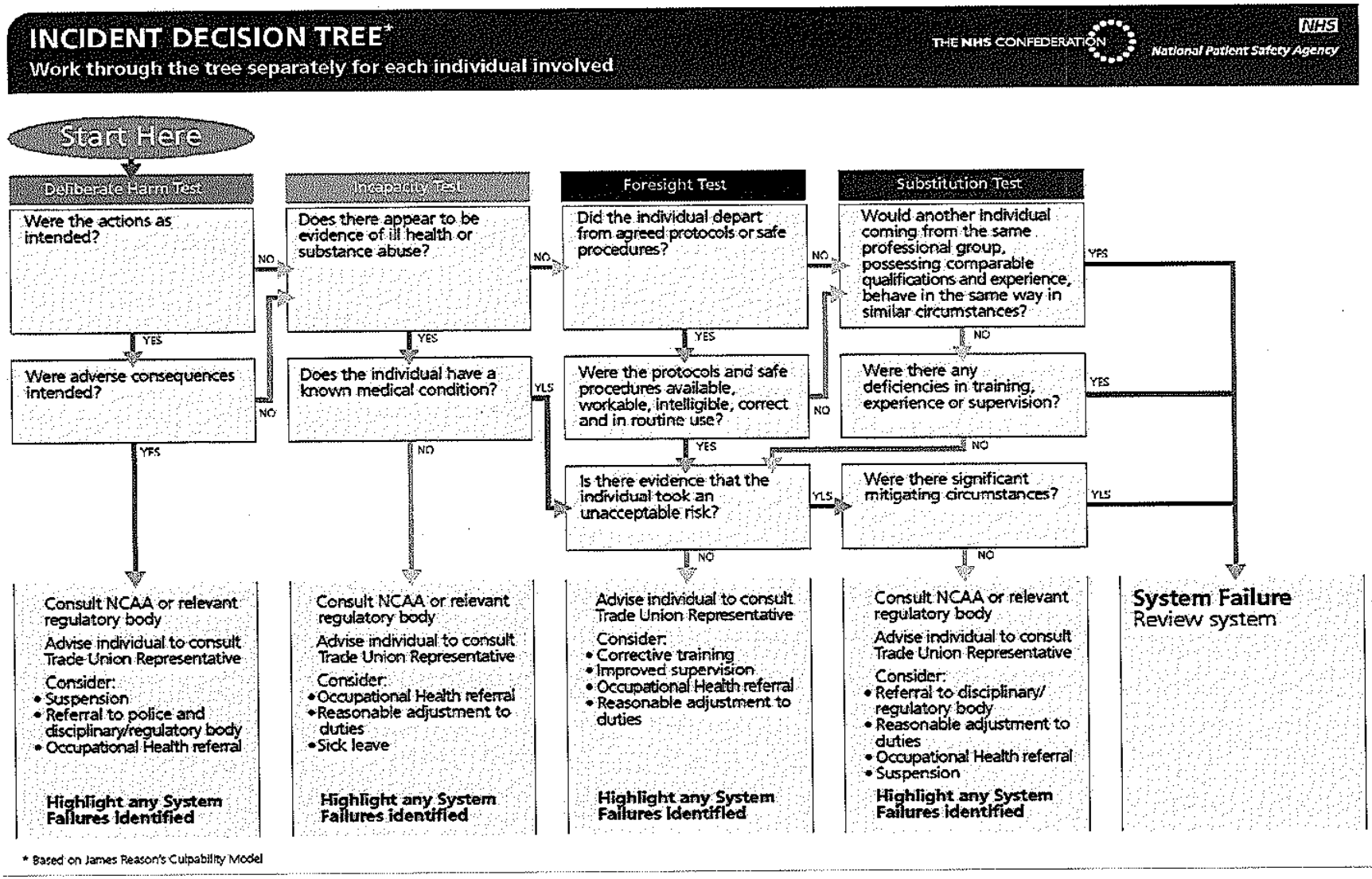
Action taken to reduce the likely recurrence of an incident: *Note here any action taken to reduce the likelihood of a recurrence. This may include:*

- *Revision to written procedures*
- *Training needs identification (note date of completion or indicate a timescale for completion of training)*
- *Individual and shared learning (note any relevant dates e.g. dates for staff meetings at which the shared learning did/will take place)*

Being open: *This section must identify how the patient has/is going to be informed and a formal apology given after the radiation incident*

Note: The trust only requires a RCA form to be completed for Serious Incidents (SI). It is not anticipated that a radiation incident alone (i.e. where no adverse outcome other than exposure to ionising radiation occurred) will constitute a SI. However, an investigation sufficient to address the above listed headings will still be required whenever a radiation incident is notifiable to an enforcing authority.

Figure 1. The National Health Service's Incident Decision Tree for responding to patient safety events



* Based on James Reason's Culpability Model

Appendix 10

Guidance on the Development and Writing of Statements

1. Introduction

Staff are often requested to provide statements in response to complaints, untoward incidents and claims against the Trust etc. The person providing the statement may have been directly involved in, or witnessed, a specific event. On occasion a statement is requested to clarify/confirm normal working practices in a given situation. When developing a statement it is important to cover all of the events in question.

Whatever the reason for providing a statement it is important that the Trust has a standard proforma to assist staff with such a task.

2. Purpose

The following standards should be applied whenever possible:

- Use Trust headed paper.
- Have the statement typed whenever possible. If this is not possible legibility should be ensured by printing the statement in black ink.
- Leave double spacing between each line of text.
- Number each page (bottom right of each sheet).
- Number each paragraph (left hand margin at first line of each paragraph).
- Statement should be single sided.

4. Content of Statements

A statement must be in the words of the witness though assistance can be given by a third party e.g. Head of Department, Care Group Manager.

The following guidelines should be applied:

- The statement should be in narrative form in the first person.
- Events should be complete and stated in chronological order.
- Events should be timed.
- Must provide all of the necessary factual detail and where specific issues are identified, i.e. via a complaint, respond to each of those issues.
- Must sufficiently reference any documents referred to (attach if appropriate).
- The first paragraph should include your full name and contact address e.g. I, Joe Smith c/o The University Hospital of North Durham, Durham City will state as follows:-
- The second paragraph should include details of your professional qualifications and employment details e.g. `I am employed by County Durham and Darlington NHS Foundation Trust and I am a Registered Qualified Nurse. My qualifications are R.G.N. and I have a Diploma in Nursing Science. I have worked on surgical Wards for the Trust since 1993 and I am currently employed on a full time basis on Care Ward'.
- Subsequent paragraphs should contain detailed relevant information (in chronological order) relating to the issue in hand, including the background to the incident. It is important that you record all timings in your statement.
- The final paragraph should read, `I believe that the facts in this statement are true`.

- The statement should then be clearly signed and dated (print and sign name).

5. Statements Provided in Response to Claims against the Trust

A statement developed as a direct result of a litigation claim is a privileged document i.e. it cannot be disclosed without agreement of the Legal Services Manager and/or the Trust Solicitors/NHS Litigation Authority.

The Legal Services Manager and/or the Trust Solicitors to ensure compliance with the format determined within the Pre Action Protocol must facilitate development of these statements.

The Front sheet must detail the name of the maker of the statement, version number, date and number of exhibits e.g. articles, publication and accompanying reports etc.

6. Further Considerations

If you have been asked to provide a statement on issues that are outside your expertise/knowledge then you should discuss this with the Legal Services Manager.

Statements must omit hearsay, rumour, similar fact and opinion. You should simply state the facts.

It should be remembered that statements provided for one purpose may be used for another e.g. statements used for follow up of untoward incidents may be provided to assist the Complaints Department respond to a formal complaint. Statements provided during a complaint investigation are can be disclosed in the event that a claim is made.

AGENCY	WHEN TO BE INFORMED/CALLED UPON FOR SUPPORT IN AN INVESTIGATION	REPORTED BY	PROCESS FOR REPORTING
Health & Safety Executive (RIDDOR)	• Death or major injury (fracture, amputation, loss of sight, etc.) • Injury at work resulting in over seven day absence • Work related disease (e.g. asbestos, etc.) • Dangerous Occurrence (gas leak, Glutaraldehyde spillage, etc.) *For a full list of RIDDOR reportable events, contact the Non-Clinical Risk Management Department*	Non-Clinical Risk Management	Via a Health and Safety Executive online reporting portal Reported within 15 days of the incident occurring
NHS Litigation Authority	• High probability of a claim against the Trust	Legal Services	Via an online reporting portal Must be reported within 7 days of the claim identification
Environment Agency	• Discharge which results in pollution of land/air/water	Non-Clinical Risk Management Radioactive Waste Advisor, Medical Physics (radioactive substances incidents)	To be reported immediately to the Environment Agency via email or telephone
Health & Safety Executive (Ionising Radiations Regulations 1999	• Overexposure to radiation of a member of staff or public, other than as part of a patient's diagnosis or treatment • Spillage of radioactive material leading to significant contamination, loss of a significant amount of radioactive material • Exposure to radiation of a patient much greater than intended as a result of an equipment fault • Unplanned exposure of a worker or member of the public to a high-activity sealed source	Radiation Protection Advisor/ Medical Physics Department or Department Manager	The Trust's local HSE Radiation Specialist Inspector must be contacted directly Safety Committee (incidents involving patient exposure much greater than intended) See Appendix 8 of this policy for further information.
Care Quality Commission (Ionising Radiations (Medical Exposure) Regulations 2000))	• Exposure to radiation of a patient much greater than intended as a result of human error	Department Manager (e.g. Radiology Manager) following advice from the Radiation Protection Advisor	CQC online incident notification within 2 weeks of the exposure. Report sent following investigation & review at Safety Committee. See Appendix 8 of this policy for further information.
NHS England Screening Programmes	• Incidents relating to any of the 11 screening programmes	Breast Screening Cervical Screening Anti-natal which includes sickle cell and thalassaemia	Via a telephone call directly to NHS England Screening Lead, which is then followed up in writing or via e-mail with links from our own Trust lead for the relevant screening

		screening Fetal anomaly Infection disease in pregnancy Newborn and infant physical examination screening Newborn hearing screening Newborn bloodspot NHS diabetic eye screening Abdominal aortic aneurysm screening Bowel cancer screening	programme Must be reported within 24 hours Please see: http://www.screening.nhs.uk/publications Screening in the UK2011-2012
Environment Agency (Environmental Permitting Regulations 2010)	• Escape of radioactive material from any container or location in which it is kept • Loss, theft or attempt theft of radioactive material • Unauthorised use of, damage to, or loss of radioactive substance from a radioactive source • Unplanned exposure of a worker or member of the public to a high-activity sealed source	Radiation Protection Advisor/Radioactive Waste Advisor, Medical Physics	The Trust's local EPR 10 EA inspector must be contacted by telephone or via the national incident hotline
Secretary of State for Transport (Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009)	• A radiological emergency during transportation of radioactive materials • The theft or loss of radioactive material during transportation	Medical Physics Department	The Office for Nuclear Regulation must be contacted directly
Environment Agency	• A radiological emergency during transportation of radioactive materials	Medical Physics Department	The Office for Nuclear Regulation must be contacted within 48 hours of notification.
Police	• The theft or loss of radioactive material during transportation	Medical Physics Department or Local Security Management Specialist	The Trust's local contact at County Durham Police will be contacted within 48 hours of notification.
National Reporting Learning System	• All patient safety incidents	Patient Safety Team	Via the SafeGuard Risk Management System and NRLS online portal
Care Quality Commission via NRLS	• Receive reports from the National Reporting Learning System (NRLS) and identify cases for further information from the Trust (Outcome 18)	Patient Safety Team	Via the SafeGuard Risk Management System and NRLS online portal
Care Quality Commission	• Death or unauthorised absence of a person who is detained or liable to be detained under the Mental Health Act (1983)	Any member of staff can report this onto Safeguard system as an incident	Directly to Care Quality Commission
HM Coroner	• Unexpected/unexplained death of patients • Actual or suspect unlawful activity (e.g. death of patients)	Any medical member of staff can report an	Directly to the HM Coroner or via Legal Services

		unexpected/unexplained death	
Medicines and Healthcare Products Regulatory Agency	• Incidents involving unexpected drug reactions resulting in injury/harm • Incidents where defective equipment is involved and has resulted in injury/harm to patients • Incidents that are likely to significantly affect the safety of patients involved in a clinical trial of an investigational medicinal product or medical device leading to the temporary halt of a trial • Incidents that are likely to significantly affect the scientific integrity of the clinical trial of an investigational medicinal product or medical device leading to the temporary halt of a trial	Non-Clinical Risk Management (MHRA Lead)/Research Lead/Pharmacy Medical Physics Quality Controller (Radioactive Substances Specials Licence)	MHRA
Police	• Actual or suspected unlawful activity (e.g. theft)	Local Security Management Specialist	The Trust's local contact at County Durham Police will be contacted within 72 hours where appropriate.
NHS Protect	• Actual or suspected major theft/loss of Trust property/physical assault	Local Security Management Specialist	Via the SIRS online reporting portal within 30 days of incident reported.
Lead Commissioner	• All Serious Incidents (SI)	Patient Safety Team	To lead commissioners via STEIS at the North East Commissioning Support Unit Must be reported within 48 hours of becoming aware of the incident/SI
Social Services	• All incidents reported on the Safeguard system where abuse or suspected abuse has been caused to a child or vulnerable adult	Any member of staff can report a Safeguarding incident	Incidents reported under the Safeguarding category automatically trigger to the Safeguarding Adult/ Children lead so that they can follow up appropriately
Commissioners	• All incidents reported to CDDFT that are not the responsibility of the Trust, e.g. pressure sores from nursing homes on admission, GP errors	Patient Safety Team	Monthly report to Lead Commissioner at North East Commissioning Support Unit
Information Commissioners	• All Level 2 SIs and above	Information Governance Manager	Directly to the Information Commissioner

Equality Analysis/Impact Assessment

Full Assessment Form **v2/2011**

Care Group/Department:	**Nursing & Governance**
Title of policy, procedure, decision, project, function or service:	**Incident Management Policy**
Lead person responsible:	**Delcy Wells, Patient Safety Lead**
People involved with completing this:	**Delcy Wells, Patient Safety Lead, Chris Rooney, Head of Non-Clinical Risk Management, Jill Salked, Patient Experience Manager, Tracey Cadas, Legal Services Manager, Joanne Todd, Associate Director of Governance & Patient Safety**

Type of policy, procedure, decision, project, function or service:

Existing	Yes☐
New/proposed	☐
Changed	☐

Step 1 – Scoping your analysis

What is the aim of your policy, procedure, project, decision, function or service and how does it relate to equality?

To ensure staff are aware of their responsibilities regarding reporting, analysing and investigating incidents.

Who is the policy, procedure, project, decision, function or service going to benefit and how?

Staff, Patients, visitors, contractors and external stakeholders.

What outcomes do you want to achieve?

No incidents

What barriers are there to achieving these outcomes?

Not adhering to policies and guidelines and not attending training

How will you put your policy, procedure, project, decision, function or service into practice?

Monitoring incidents and visiting departments when incidents have occurred and stressing the importance of following correct procedures and attending training

Does this policy link, align or conflict with any other policy, procedure, project, decision, function or service?

Risk Management Strategy, Claims Policy, Complaints Policy, Health & Safety Policy, Supporting Staff Policy, Being Open Policy and CLIPS document.

Step 2 – Collecting your information

What existing information / data do you have?

Trends, audit results, action logs, reports

Who have you consulted with?

Patient Experience Department, Non-Clinical Risk Management Department, Legal Services Department, Safety Committee.

What are the gaps and how do you plan to collect what is missing?

N/A

Step 3 – What is the impact?

Using the information from Step 2 explain if there is an impact or potential for impact on staff or people in the community with characteristics protected under the Equality Act 2010?

Ethnicity or Race

No

Sex/Gender

No

Age

No

Disability

No

Religion or Belief

No

Sexual Orientation

No

Marriage and Civil Partnership

No

Pregnancy and Maternity

No

Gender Reassignment

No

Other socially excluded groups or communities e.g. rural community, socially excluded, carers, areas of deprivation, low literacy skills

No

Step 4 – What are the differences?

Are any groups affected in a different way to others as a result of the policy, procedure, project, decision, function or service?

No

Does your policy, procedure, project, decision, function or service discriminate against anyone with characteristics protected under the Equality Act?

No

If yes, explain the justification for this. If it cannot be justified, how are you going to change it to remove or mitigate the affect?

N/A

Step 5 – Make a decision based on steps 2 - 4

If you are in a position to introduce the policy, procedure, project, decision, function or service? Clearly show how this has been decided.

Agreed at Safety Committee and approved at the Quality & Healthcare Governance Committee

If you are in a position to introduce the policy, procedure, project, decision, function or service, but still have information to collect, changes to make or actions to complete to ensure all people affected have been covered please list:

N/A

How are you going to monitor this policy, procedure, project or service, how often and who will be responsible?

Monitoring will be carried via investigation of incidents, trends and audits