Incident Reporting Policy and Procedures
August 2014
TRUST POLICY DOCUMENT

Policy Title: Incident Reporting Policy and Procedures

Policy Reference No: MED08/008

Implementation Date: November 2008

Revised: October 2012

October 2013

August 2014

Review Date: August 2017

Responsible Officer: Medical Director
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1.0 INTRODUCTION

1.1 The Western Health and Social Care Trust (“the Trust”) is committed to the on-going development of a safer service and improved clinical and social care for its patients, clients, visitors and staff. It recognises that no health and social care environment will ever be absolutely safe and, on occasions, errors or incidents will occur. Equally it recognises that when incidents occur it is important to identify causes to ensure that lessons are learned to prevent recurrence.

1.2 This document replaces the Western Health & Social Care Trust Incident Reporting Policy and Procedures dated October 2012.

1.3 Trust staff must report all incidents, both actual and ‘near misses’, so that real opportunities for improvement and risk reduction are taken. To enable this to occur, staff must make themselves fully aware of this policy and the arrangements in place for the management, reporting and investigation of incidents. Professional staff should also ensure they comply with their own professional guidelines (e.g. General Medical Council, Nursing & Midwifery Council, Northern Ireland Social Care Council) regarding the reporting and investigation of incidents. Members of Trust staff must ensure that incident reports are made promptly and accurately.

1.4 The Trust wishes to make it clear that incident reporting will not result in disciplinary proceedings, except in the most exceptional circumstances, for example where there has been a breach of law, gross negligence or professional misconduct.

1.5 This policy operates in support of and in conjunction with existing external statutory reporting requirements, such as to the Health & Social Care Board (HSCB), Regulation & Quality Improvement Authority (RQIA), Health & Safety Executive Northern Ireland (HSENI), Northern Ireland Adverse Incident Centre (NIAIC), Department of Health & Social Services and Public Safety Northern Ireland (DHSSPSNI), Police Service of Northern Ireland (PSNI), and HM Coroner.

1.6 This policy has been developed to complement arrangements set out in the following DHSSPSNI and Trust policies and procedures:

- HSCB Serious Adverse Incident Procedure October 2013
- Risk Management Policy
- Falls Prevention Policy
- Health & Safety Policy
- Public Interest Disclosure (Whistle-blowing) Policy
- Guidance on Risk Assessment
- Infection Prevention and Control Policies and Guidelines
- Theft, Fraud & Corruption Policy
- Major Emergency Plan
- Disciplinary Policy
- Zero Tolerance and Security Policy
- Harassment Policy
• Fire Safety Policy
• Protocol for Securing Records/Files (for Future Independent Inquiries or Case Management Reviews)
• Safeguarding Vulnerable Adults Regional Policy and Procedural Guidance 2006
• Protocol for Joint Investigation of Alleged and Suspected Cases of Abuse of Vulnerable Adults 2009
• Western Health & Social Care Trust Operational Guidelines for Adult Safeguarding 2010

This is not an exhaustive list. The above Policies and Procedures can be found on the Trust’s intranet site, and where a policy has been further referred to within this Policy, a web-link has been provided.

2.0 PURPOSE and OBJECTIVES OF THE POLICY

The main purpose and objectives of this Policy are:-

- To comply with relevant legislation and standards relating to the reporting of incidents.
- To ensure the Trust has a clearly defined responsibility and accountability framework in place to appropriately manage incidents.
- To ensure all incidents are dealt with appropriately and in a timely and consistent manner.
- To provide a means of analysing trends in incidents and identification of factors contributing to incidents to assist in implementation of service improvement and risk reduction strategies, thereby minimising risk to staff, patients, clients and visitors and the organisation.
- To provide a record of the circumstances of each incident, should this be required at a later date.

3.0 SCOPE OF POLICY

This policy applies to all employees of the Western Health & Social Care Trust and covers all aspects of the Trust’s business including incidents involving:-

• In-patients
• Out-patients
• Clients in receipt of domiciliary care services at home
• Clients in receipt of residential care (e.g. children and older people)
• Permanent and temporary staff
• Locum/agency staff
• Trade Union Representatives
• Visitors
• Volunteers
4.0 DEFINITIONS AND TYPES OF INCIDENTS

4.1 Incident Report Form

The Trust currently operates two methods of reporting an incident, as follows:-

- On-line reporting via Datix-Web (incidents are input via the Datix Incident Form 1 (DIF1) which is available on the Trust intranet under “Useful Links” (D). http://wto-apps/Datix/live/index.php. The majority of incidents are reported this way.

- Incident Report Forms contained within the A3 Incident Report books available in all wards/facilities (see Appendix A). This method of reporting should be used where staff have not yet been trained in the use of Datix-Web or in facilities without access to the intranet.

Where the term “incident report form” is referred to throughout this policy, it should be read as meaning either of the above reporting methods, unless stated otherwise.

4.2 Definition of “Incident”

The DHSSPSNI document “Safety First: A framework for Sustainable Improvement in the HPSS” defines an error or incident as

“Any event or circumstances that could have or did lead to harm, loss or damage to people, property, environment or reputation”.

This definition includes ‘near misses’ as it acknowledges that not all errors result in harm to patients and service users.

4.3. Examples of Types of Incidents

Examples of the type of incidents that must be reported are as follows:-

Clinical Care: Any event or omission arising during clinical care that resulted, or could have resulted, in unexpected physical or psychological harm to a patient or client. Examples include incorrect prescription, dispensing or administration of drugs, incorrect patient/client assessment or treatment, health records not available during consultation, misfiled notes, delayed diagnosis.
Social Care: Any event or omission arising during the provision of social care (either in a Trust or non-Trust facility or a patient/client’s home) that results, or could have resulted, in unexpected physical or psychological harm to a client/member/resident, for example, failure to provide an agreed service, self-harm, suicide, absconding by clients/residents or looked after children, unexplained/sudden absence of a vulnerable adult in receipt of a social care service.

Personal Accident: Slips/trips/falls, cuts, moving and handling incidents, needle stick injuries, electrocution, etc.

Violence/Abuse: Assault (physical, verbal or sexual); violent, aggressive or severely disruptive behaviour by patients, clients, staff, visitors, relatives, or member of the public.

Security: Break-in, vandalism, damage to property, theft. Any breach of information security involving the confidentiality, integrity or availability of data (both hard copy and electronic data).

Equipment: Equipment failures, malfunctions etc. of medical and non-medical equipment or plant, unavailability of equipment.

Fire: Actual fires (whether by arson or unintentional). NB: Unwanted fire alarm activations should not be reported via Datix, but should be recorded in 'Fire Alarm Report Book' and copy forwarded to Trust Fire Safety Department

Data Breach: Where technical and/or organisational failing has resulted in the unauthorised or unlawful processing of personal data, including accidental loss, disclosure, destruction of, or damage to, personal identifiable information about patients, clients or staff.

Major Incidents reportable under the Emergency Planning Policy: Serious accidents causing many casualties; developing infectious disease epidemic; terrorism, accidental major chemical/biological/radiological/nuclear release/explosion; failure of utilities; natural disaster (e.g. flooding), or other incident that could cause many people to be injured, made homeless or have their normal lives disrupted. Please refer to the Trust’s Emergency Planning Policy at http://whsct/IntranetNew/Documents/Emergency%20PlanningPolicy.pdf

Other: Incidents that do not fall into any of the aforementioned categories.

The examples provided above are not an exhaustive list. If a staff member is uncertain whether to report an incident they should refer to their line manager in the first instance or contact the Risk Management Department at MDEC.
All reported incidents are recorded on the Trust incident reporting database (Datix) and categorised using the Common Classification System (CCS) Codes.

4.4 Incidents involving Physical or Verbal Abuse


4.5 Incidents Involving Vulnerable Adults


Where a concern has been raised which indicates that a client/patient has been abused by an employee of the Trust, or an employee of an Independent Care Provider, an incident report form must be completed and a referral made to a Designated Officer. If a member of staff is unsure whether to report an incident, they should refer to their line manager or a Designated Officer within their Directorate for guidance.

4.6 Incidents relating to Children in Need and Looked After Children

All incidents relating to Children in Need and Looked After Children must be reported via the Trust’s incident report form. Arrangements are in place to ensure that incidents are then reported to the HSCB in accordance with the letter from the Director of Social Care and Children, HSCB, dated 16 August 2010 entitled “Reporting of Untoward Events relating to Children in Need and Looked After Children”.

As well as reporting incidents referred to under point 4.3 above, the following circumstances should also be reported:-

- The admission of under-18s to adult mental health and learning disability facilities.
- Children from a Looked After background who abscond from care settings, which includes trafficked children and unaccompanied/asylum seeking children.
- Children from a Looked After background who are admitted to the Juvenile Justice Centre or Young Offenders Centre.
- Placements outside of the regulated provision for 16-17 year olds.
- Serious incidents necessitating calling the police to a children’s residential home.
4.7 Health Care Associated Infection (HCAI) incidents

Health Care Acquired Infections must be reported in accordance with the incident reporting policy and the level of investigation will be determined by the grading. Root cause analysis must be completed where healthcare interventions may have resulted in infection.

4.8 Discrepant Diagnostic Reports

Discrepant reports in diagnostics (radiology, pathology and endoscopy) should be reviewed by an appropriate multidisciplinary team. The patient impact of such reports should be assessed using the trust risk rating matrix and impact assessment table, and appropriate cases logged on Datix as an incident.

4.9 Serious Adverse Incident Criteria

Certain incidents by their nature are considered to be a “Serious Adverse Incident” (SAI) and are reportable to the Health & Social Care Board (HSCB).

The following criteria will determine whether or not an adverse incident constitutes an SAI.

- serious injury to, or the unexpected/unexplained death of:
  - a service user (including those events which should be reviewed through a significant event audit)
  - a staff member in the course of their work
  - a member of the public whilst visiting a HSC facility;

- any death of a child in receipt of HSC services (up to eighteenth birthday). This includes hospital and community services, a Looked After Child or a child whose name is on the Child Protection Register;

- unexpected serious risk to a service user and/or staff member and/or member of the public;

- unexpected or significant threat to provide service and/or maintain business continuity;

- serious self-harm or serious assault (including attempted suicide, homicide and sexual assaults) by a service user, a member of staff or a member of the public within any healthcare facility providing a commissioned service;

- serious self-harm or serious assault (including homicide and sexual assaults) on other service users,
- on staff or
- on members of the public by a service user in the community who has a mental illness or disorder (as defined within the Mental Health (NI) Order 1986) and known to/referred to mental health and related services (including CAMHS, psychiatry of old age or leaving and aftercare services) and/or learning disability services, in the 12 months prior to the incident;

- suspected suicide of a service user who has a mental illness or disorder (as defined within the Mental Health (NI) Order 1986) and known to/referred to mental health and related services (including CAMHS, psychiatry of old age or leaving and aftercare services) and/or learning disability services, in the 12 months prior to the incident;

- serious incidents of public interest or concern relating to:
  - any of the criteria above
  - theft, fraud, information breaches or data losses
  - a member of HSC staff or independent practitioner.

The new HSC Regional Risk Matrix, implemented within the Trust from 1 October 2013, may assist staff to determine the level of ‘seriousness’ of an incident. The Matrix is included at Appendix E of this Policy.

Any incident which meets one or more of the above criteria should be notified immediately to the Risk Management Department Hotline (Direct Dial Number 028 71611493) before the end of the working shift by the relevant duty manager for onward reporting to the HSCB and, where relevant, the RQIA.

Please see Point 7.2 below for further information on reporting SAIs.

4.10 Reporting of Serious Data Breaches to the Information Commissioner

The seventh principle of the Data Protection Act 1998 (DPA) requires that ‘appropriate technical and organisational measures shall be taken against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data’.

An incident report form should be submitted for all data breaches. The Senior Information Risk Owner and the Head of Records and Information Governance will then determine whether the data breach should be reported to the Information Commissioner’s Office after considering the following:-

- Potential detriment to individuals
- Volume of data affected
- Sensitivity of data

The ICO will assess the nature and seriousness of the data breach and the adequacy of any remedial action taken, and will define a course of action to be taken.
It is the responsibility of the manager of the area where the data breach occurred, or those with responsibility for the information / records involved, to investigate the incident and up-date the Trust's incident reporting system (Datix), whether or not the incident is reported to the ICO.

Managers with corporate responsibility for particular areas also need to be informed of and/or involved in the investigation to ensure that appropriate action is being taken to resolve the issue and that learning is appropriately disseminated.

5.0 ROLES AND RESPONSIBILITIES

**Chief Executive**, as Accountable Officer is responsible for ensuring incidents are managed appropriately in accordance with Trust policies and external statutory reporting requirements. The Chief Executive is also responsible for implementation of a safety conscious culture within the organisation.

**Lead Director** – The Chief Executive has nominated the Medical Director as the nominated Director with lead responsibility for ensuring appropriate policies are in place to enable effective management of incidents to include reporting, analysing, implementation of remedial action and that learning is incorporated into professional practice, systems and procedures.

**All Directors and Assistant Directors** – are responsible for:
- Dissemination of this policy and procedures within their area of responsibility and ensuring its promotion and implementation by providing support and advice to managers and staff within their remit.
- Ensuring that incidents are reviewed within their area of service, implementing any recommendations made as a result of investigation, and provision of feedback to relevant staff.
- Ensuring that any Directorate specific and Trust-wide learning is identified and communicated to the appropriate staff.
- Monitoring progress of investigations and closure of incidents.
- Ensuring that all staff have access to advice and training on incident reporting and management.
- Ensuring that appropriate senior staff are identified and receive training in incident investigation/Root Cause Analysis.
- Ensuring that action plans developed in response to incident investigation/root cause analysis are monitored through to implementation and completion.

**Head of Clinical Quality & Safety (HCQS)** is responsible for the development and implementation of this policy and associated procedures. The HCQS will be required to provide an assurance to the Governance Committee that the reporting arrangements are robust and appropriate and will be required to identify trends to Trust Directorates on the nature and frequency of incidents within their respective remits. The HCQS will provide advice and leadership to all Healthcare Professionals and will establish and maintain effective communication systems to ensure that information and learning is acted on in a timely manner and shared across the organisation. HCQS will participate, in conjunction with other managers, in the appropriate follow-up, investigation and
'root cause analysis' of serious incidents to ensure that learning and improvement is identified and disseminated across the Trust.

**Corporate Risk Manager (CRM)** is responsible for promoting the comprehensive and consistent reporting of incidents across the Trust and ensuring the development and maintenance of an efficient and effective and integrated risk management information system (Datix) for their recording, analysis and further action as might be required.

CRM will ensure the Trust's compliance with requirements in respect of the reporting to relevant external agencies of any incident or Serious Adverse Incident occurring within the Trust.

The Risk Management Department under the CRM's guidance, will maintain a database of incidents and SAIs, which will include learning identified.

CRM will participate, in conjunction with other managers, in the appropriate follow-up, investigation and 'root cause analysis' of serious incidents to ensure that learning and improvement is identified and disseminated across the Trust.

**Managers / Team Leaders / Supervisors / Persons in Charge** must

- Ensure all staff within their control understand and follow the reporting procedure.
- Ensure that the Incident Reporting Form is completed as soon as possible and forwarded to the Risk Management Department based in Trust Headquarters, MDEC Building, Altnagelvin Hospital no later than 5 working days post incident.
- Review all incident reports and ensure remedial (immediate and planned) action is implemented where necessary.
- Be involved in carrying out incident investigations within their area of responsibility.
- Maintain appropriate records including recording of follow-up action, lessons learned and appropriate closure of incidents.
- Review, where appropriate, a current risk assessment or undertake a new assessment following an incident.
- Complete local remedial and learning actions agreed as part of the incident investigation/root cause analysis.
- Provide feedback to staff (see point 11 below).

**All Employees** must

- Take all reasonable steps to minimise the risk of incidents occurring.
- Report to their line manager immediately (if this is not possible, no later than the end of their working shift) any incident they witness, are involved in or are informed of.
- Be aware of the location of the A3 Incident Report Book or, as Datix-Web ‘on-line’ reporting is rolled out, ensure they are aware how to utilise this method of reporting.
- Record all facts (not opinion) on the Trust’s A3 Incident Reporting Form or on-line reporting form within the stipulated timescales.
• Record appropriate details in the patient/client notes. **Please note that A3 Incident report forms or statements, or any other report produced in connection with the incident, MUST NOT be filed in patient/client notes.** However, it is important that an entry is made in the notes that an incident form has been completed. The A3 incident report number/Datix-Web reference number should be included in the entry in the patient/client notes.

• Co-operate fully with any incident investigation and provide written statements where necessary, either at the time of the incident or, if requested to do so, at a later date.

• Ensure that any equipment or material evidence involved in an incident is withdrawn from further use if it is suspected to be faulty, or to have contributed to the incident, and retained securely for subsequent investigation. This includes any clinical equipment attached to a patient at the time of death.

• Attend education/training/awareness sessions in relation to incident reporting and management

• Implement learning.

6. ACTION TO TAKE FOLLOWING AN INCIDENT

6.1 Immediate Action to be taken at the Scene of an Incident

The following provides guidance on the immediate steps that should be taken when an incident has occurred:

• The injured person or damaged property should be assessed immediately, to ascertain extent of injury/damage and identify first aid or emergency treatment, or other action required to minimise the extent of injury or damage.

• For patient/client care related incidents, contact the relevant medical team to assess. Refer as appropriate for medical/other opinion.

• Trust Security staff and/or the police are informed in the event of an actual or threatened assault, or if a potential criminal act has occurred. Also see point 6.2 below.

• The environment must be made safe to prevent further accidents or incidents and to safeguard the health, safety, welfare and security of others.

• The patient/client and/or their relatives should be informed, as soon as possible of the incident and advised of any treatment that may be necessary. This should be done before the media are involved if there is a likelihood of media interest.

• Any equipment involved in the incident which appears to have been faulty should be removed from use and clearly labelled “Do not use” until appropriate checks can be carried out. This includes any clinical equipment attached to a patient at the time of death.

• Patient/client records should be obtained and, depending on the seriousness/nature of the incident, secured to ensure all recorded information is available and cannot be altered in any way. Retrospective notes are permitted as long as these are clearly marked as
being made in retrospect. This is particularly important when there is likely to be a Co-operating to Safeguard Investigation (Children’s Order). Please refer to the Protocol for Securing Records/Files for Future Independent Inquiries or Case Management Review.

- If the original patient/client records are required by an external agency, e.g. PSNI/Coroner’s office, a photocopy of the notes must be taken and retained prior to handing over the original notes. A receipt for the original records must be obtained from the requesting agency. Any queries relating to the handover of original notes to external agencies should be directed to the relevant senior Manager in the first instance. If necessary, further advice may be sought from the Head of Clinical Quality & Safety or Corporate Risk Manager, MDEC Building, Altnagelvin Hospital (Tel No: 028 71345171 extensions 214125 or 214129).

- Any incident involving a patient or client, and the action taken, must be recorded in their healthcare record. However, the incident report form should not be filed within the patient/client’s notes.

- Where Closed Circuit Television (CCTV) is in-situ, it should be reviewed to determine if there is any relevant footage available, by the appropriate manager in accordance with the site specific CCTV code of practice. A copy of any relevant recorded footage of the incident should be made and retained.

- All evidence must be retained intact and in safekeeping for examination, e.g. photographs taken at the scene, equipment (including any attached to the patient at the time of death) and consumables (including packaging) that were part of the incident, records, documents and reports etc. Also see point 6.2 below.

- Any defective drugs or associated equipment used for their administration are withdrawn from use and retained as stated above. Also see point 6.2 below.

- Depending on the circumstances/severity of the incident, appropriate line managers/out of hour’s management/on-call staff/senior managers should be contacted as appropriate.

- Consideration should also be given to the need to activate site based emergency/contingency plans if necessary (in line with current emergency procedures).

6.2 Preserving the Scene of an Incident

Depending on the seriousness/nature of an incident, once any emergency care has been administered and immediate hazards have been removed, it may be necessary to preserve the scene of the incident until the relevant Senior Manager or Police have inspected it. This is particularly important where there is involvement of the Coroner’s office.

Important evidence, such as broken equipment, should not be destroyed or disposed of, but taken out of service and kept securely by the Senior Manager, pending further investigation.
7.0 REPORTING PROCEDURES

7.1 Reporting Incidents

A flowchart for reporting incidents is provided at Appendix B. Further details are provided below.

- Primary concern must be for the welfare of the individual(s) affected by the incident. This may require the nomination of a lead person to coordinate the immediate actions required following the incident so that the safety and care and services to other patients/clients are maintained. See Section 6.1 above.

- The individual staff member directly involved in, present at the time of an incident or to whom an incident is reported (e.g. from a member of the public or visitor) is required to complete the incident report form. This should be done as soon as possible after the incident and prior to the end of the working shift. This may be done in conjunction with their line manager or person in charge at the time of incident.

- Incident report forms should provide a clear and factual description of the circumstances of the incident. Opinion should not be provided. Abbreviations may be used, but only if they are explained in the first instance.

- Do not make offensive, personal or humorous comments.

- Where the A3 incident report form is used, or handwritten statements are provided, handwriting must be legible.

- Do not erase, overwrite or ink out entries made on A3 reporting forms. Errors or alterations should be scored out with a single line, the corrected entry written alongside and this should then be dated and signed.

- All persons involved in the incident must be clearly identified on the incident report (i.e. individual client/patient/staff/student member(s) adversely affected, staff involved in the incident itself, and witnesses to the incident). Named individuals will then be linked by Risk Management staff as “Contacts” on the Datix-system.

- Separate statements may be provided where there is insufficient space to record information on the incident report form. Depending on the circumstances, statements should also be sought from staff/students involved in the incident or who witnessed events, as appropriate. Statements must be signed and dated. Original statements should be forwarded to the Risk Management Department with the incident report form, or at a later date if this is not possible. Datix Handlers (i.e. facility/ward managers with access to Datix-Web) should attach a copy of statements to the relevant Datix record. Where access to Datix-Web is not yet available, this will be done by Risk Management staff.
• Patient/client records relevant to the incident should be retained within the patient/clients records. Copies of any relevant entries should not be attached to Datix.

• All medication incidents will be brought to the attention of the Medicines Governance Pharmacist who will consider whether completion of a medication incident statement is required. The Medicines Governance Pharmacist will contact relevant staff direct in this regard. The form is provided at “Appendix D” and can be found on the Trust intranet under the “Medicines” section.

• All falls incidents require completion of the Inpatient Falls Algorithm by the doctor treating the patient following the fall.

• Incidents involving nursing and midwifery students should be referred by the mentor to the Practice Education Team and University Link Lecturer. Consideration of the continued suitability of the practice area for students must be discussed with the Practice Education Co-ordinator. If the area is deemed unsuitable this must be communicated to the Education Providers through the Trust Executive Director of Nursing.

• Managers/Handlers with access to the DIF2 section of Datix-Web may amend incident reports if there are errors or inadequacies in the report provided, for example
  - the description of the incident is factually incorrect;
  - the description of the incident does not provide adequate information;
  - there are grammatical/typographic errors
  - names of staff have been included in free text fields

Any material amendments (e.g. description of incident) must be discussed and agreed with the member of staff who reported the incident.

NB: The Datix-web system has an audit trail function which identifies amendments made, when and by whom.

• Further guidance on completion of the A3 incident report form is available on the buff coloured pages at the front of Incident Report Books. Guidance on completion of the on-line incident report form is provided by way of labels and prompts against each field.

• If information is received subsequent to submitting an incident report which may affect the grading or description of events (e.g. injuries or damage subsequently detected, or deterioration in patient/client's condition) this must be recorded, either by Managers recording on Datix-Web DIF2 section (where available) or by communication to the Risk Management staff who will amend the Datix record accordingly.

• All A3 incident reports should be forwarded to the Line Manager/Person in charge at time and place of incident within 24 hours of the incident
occurring for sign-off. Incident reports submitted on-line will automatically be forwarded to the allocated Handler for review. The manager reviewing the incident report should ensure that all relevant information has been accurately recorded.

- The Person in Charge at time and place of the incident must notify their Head of Service/Senior Manager/Senior Professional lead of all extreme (red) rated incidents and high (amber) rated incidents which are deemed to be serious enough to require immediate attention.

- The Person in Charge at the time and place of incident must contact the on-call contact if the incident occurs out of normal working hours, e.g. the Night Sister/on call senior manager/out of hours social worker as appropriate.

- Depending on the nature and circumstances of the incident, the Person in Charge at time and place of incident may wish to consider contacting the PSNI.

- Serious adverse incidents, (see point 4.9 for criteria and 7.2 below for process) must be reported through to the Director/Assistant Director/Professional Lead for the area concerned before the end of the working shift by the relevant duty manager.

- The white copy of the completed A3 incident forms must be sent to the Risk Management Department within 5 working days following the incident, for inputting on to Datix. The address is as follows:

  Risk Management Department  
  Trust Headquarters  
  MDEC Building  
  Altnagelvin Hospital  
  Glenshane Road  
  Londonderry  
  BT47 6SB

  The pink copy must be forwarded to the relevant Head of Service.  
The yellow copy must be retained in the Incident Reporting Book.

  Incident reports **should not** be filed in the patient’s records.

  Incident reports **must not** be shared with Education Providers.

  Members of staff using the Datix-Web on-line reporting method are advised to print a copy of the incident report for their records and retain this in a central file within the ward/department/facility.

- The Datix-Web system has been set-up to provide automatic e-mail alerts to appropriate managers each time an incident is input. These alerts are triggered depending on a number of factors including the location, type, and grade of the incident.
If a member of staff is concerned about the appropriateness of completion of an incident form he/she should contact a member of the Risk Management Team for advice.

If a member of staff is unable to complete an incident form, for example, due to disability or where English is not their first language, he/she should contact the a member of the Risk Management Team (contact details above) so that assistance can be provided and the incident documented accordingly.

### 7.2 Reporting Serious Adverse Incidents

As from 1 October 2013, a new criteria for Serious Adverse Incidents (SAIs) was implemented, as set out at **Point 4.9** above.

Serious adverse incidents must be reported to the Incident Reporting Hotline (Direct Dial Number 028 71611493) before the end of the working shift by the relevant duty manager. This is in addition to completion of the A3 incident report form or reporting the incident via Datix-Web.

Incidents occurring out-of-hours may also be reported via the Hotline number where staff can leave a voicemail message.

The hotline is regularly checked by Risk Management staff.

The following information will be required when reporting SAIs via the hotline:-

- Date and time of incident
- Location
- Description of Incident
- Directorate/Sub-Directorate
- Immediate Action Taken
- Other organisations that have been informed of the incident, e.g. PSNI, Coroner, RQIA.
- Names of key staff involved
- Contact details of member of staff reporting the incident
- In cases of incidents involving patients/clients, whether the patient/client and/or their family have been informed that the incident has occurred and will be reported as an SAI.

If you have any doubts as to whether an incident should be reported as a Serious Adverse Incident, please contact the Risk Management Department on the Hotline number above or ring 028 71345171 exts 214133, 214135 or 214136.

The Risk Management Department will prepare a notification report using a standard proforma provided by the HSCB. The relevant Trust Director and Head of Clinical Quality and Safety will approve the proforma. This will then be forwarded to the HSCB (and RQIA where appropriate), and copied to the Chief Executive, Deputy Chief Executive, Medical Director, Director of Nursing,
relevant Trust Director(s) and Assistant Director(s), Investigation Lead, Head of Clinical Quality & Safety, and Corporate Risk Manager.

The Risk Management Department will act as the point of contact for the HSCB/RQIA should they require any further information. The Risk Management Department will liaise with the Investigation Lead and relevant Managers regarding timescales and documentation for completion of the SAI investigation report and co-ordinate feedback to the HSCB/RQIA within timescales given.

7.3 Early Alert System

In accordance with DHSSPSNI Circular HSC (SQSD) 10/2010 - Establishment of an Early Alert System, which is available at:
http://whsct/IntranetNew/intranet%20documents/Useful%20documents/HSC%20(SQSD)%2010-10.pdf a senior person from the organisation, at Director level or higher, must communicate with the senior member of staff in the Department of Health, Social Services and Public Safety for Northern Ireland, (i.e. Deputy Secretary, Chief Professional Officer or Assistant Secretary, and an equivalent senior Executive in the HSCB and the Public Health Agency, as appropriate) regarding any event which meets the criteria for Early Alert reporting as per the Circular. The Risk Management Department will submit the appropriate form.

7.4 Raising Concerns

On occasions staff may wish to raise concerns regarding an issue which does not relate to one specific “incident”. In the first instance staff should report these concerns using the Trust Incident Reporting mechanism and notify their line manager, Clinical Lead, Divisional Lead or Assistant Director, as appropriate.

This does not exclude staff from raising concerns under the Public Interest Disclosure (Whistle-Blowing) Policy where appropriate.

The Risk Management Department will also record concerns raised in writing by clinicians to the Medical Director on the Datix system, and investigation and closure will be monitored.

Where a risk cannot be managed at a local level, the relevant manager should consider including the risk on the Trust’s Risk Register as per the Risk Management Policy.

A ‘Word’ version of the “new risk form” is posted on the Trust’s intranet adjacent to the Strategy.
7.5 External Reporting Arrangements

On occasions, other organisations must be notified of an incident in accordance with legislation or HSC/DHSSPSNI procedures.

The Risk Management Department will be responsible for reporting the following:

- Serious Adverse Incidents to the HSCB/PHA (and where relevant, RQIA) (see 7.3 above),
- Early Alerts to DHSSPSNI (see 7.4 above), and
- Injuries, diseases, and dangerous occurrences to the Health & Safety Executive for NI or relevant Local Authority (see point 7.7 below).

Heads of Service/Senior Managers in charge at time of the incident or their delegated officer/Professional Lead, will be responsible for ensuring other relevant external organisations are notified as appropriate, e.g. PSNI, HM Coroner and RQIA.

Where the PSNI are called to attend, or notified of, an incident, it is generally the responsibility of the relevant manager to follow-up with the PSNI on the outcome of their investigation. However, it is recognised that some more serious incidents may require senior managers/Directors to liaise with the PSNI. The outcome of PSNI investigations must be recorded on the Datix incident database. Any concerns regarding the PSNI’s response to an incident must be communicated to the Trust Police Liaison Officer for the relevant Directorate, in order that appropriate action can be taken.

Where incidents highlight serious concerns regarding the behaviour or practice of Trust employed professional staff, the Trust’s Medical Director/Director of Nursing/Director of Social Services (as applicable) will be responsible for reporting to relevant appropriate professional bodies.

Where a member of staff who is employed via an agency/contractor is involved in an incident whilst working in Trust facilities, it is the responsibility of their employer to report as appropriate to relevant professional bodies. However, the appropriate Trust manager must ensure that any concerns are highlighted immediately to the employing agency/contractor.

Members of staff are reminded of their responsibilities regarding reporting of deaths to the Coroner. Please refer to page 17 of the DHSSPS Guidance on Death, Stillbirth & Cremation Certification. This guidance is available in each ward and at http://whsct/intranetnew/intranet documents/useful documents/Guidance on Death Stillbirth and Cremation Certification.pdf.

7.6 Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (NI) 1997 (RIDDOR)

If a death, major injury or dangerous occurrence occurs as a result of a work-related incident, managers should contact the Trust’s Health & Safety Officer on extension 214120 to verbally report the incident prior to submitting the incident report form. The Health & Safety Officer will then decide if the
incident is reportable under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (NI) 1997 (RIDDOR) and, if so, notify the Health & Safety Executive Northern Ireland (HSENI) or relevant Local Authority (as appropriate).

Reportable major injuries are as follows:

- Fracture other than to fingers, thumbs or toes;
- Amputation
- Dislocation of the shoulder, hip, knee or spine;
- Loss of sight (temporary or permanent);
- Chemical or hot metal burn to the eye or any penetrating injury to the eye;
- Injury resulting from an electric shock or electrical burn leading to unconsciousness or requiring resuscitation or admittance to hospital for more than 24 hours;
- Unconsciousness caused by asphyxia or exposure to harmful substance or biological agent;
- Acute illness requiring medical treatment, or loss of consciousness arising from absorption of any substance by inhalation, ingestion or through the skin;
- Acute illness requiring medical treatment where there is reason to believe that this resulted from exposure to a biological agent or its toxins or infected material;
- Any other injury leading to hypothermia, heat induced illness or to unconsciousness; or requiring resuscitation; or requiring admittance to hospital for more than 24 hours.

Details of all injuries sustained must be clearly documented on the incident report.

If an injury is detected subsequent to an incident report being submitted, it is the responsibility of the manager of the facility where the incident occurred to provide details of the injury to the Trust’s Risk Management Department. A decision will then be made whether to report under RIDDOR.

The Occupational Health Department will notify managers if it is determined that a member of staff is suffering from a work-related disease or condition reportable under RIDDOR. The Manager must then submit an incident report to the Risk Management Department, so that the information may be recorded appropriately and provided to the HSENI.

All dangerous occurrences (even where no injury is sustained) must also be reported to the Risk Management Department.

Reportable dangerous occurrences, which may be relevant to the health & social environment, are summarised below:

- Collapse, overturning or failure of load-bearing parts of lifts and lifting equipment;
- Explosion, collapse or bursting of any closed vessel or associated pipework;
• Failure of any freight container in any of its load-bearing parts;
• Plant or equipment coming into contact with overhead power lines;
• Electrical short circuit or overload causing fire or explosion;
• Any unintentional explosion, misfire, failure of demolition to cause the intended collapse, projection of material beyond a site boundary, injury caused by an explosion;
• Accidental release of a biological agent likely to cause severe human illness;
• Failure of industrial radiography or irradiation equipment to de-energise or return to its safe position after the intended exposure period;
• Malfunction of breathing apparatus while in use or during testing immediately before use;
• Collapse or partial collapse of a scaffold over five metres high, or erected near water where there could be a risk of drowning after a fall;
• Dangerous occurrence at a pipeline;
• A dangerous substance being conveyed by road is involved in a fire or released;
• Unintended collapse of: any building or structure under construction, alteration or demolition where over five tonnes of material falls; a wall or floor in a place of work; any false-work;
• Explosion or fire causing suspension of normal work for over 24 hours;
• Sudden, uncontrolled release in a building of: 100kg or more of flammable liquid; 10kg of flammable liquid above its boiling point; 10kg or more of flammable gas; or of 500kg of these substances if the release is in the open air;
• Accident release of any substance which may damage health.

The Health & Safety Officer, in conjunction with relevant managers, will determine whether an incident meets the criteria of a reportable dangerous occurrence and, if so, submit the appropriate report to HSENI.

Please contact the Health & Safety Officer, Risk Management Department, MDEC, Altnagelvin Hospital, Tel No 028 71345171 ext 214120, for further advice regarding RIDDOR.

7.7 Reporting of Incidents to the Northern Ireland Adverse Incident Centre (NIAIC)

The key aim of the Northern Ireland Adverse Incident Centre (NIAIC) is to record and investigate reported incidents involving medical devices, non-medical equipment, plant and building items used within the healthcare environment in Northern Ireland and to issue warning notices and guidance to help prevent recurrence and avert patient, staff, client or user injury.


Adverse incidents involving a medical device, non-medical equipment or plant, or its instructions for use should be reported to NIAIC, especially if the incident has led to or, were it to occur again, could lead to:
• Death, life-threatening illness or injury
• Deterioration in health or permanent impairment of body structure or function
• The necessity for medical or surgical intervention (including implant revision)
• Hospitalisation or prolongation of existing hospitalisation
• Unreliable test results and associated risk of mis-diagnosis or inappropriate treatment
• Fetal distress, fetal death, congenital abnormality or birth defect
• Ongoing faults that successive service/maintenance visits have failed to rectify

Subject to the above, specific advice on reporting incidents involving coronary stents, hip and knee joints, and breast implants to the national registers should be followed. This advice is available on the MHRA website, along with a range of other product-specific information (www.mhra.gov.uk > Safety information > General safety information and advice > Product-specific information and advice). Please note that reporting to MHRA does not negate the requirement to report incidents within the Trust and to NIAIC.

Please also report potential problems that are part of an identified manageable risk as this can provide open learning to others and prevent the risk occurring.

Other minor safety or quality problems should also be reported as these can help demonstrate trends or highlight inadequate manufacturing or supply systems.

Incidents that appear to be caused by human error should also be reported to NIAIC because

• the error may be partly (or wholly) due to deficiencies in the design of the device or instructions for use
• they may prompt promulgation of advice or device design improvements that will help prevent repetition of mistakes.

Examples of medical devices, estates equipment and plant are provided at Appendix D.

Incidents involving equipment and medical devices will be notified to the Trust Nominated Liaison Officer/Senior Medical Engineering Manager (TNLO), Estates Department, and other relevant managers via automatic e-mail alerts.

Where the incident does not fall within the remit of the TNLO, he will inform the relevant manager. Relevant managers will include:-

- Quality Assurance Pharmacist
- Theatre Manager
- Radiology Manager
- Occupational Therapy Manager
- Manual Handling Advisers
The manager will review each incident to determine whether the equipment falls within their remit and, if so, decide whether the incident should be reported to NIAIC. They will also be responsible for completing and forwarding the Adverse Incident Report Form A1 to NIAIC, liaising with NIAIC regarding action required, feedback to relevant staff and closure of incident. Copies of the A1 report and correspondence from NIAIC must be attached to the relevant Datix record.

Risk Management staff will provide assistance to ensure that accurate information regarding incidents reported to NIAIC is available.

7.8 Reporting of Incidents identified by other HSC Trusts, Family Practitioner Services or Independent Sector Providers relating to Trust staff or services

Incidents involving concerns regarding Trust staff or services which have been identified by another HSC Trust, Family Practitioner Services or independent sector provider, should be referred to the Risk Management Department in the first instance. The Risk Management Department will ensure the incident is appropriately recorded on Datix and liaise with members of Trust staff re investigation and provision of a response to the reporting organisation.

7.9 Reporting of Incidents relating to services provided by other HSC Trust, Family Practitioner Services, or Independent Sector Providers

Incidents involving concerns regarding services provided by another HSC Trust, Family Practitioner Services or independent sector providers, should be reported in the normal way on the Trust’s incident report form. Risk Management staff will then liaise with the relevant organisation to request that the incident is reported and feedback provided to the Trust.

8.0 INCIDENT GRADING

All incidents must be graded at the time of reporting the incident using the regionally agreed Impact Assessment Table and Risk Evaluation Matrix (see Appendix E).

All incidents must be graded as follows:-

- **Step 1** - grade according to the **actual impact/severity** on the individual and/or organisation.
- **Step 2** – determine the **potential impact/severity** and **likelihood** of recurrence
- **Step 3** - calculate overall risk rating (i.e. Red, Amber, Yellow or Green)

Staff using the Datix on-line reporting form (DIF1) will be able to input this information directly onto the incident reporting form.

Staff using the A3 incident report book should risk assess the incident based on **potential** future risks and record this on the risk rating matrix on the form. Risk Management staff will determine the **actual impact/severity** based on information provided on the report and input this information onto Datix.
Step 1 – What is the actual impact/severity of the event?

Use the Impact Assessment Table at Appendix E to determine the actual impact/severity of the event by considering the outcome of the incident in terms of harm to:

- people
- quality & professional standards or guidelines/
- reputation,
- finance, information & assets, resources or
- environment.

If two or more areas have been affected by the incident, consider which has been affected the most to assist in your judgement of the impact/severity of the incident. The impact/severity categories are as follows:-

1. Insignificant
2. Minor
3. Moderate
4. Major
5. Catastrophic

This information will be recorded within the “Actual Impact/Severity” field within Datix.

Step 2 – Assessment of potential future risks

This grading is required to alert the organisation to incidents that, should they occur again in similar circumstances, have the potential for serious harm to services users/staff, or major impact on the organisation, in order that appropriate preventative measures may be implemented.

In order to obtain a realistic assessment of potential future risk you need to consider:-

- Potential Impact/Severity – Think about the potential impact if the incident were to occur again without having implemented further control measures to make the impact less severe and grade accordingly (refer to Table 1 above). You should also consider the most likely or typical impact for that type of incident.

- Likelihood - how likely it is that the event will occur again? This can be done by considering the likelihood table below and shown at Appendix E:

**Table 1 - Likelihood**

<table>
<thead>
<tr>
<th>Descriptor</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Almost Certain</td>
<td>Will undoubtedly happen/ recur on a frequent basis</td>
</tr>
<tr>
<td>Likely</td>
<td>Will probably happen/recur, but is not a persisting issue/circumstances</td>
</tr>
<tr>
<td>Possible</td>
<td>Might happen or recur occasionally</td>
</tr>
<tr>
<td>Unlikely</td>
<td>Do not expect it to happen/recur but it may do so</td>
</tr>
<tr>
<td>Rare</td>
<td>This will probably never happen/recur</td>
</tr>
</tbody>
</table>
Step 3 - What is the overall risk rating for this incident?

Plotting the Potential Impact/Severity and Likelihood on the risk rating matrix (Table 2 below) will give an overall risk rating for the incident.

NB: The grading will automatically be calculated when the incident is input onto Datix.

Table 2 - Risk Matrix

<table>
<thead>
<tr>
<th>Likelihood Scoring Descriptors</th>
<th>Insignificant (1)</th>
<th>Minor (2)</th>
<th>Moderate (3)</th>
<th>Major (4)</th>
<th>Catastrophic (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Almost Certain (5)</td>
<td>Medium</td>
<td>Medium</td>
<td>High</td>
<td>Extreme</td>
<td>Extreme</td>
</tr>
<tr>
<td>Likely (4)</td>
<td>Low</td>
<td>Medium</td>
<td>Medium</td>
<td>High</td>
<td>Extreme</td>
</tr>
<tr>
<td>Possible (3)</td>
<td>Low</td>
<td>Low</td>
<td>Medium</td>
<td>High</td>
<td>Extreme</td>
</tr>
<tr>
<td>Unlikely (2)</td>
<td>Low</td>
<td>Low</td>
<td>Medium</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Rare (1)</td>
<td>Low</td>
<td>Low</td>
<td>Medium</td>
<td>High</td>
<td>High</td>
</tr>
</tbody>
</table>

Grading of potential future risks following incidents helps to inform the extent of investigation required and the level at which investigation should be conducted. Grading should be based on best judgement taking into consideration all facts known about the incident at the time of occurrence. Depending on the findings during investigation, the grade may need to be amended. However, down-grading of red incidents should not be carried out unless approved by the Head of Clinical Quality & Safety.

9.0 INCIDENT INVESTIGATION AND CLOSURE

9.1 Extent of Investigation

Responsibility for investigation of incidents lies with the manager of the service that was responsible for one or more of the following:-

- The circumstances which led to the incident occurring
- The staff involved in the incident
- The equipment or other asset/facility involved in the incident

All incidents will be allocated a “Handler” on Datix, who will have responsibility for investigation of the incident and closure. If a Handler is of the view that they should not have responsibility for management of an incident, they should liaise with the appropriate manager to seek agreement for them to take on the role of Handler, and reallocate the incident accordingly. However, it should be noted that some investigations will require input from two or more service areas, and in these cases,
agreement should be sought on who will perform the role of Handler to ensure that Datix-Web is up-dated following investigation.

Advice regarding responsibility for investigation of incidents and the role of “Handlers” will be provided during Datix-Web training for managers. Alternatively, please contact Risk Management staff on 71345171 ext Nos 214133 / 34 / 35 / 36.

The investigation of incidents and ‘near misses’ must be thorough and comprehensive to ensure causes are identified and remedial action taken. Please refer to the table below for further information on the level of investigation required.

Should the circumstances of the incident be in dispute, or the veracity of any statements made be in doubt, it is important that any discrepancies are explored with those involved, or further enquiries made to support (or disprove) the version of events in question. This should be done at an early stage of the investigation.

Regardless of the grading of the incident, ‘action taken to prevent recurrence’ must be formally recorded in the Investigation section of Datix.

In addition, any ‘lessons learned’ should also be recorded in the Lessons Learned section of Datix. However, it should be noted that not every incident will result in new learning.

‘Lessons learned’ include issues that have not previously been identified as a risk (e.g., they may have been unforeseeable), identification of new methods of treatment/care/service provision that result in safer/higher quality care, or any other issues that need to be brought to the attention of staff within other Departments/Specialties/Departments as they are considered to be a Trust-wide risk, or need to be highlighted at regional/national level. The Risk Management Department will implement procedures to monitor the implementation of recommendations/lessons learned following investigation of Serious Adverse Incidents.

Staff are also encouraged to submit articles for inclusion in the Trust’s “Share to Learn” newsletter to highlight learning across the Trust. Please contact the Risk Management Department for further information.

Managers/Supervisors who have been trained on the use of Datix–Web (Handlers) must use the system to record this information. The Handler assigned to each incident has responsibility for ensuring that an appropriate level of investigation is carried out, all relevant information/documentation is attached to the Datix record, and that the incident is closed following completion of the investigation.

Where Managers/Supervisors do not yet have access to Datix-Web, the information must be provided to the Risk Management Department who will record on Datix. Arrangements are in place to support staff in this regard.

The extent of investigation required will be influenced by the grading:-
<table>
<thead>
<tr>
<th>Incident Grading/Type</th>
<th>Level of investigation required</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Green (Low)</strong></td>
<td>These incidents generally require minimum investigation that can be undertaken adequately by the ward/departmental manager. However, they must be monitored regularly to identify patterns or trends and, where necessary, develop and implement actions. It is acceptable for the ward/departmental manager to close such incidents following investigation and recording of findings and lessons learned on Datix. Investigation of this grade of incident should normally be completed and closed within 5 working days.</td>
</tr>
<tr>
<td><strong>Yellow (Medium)</strong></td>
<td>These incidents generally require minimum investigation that can be undertaken adequately by the ward/departmental manager. However, they must be monitored regularly to identify patterns or trends and, where necessary, develop and implement actions. It is acceptable for the ward/departmental manager to close such incidents following investigation and proper recording of findings and lessons learned on Datix. Investigation of this grade of incident should normally be completed and closed within 5 working days.</td>
</tr>
<tr>
<td><strong>Amber (High)</strong></td>
<td>The degree of seriousness of these incidents may require multi-disciplinary or independent investigation. The Head of Service/General Manager for the area where incident occurred is responsible for ensuring an appropriate level of investigation is conducted, formal recording and dissemination of findings, actions taken, lessons learned and closure of these incidents. Where necessary advice can be sought from the Head of Clinical Quality &amp; Safety or Corporate Risk Manager. Investigation of this grade of incident should normally be completed and closed within 20 working days.</td>
</tr>
<tr>
<td><strong>Red (Extreme)</strong></td>
<td>The Assistant Director for the Service area is responsible for ensuring that a thorough investigation is undertaken. The Assistant Director will agree with the Director and the Head of Clinical Quality and Safety whether a Root Cause Analysis is required and will appoint a lead investigating officer (who is appropriately trained), within 5 days of the incident being reported. The Risk Management Department maintains a list of staff trained in Root Cause Analysis. Investigation of this grade of incident should, where possible, be completed within 20 working days. However, it is recognised that this may not always be possible due to the complexity of these types of incidents. Closure or down-grading of red incidents requires approval by the Head of Clinical Quality &amp; Safety, who, in conjunction with the Corporate Risk Manager, will review investigation/closure of red incidents on a monthly basis.</td>
</tr>
<tr>
<td>Deaths</td>
<td>Where a death has occurred, the incident should be reported as a Serious Adverse Incident, and a Root Cause Analysis investigation should be undertaken. The Director will appoint a lead investigating officer (who is appropriately trained), within 5 days of the incident being reported. The Risk Management Department maintains a list of staff trained in Root Cause Analysis. Investigation of this grade of incident should, where possible, be completed within 20 working days. However, it is recognised that this may not always be possible due to the complexity of these types of incidents. Closure or down-grading of red incidents requires approval by the Head of Clinical Quality &amp; Safety, who, in conjunction with the Corporate Risk Manager, will review investigation/closure of red incidents on a monthly basis.</td>
</tr>
</tbody>
</table>
Incident Grading/Type | Level of investigation required
--- | ---
 | officer within 5 days of the incident being reported.  
The death should be reported to the Coroner. Please refer to page 17 of the DHSSPS Guidance on Death, Stillbirth & Cremation Certification. This guidance is available in each ward and at http://whsct/intranetnew/intranet/documents/useful/documents/Guidance_on_Death_Stillbirth_and_Cremation_Certification.pdf  
Please also refer to the Memorandum of Understanding where multiple agencies are involved. http://whsct/IntranetNew/intranet%20documents/Useful%20documents/mou_investigating_patient_or_client_safety_incidents.pdf.

Serious Adverse Incidents (SAIs) | The new SAI procedure has three levels of investigation as set out at point 9.2 below. The level of investigation required will depend on the circumstances and complexity of the SAI.  
Service Users and/or their family must be advised by the Investigation Lead that the incident has been reported to the HSCB and that a review is taking place. Depending on the circumstances, it may also be necessary to involve the service user or the family in the review process as appropriate. Following completion of the review the Service User and/or their family should be given the opportunity to meet with the Investigation Lead to discuss the outcome of the review  
The level of patient/client/family involvement must be clearly stated within the investigation report.  
The relevant Director must ensure that all Directorate specific recommendations are implemented and that any Trust-wide learning is shared with the Head of Clinical Quality & Safety.  
The Head of Clinical Quality & Safety will ensure that action taken, lessons learned, and closure of the incident is formally recorded on Datix and will also ensure that any Trust-wide learning is shared with all Directors via the Safety & Accountability Forum. This Forum will monitor progress of recommended actions.

9.2 Investigation of Serious Adverse Incidents

A new regional process for investigating SAIs was implemented on 1 April 2014.  
The level of investigation required will depend on the complexity of the incident. There are three levels of investigation as detailed below:-
Level 1 Investigation – Significant Event Audit (SEA)

Most SAI notifications will enter the investigation process at this level and an SEA will immediately be undertaken, and completed within 4 weeks of the SAI being reported (6 weeks by exception) to:-

- assess why and what has happened
- agree follow-up actions
- identify learning.

The possible outcomes from the investigation may include:-

- incident is closed – there is no new learning
- incident is closed – with learning
- incident requires level 2 or 3 investigation

Level 2 – Root Cause Analysis (RCA)

Following a SEA, some SAIs will be identified as requiring a Level 2 Root Cause Analysis (RCA) investigation. A number of senior Trust staff have received RCA training. A list of these staff is maintained by the Risk Management Department and may be referred to when deciding on membership of investigation teams.

Appendix F sets out the main steps required for a RCA Investigation.

When a Level 2 (or 3) investigation is instigated immediately following notification of a SAI, the Trust must inform the HSCB/PHA/RQIA, within 4 weeks, of the Terms of Reference and membership of the Investigation for consideration by the Designated Review Officer (DRO).

The investigation must be conducted to a high level of detail by a multi-disciplinary team and chaired by someone independent to the incident, but who can be within the same organisation. Level 2 RCA investigations may involve two or more organisations. In these instances, it is important a lead organisation is identified and that all organisations contribute and approve the final investigation report.

Level 2 investigation reports must be written in the relevant format (a template will be made available by Risk Management staff to the investigation team) and submitted to the HSCB within 12 weeks from the date the incident was discovered, or within 12 weeks from the date of the SEA. Each SAI report is reviewed by the Head of Clinical Quality & Safety and relevant Director and Assistant Director before it is submitted.

A brief guide to Root Cause Analysis is provided at Appendix F.

Level 3 – Independent Investigation

Level 3 investigations will be considered for SAIs that:-

- are particularly complex, involving multiple organisations;
- have a degree of technical complexity that requires independent expert advice;
- are very high profile and attracting a high level of both public and media attention.
In some cases, the whole team may be independent to the organisation(s) where the incident has occurred. The Chair and Membership of the investigation team and timescales for reporting the findings, will be agreed by the DRO at the outset.

A protocol has been developed for the investigation of specific SAIs which involve an alleged homicide perpetrated by a service with a mental illness or disorder (as defined within the Mental Health (NI) Order 1986) and known to/referred to mental health and/or learning disability services, in the 12 months (1 year) prior to the incident. The Protocol is available at Appendix 13 of the HSCB Serious Adverse Incident Procedure October 2013 which is available on the Trust intranet under “Useful Documents (S)”.  

9.3 Joint Investigation of Incidents with Other Organisations

A Memorandum of Understanding has been agreed between the DHSSPS on behalf of the Health and Personal Social Services (HPSS), PSNI, the NI Court Service (Coroners Service Branch) and the Health & Safety Executive (HSE) for Northern Ireland.


The purpose of the Memorandum is to promote effective working relationships between the organisations and will take effect in circumstances of an unexpected death or serious untoward harm involving patients or clients receiving care and treatment from the HPSS in Northern Ireland requiring investigation by the police (PSNI), coroner’s office or Health & Safety Executive Northern Ireland (HSENI) separately or jointly. This may be the case when an incident has arisen from or involved:

- Criminal intent, recklessness and/or gross negligence
- In the context of health and safety, a work-related death.

Further advice on the applicability of the Memorandum can be obtained from the Head of Clinical Quality and Safety or Corporate Risk Manager, Trust Headquarters, MDEC Building, Altnagelvin Hospital, Tel No 028 71345171 exts 214123 or 214129.

9.4 Reviews to be led by the Governance Team

On occasions it is evident that incidents which are serious and involve more than one Directorate or Division should be reviewed independently of the service involved. The Chief Executive, Medical Director or Service Director may ask the Head of Clinical Quality & Safety and/or others with specialist knowledge to lead on the Investigation. Examples include incidents which could attract media attention, incidents with a prima facie indication for potential immediate regional action, or incidents which may trigger a ‘look back’ exercise to review care/treatment provided to patients/clients over a specific period of time.
A root cause analysis must be undertaken and reports submitted in accordance with the timescales set out in the HSCB Serious Adverse Incident Procedure or as agreed with the Designated Review officer.

9.5 Completion of Investigation

Where relevant, written investigation reports must be shared with the professional member of staff with overall responsibility for the care of the patient/client, and any other member of staff who was directly involved in the incident, for comment and checking of factual accuracy.

The final version of the report should also be made available to these staff in order that they are aware of any recommendations personal to them. It is important that this is done on a timely basis. The Risk Management Department will implement procedures to monitor provision of feedback to staff, including junior medical staff and student nurses.

It should be noted that in cases where a disciplinary investigation is being contemplated and is referred to within an investigation report, consideration should be given to the extent to which this information is shared with the parties. Advice should be obtained from the Human Resources Directorate where necessary.

Generally investigations following incidents should normally be completed and closed within the timescales as set out in the table at 9.1 above. However, it is recognised that this may not always be possible depending on the seriousness, circumstances, and number of individuals involved.

Where incidents involve children or vulnerable adults, consideration must be given to the requirements of relevant regional protocols.

Following completion of investigation, staff charged with investigation of incidents must review the initial risk rating and amend, as necessary, to reflect more accurately the impact of the incident on the individuals concerned or the organisation. It is essential that ‘action taken to prevent recurrence’, ‘lessons learned’, and incident closure is recorded on Datix.

Any learning points, safety improvements or actions taken as a result of incident investigation must be brought to the appropriate Directorate and Sub-Directorate Governance Group and Ward/Department meetings for discussion, review of patterns/trends and consideration of ongoing risks for inclusion on risk registers. The Chairperson of the Directorate and Sub-Directorate Governance Group should consider opportunities for organisational learning and, as applicable, share across Directorates, the Trust and/or regionally.

10.0 COMMUNICATION

10.1 Communicating with Patients/Clients and/or Relatives

The lead member of staff responsible for the treatment and/or care will retain the responsibility for communicating with the patient/client and their relatives about the incident. However, there may also be a liaison person at a senior level identified to make contact with the family. The following points should be noted:
• Following an early/initial assessment, patients/clients and relatives (bearing in mind issues of patient/client confidentiality) should be provided with explanations of what has happened, why it happened, how it will be investigated and how lessons will be learned from the incident. However, if in conjunction with the relevant Assistant Director, the professional head/consultant considers there are compelling professional or other reasons not to discuss the incident with the patient/client’s relative(s) a clear record should be made of this in the patient/client records.

• The patient/client and/or relative(s) should be informed of any external organisation the Trust is reporting to and why. Where an incident is reported to the HSCB as a Serious Adverse Incident, the patient/client and/or relatives must be informed. Advice on the level of patient/client and/or family involvement will be provided to the Lead for each SAI investigation.

• If deemed appropriate, an apology should be given, acknowledging that an apology is not an admission of liability.

• If appropriate, a meeting should be offered to the patient/client and/or relative(s) with the relevant Trust personnel. A summary of the points discussed and any agreements made should form part of the overall investigative paper work and a copy provided to the patient/client and/or relative(s).

• The patient/client and/or relatives should be given the opportunity to meet with appropriate staff to get feedback from the investigation process.

Further guidance on communicating with patients/clients and their relatives is available in the Being Open Protocol. (web-link will be inserted once available).

10.2 Communicating with the Media

All communications with the media should be co-ordinated by the Head of Communications on behalf of the Office of the Chief Executive.

11.0 LEARNING, FEEDBACK AND SUPPORT FOR STAFF

It is important that the Trust learns from incidents that occur. Directorates must ensure that they have a system in place to identify and share learning, for example, by including this issue as a standing item on the agenda of Ward/Department/Sub-Directorate and Directorate Governance meetings.

Teams should review incidents as part of their internal governance arrangements so that they can work together to consider how to improve systems and processes.

Working Groups with corporate responsibility for specific areas of risk will also consider incident reports relevant to their area of responsibility to review trends and recommend and monitor action required.
The staff member who has led the incident investigation must ensure that appropriate feedback is provided to the person who reported the incident and any other staff involved (bearing in mind any staff confidentiality issues). In particular, staff who may have been involved in an error should be provided with appropriate support and, if necessary, training to improve their practice. Where a system error has been identified, staff should be advised of action being taken to improve systems to prevent recurrence.

Where Trust-wide learning has been identified, it is the responsibility of the member of staff leading the investigation to ensure that this is communicated to the appropriate managers/departments.

The Head of Clinical Quality & Safety will ensure that there has been appropriate feedback provided to those staff who report red incidents.

Reports on learning identified through the investigation process can be produced from Datix and will be provided to senior managers on a regular basis. Teams are also encouraged to avail of this facility. Please contact Risk Management staff at MDEC Building, Altnagelvin Hospital, Tel No 71345171, Ext Nos 214133/34/35.

The Quality & Safety Department will also produce a learning newsletter entitled “Share to Learn”. Directorates are encouraged to contribute to the production of this newsletter.

The Regional Health and Social Care Board (HSCB) and the Public Health Agency (PHA) are responsible for identifying and disseminating regional learning from Serious Adverse Incidents (SAIs), complaints and patient client experience.

Themes and regional learning is typically disseminated to HSC Trusts and other relevant organisations and/or providers through Learning Letters and the ‘Learning Matters’ newsletter.

To ensure that all regional learning is easily accessible by staff, the Learning Letters and Newsletter are available through the following link: http://intranet.hscb.hscni.net/documents/Safety_and_Quality_Learning_Letters.html. This link is also available on the intranet under ‘S’ in Useful Links.

Following an incident where a member of staff has been affected, the line manager should provide support and consider follow up action that may include:

- Formal/informal debriefing and support of staff individually or as a group
- Make staff aware of services provided by Occupational Health and the staff counselling service
- If the staff member is unable to attend work as a result of the incident, the absence should be managed in accordance with the Trust’s Policy on Managing Attendance at Work.

In the event of an employee becoming a victim of abuse or violence at work, Managers must ensure that appropriate support is given.

Where further investigation has been carried out, e.g. by another organisation, and/or remedial action taken, line managers, heads of service, assistant directors and
directors should ensure they have systems in place to provide feedback at a local level to members of staff who have reported or been involved/affected by the incident.

Where a member of staff has been injured as a result of a work-related incident they may be eligible to claim one or more of the following benefits:

- Temporary/permanent injury benefit
- Industrial Injuries Disablement Benefit
- Criminal Injuries Compensation Scheme (Incident needs to be reported to PSNI within 48 hours of occurrence)

Guidance on application for any of these benefits/schemes can be obtained from your Staffside/Trade Union organisation or by contacting:

**Temporary Injury Benefit** – WH&SCT Salaries & Wages Department, Lilac Villa, Gransha Park, Londonderry, Ext 212323.

**Permanent Injury Benefit** – Superannuation Branch, Duke Street, Waterside, Londonderry, BT47 6FP, Tel 71319000. Fax: 02871 319144, Web-site: [www.hscpensions.hscni.net](http://www.hscpensions.hscni.net)

**Industrial Injuries Disablement Benefit** – Industrial Injuries Branch, Castlecourt, Royal Avenue, Belfast, BT1 1SD. Tel: 028 9082 3318. Web-site: [http://www.nidirect.gov.uk/apply-for-industrial-injuries-disablement-benefit](http://www.nidirect.gov.uk/apply-for-industrial-injuries-disablement-benefit)

**Criminal Injury Compensation** – Compensation Services, 6th floor, Millennium House, 25 Great Victoria Street, Belfast BT2 7AQ. Telephone: 0300 200 7887. Web-site: [http://www.dojni.gov.uk/index/compensation-services.htm](http://www.dojni.gov.uk/index/compensation-services.htm)

### 12.0 EDUCATION AND TRAINING

All staff, including medical staff, must receive information regarding Incident Reporting and associated policy and procedures at time of induction. Information on incident reporting is provided as part of the Corporate Induction Programme and awareness training is provided on an ongoing basis.

Managers must ensure that all staff are made aware of location of Incident Reporting Policy and Procedures, the A3 incident Report Book and, as on-line reporting is rolled out, be afforded time to make themselves familiar with the process. Risk Management staff will provide training and support on incident reporting and use of Datix-Web.

Directors and senior managers must identify and facilitate training of their staff in use of Datix-Web to report, record follow up actions taken, lessons learned and closure of incidents.

Directors and senior managers must identify and facilitate training of their staff in incident investigation. The Quality & Safety Department will arrange for root cause analysis training to be provided for senior staff on an ongoing basis.

The Risk Management Team will produce quarterly reports on incidents for discussion at Directorate Governance meetings and the Trust’s Governance Committee. Any
identified unmet education and training needs in relation to incident reporting/investigation must be communicated to these forums so that appropriate action may be taken.

13. REVIEW OF POLICY

This policy will be reviewed in three years following approval, or sooner in the event of significant change in legislation, guidance or Trust practices.

14. EQUALITY & HUMAN RIGHTS

EQUALITY AND HUMAN RIGHTS STATEMENT: The Western Health and Social Care Trust's equality and human rights statutory obligations have been considered during the development of this policy.

Signed: _____________________________(Chairman) Date: __________2014
1. Which category best fits this incident?

<table>
<thead>
<tr>
<th>Clinical Care</th>
<th>Social Care</th>
<th>Personal Violence/Accident Abuse/Harassment</th>
<th>Security/Damage to Property</th>
<th>Equipment Fire Other</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

2. When and Where?

<table>
<thead>
<tr>
<th>Date of Incident</th>
<th>Time (24hr)</th>
<th>Facility/Hospital</th>
<th>Directorate</th>
<th>Ward/Department</th>
<th>Exact Location</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

3. Personal Details of Person Affected/Injured

<table>
<thead>
<tr>
<th>Title</th>
<th>Surname</th>
<th>First</th>
<th>Date of Birth</th>
<th>Address</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

Inpatient | Outpatient | Staff | Client/Resident | Looked After Child | Visitor | Other |
<table>
<thead>
<tr>
<th></th>
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<tbody>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient/Client/Staff Number</td>
<td>Delete as appropriate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. Other Persons Directly Involved In Incident

(incl. name, address, role/status e.g. nurse, doctor, inpatient/perpetrator, person supervising patient/resident , community care worker et al)

5. Did Anyone Witness the Incident? YES ☐ NO ☐

<table>
<thead>
<tr>
<th>Witness 1 (Forename, Surname, Address, Telephone &amp; Job Title)</th>
<th>Witness 2 (Forename, Surname, Address, Telephone &amp; Job Title)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Signature ………………………… Signature …………………………

Please provide details of additional witnesses & statements on separate page

6. Factual Description of Incident

Give brief details

7. For Clinical Incidents only – Insert Trigger List Codes

Refer to Specialty Trigger Lists

8. Nature of Injury?

9. Treatment Given?

| e.g. First Aid, A&E Dept, Occupational Health, Hospital Admission |

10. Contributing Factors? (Please list all factors which may have had an influence on this incident)

11. Medication Related Incidents Only

Give details e.g. Name of Drugs, Quantity, Lot No.

12. Equipment Related Incidents Only

Give details e.g. type, Model No & Asset No.

13. Outline Any Action Taken To Prevent Recurrence (IMMEDIATE and PLANNED FOLLOW-UP)

Give brief details

14. Police Informed?

| YES ☐ NO ☐ |

| Which Station? |

<table>
<thead>
<tr>
<th>Name of PSNI Officer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ref. No.</td>
</tr>
</tbody>
</table>

15. Reporting Details

Person Recording Incident

<table>
<thead>
<tr>
<th>Print Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Job Title</td>
</tr>
</tbody>
</table>

Signature: ………………………… Date & Time ……………

To Whom Was The Incident Reported?

<table>
<thead>
<tr>
<th>Full Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Job Title</td>
</tr>
</tbody>
</table>

Signature ………………………… Date ……………

Print Name

16. To Be Completed by Person In Charge at Time & Place of Incident

| Yes ☐ No ☐ N/A |

<table>
<thead>
<tr>
<th>Details of Person in Charge at Time &amp; Place of Incident</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full Name</td>
</tr>
<tr>
<td>Job Title</td>
</tr>
<tr>
<td>Tel. No.</td>
</tr>
<tr>
<td>Works Docket No. / Job Requisition No?</td>
</tr>
<tr>
<td>Does this incident relate to a research project?</td>
</tr>
<tr>
<td>YES ☐ NO ☐ N/A</td>
</tr>
</tbody>
</table>

| Ref. No |
| Patient/Client Informed? |
| Next of Kin/Relatives Informed? |
| Other Departments/External Bodies Informed? |
| E.g. SAI, Social Services, RQIA, Coroner, Mental Health Commission |

17. What Risk Classification Does This Incident Merit?

<table>
<thead>
<tr>
<th>Low</th>
<th>Medium</th>
<th>High</th>
<th>Extreme</th>
</tr>
</thead>
</table>

18. Details of Person in Charge at Time & Place of Incident

<table>
<thead>
<tr>
<th>Full Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Job Title</td>
</tr>
<tr>
<td>Tel No.</td>
</tr>
<tr>
<td>Date Completed</td>
</tr>
</tbody>
</table>

By completing and signing this form you are verifying that the information contained within it is correct to the best of your knowledge

Signature ………………………… Date …………… Time ……..

19. ENSURE FULL INVESTIGATION & FOLLOW UP
Incident Occurs
Ensure patient/client/staff/area is safe. Seek help as required. Ensure care/services maintained

VERBAL REPORT TO PERSON IN CHARGE OF SHIFT - must be made IMMEDIATELY.

Person In Charge to inform family if patient/client related Incident

 Guidance - See inside front cover of A3 Incident Reporting Book or Online Report form. If unclear, contact Risk Management Team on 028 71345171 ext 214133/ 34/ 35/ 36 or 214120

Include name of person affected, name(s) of others involved. Attach witness statements, photographs of accident area as applicable. Grade incident using Risk Rating Matrix.

If using A3 report form, see below.

Top copy (white) forward to Risk Management Dept, within 3 working days

2nd copy (pink) forward to relevant Senior Manager (eg Head of Service)

3rd copy (yellow) remains in book - must be a LEGIBLE copy

INVESTIGATE & CLOSE INCIDENT

Low (Green) - Ward/Department Manager
Moderate (Yellow) - Ward/Department Manager
High (Amber) - Head of Service
Extreme (Red) - Assistant Director in conjunction with Head of Safety & Quality

Suggested List (dependant on seriousness/type of incident - not exhaustive):

Senior Manager/Assistant Director of Nursing for Governance, Quality & Performance/Senior Professional Lead - Immediate contact required for Extreme (Red) and High (Amber) graded incidents.

On-call contact if out of normal working hours (e.g. Night Sister, On-Call Senior Manager, Out-of-Hours Social Worker)

Senior Manager/Assistant Director of Nursing for Governance, Quality & Performance/Senior Professional Lead or their delegated Manager to:

• Escalate Extreme (Red) and High (Amber) rated incidents to the relevant Director, Assistant Director, Service Manager, Divisional Clinical Director, as appropriate by end of day/shift.

And consider informing:
• Serious Adverse Incident Hotline - Tel No: 02871611493
  Refer to Sections 4.9 and 7.2 of WHSCT Incident Reporting Policy for criteria and more detail.

• Regulation and Quality Improvement Authority (RQIA)
• Communications Department (if likely to be media interest)
• Northern Ireland Adverse Incident Centre (NIAIC)
• Vulnerable Adults Designated Officer
• Coroner

NOTE: Risk Management Department will notify statutory bodies in relation to RIDDOR reportable incidents
Appendix C

**Medication Incident Statement**

1. Document incident using Trust incident form or Datix-Web online reporting form.
2. Please complete this form and return to Medicines Governance Pharmacist (Pharmacy Dept, Altnagelvin Hospital) within 5 working days of incident.
3. For controlled drug incidents, please state all staff members on duty

<table>
<thead>
<tr>
<th>Incident Number (see report book)</th>
<th>W</th>
<th>Web Reference</th>
<th>Web</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of Incident</td>
<td>Facility</td>
<td>Ward/Dept</td>
<td></td>
</tr>
</tbody>
</table>

**Prescribing/administration/dispensing error?**

<table>
<thead>
<tr>
<th>Incorrect Medicine(s) + Dose(s) + Strength(s) + Rate(s)</th>
<th>What was presc/admin/disp in error:</th>
<th>Correct Medicine(s) + Dose(s) + Strengths + Rate(s)</th>
<th>What should have been presc/admin/disp:</th>
</tr>
</thead>
</table>

**Route Administered**

<table>
<thead>
<tr>
<th>Form Administered</th>
<th>Correct Route</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Form Administered</th>
<th>Correct Form</th>
</tr>
</thead>
</table>

**Statement of Incident** (Be factual, concise, state times & dates)

**Factors Contributing to the Incident**

**What changes / improvement strategies / learning have been introduced to your ward/department to prevent this incident happening again?**

<table>
<thead>
<tr>
<th>Improvement Strategies / Lessons learned</th>
<th>Action by</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td></td>
</tr>
</tbody>
</table>

Staff Signature: ____________________  Print Name: __________________  Date: _______

Line Manager: _______________________  Print Name: ___________________  Date: _______

Incident Reporting Policy & Procedures  Page 40
Examples of Medical Devices

Source: Northern Ireland Adverse Incident Centre (NIAIC): Reporting Adverse Incidents and Disseminating Alerts, Northern Ireland Version of DB2010(01).

Anaesthetic equipment
Blood warming cabinets
Catheters (e.g. urinary, cardiac)
Chiropody equipment
Dental equipment and materials
Dressings
Endoscopes
Examination gloves
Hospital beds
Implants – powered (e.g. implantable defibrillators, pacemakers) and non-powered (e.g. heart valves, orthopaedic implants, bone cements)
Incontinence products
IV administration sets and pumps
Ophthalmic equipment
Patient monitoring equipment (e.g. cardiac monitors)
Physiotherapy equipment
Radiotherapy equipment (brachytherapy, external beam)
Sphygmomanometers
Surgical instruments and equipment
Syringes and needles
Thermometers
Urine drainage systems
Vaginal specula
X-ray systems, ultrasound imagers and CT/MR scanners

For patient transportation or moving (but not including ambulance vehicles themselves):
Carry chairs
Hoists and slings
Portering chairs
Slider boards and standing aids
Stretchers and trolleys

For critical care:
Defibrillators
Resuscitators
Ventilators

For people with reduced mobility or physical impairment:
Communication aids
Environmental controls
Hearing aids
Orthotics
Prosthetic limbs
Pressure relief mattresses, cushions or pads
Supportive seating
Walking aids
Wheelchairs (powered and non-powered)

For daily living:
Bathing and showering equipment
Commodes
Incontinence products
Prescribable footwear
Special chairs
Urine drainage systems

In vitro diagnostic medical devices and their accessories:
Blood gas analysers
Blood glucose meters
Hepatitis and HIV test kits
Pregnancy test kits
Specimen collection tubes
Urine test strips

Also included are:
Condoms
Contact lenses and care products
Intra-uterine devices (IUDs)

NIAIC are also interested in products which, whilst not themselves medical devices, are used closely in conjunction with these devices. For example:
Benchtop sterilizers
Blood and tissue storage systems
Disinfecting and sterilizing equipment
Chemical and biological indicators used in sterilization processes
Examples of Estates Equipment and Plant

Building, building components and lifts

Demolitions and construction carried out under CDM regulations, including plant

Engineering plant and services of all types (e.g. boilers, generators, heating, ventilation, water, drainage, electrical installations) and any other fixed plant equipment, but not medical devices

Fire protection installations and equipment
Permanently installed sterilizers, bedpan washers and disposal units

Equipment in laundries, catering departments, workshops and any other plant or equipment used for maintenance or cleaning

Piped medical gas and vacuum systems, cryogenic liquid systems (CLS) including vacuum insulated evaporators (VIE’s) and anaesthetic gas scavenging systems
Fixed luminaries including examination lamps

Communications equipment (e.g. telephone and bed head services, nurse call systems paging systems, alarm and audio equipment.

Lightning protection and electrostatic discharge systems

Incinerators and other clinical waste treatment equipment

Environmental aspects (buildings) of the Control of Substances Hazardous to Health (COSHH) Regulations

Installation aspects of fume cupboards and microbiological safety cabinets, including ductwork and their interaction with ventilation systems

Ambulances and similar vehicles
### WH&SCT Impact Table – with effect from 1 October 2013

<table>
<thead>
<tr>
<th>DOMAIN</th>
<th>INSIGNIFICANT (1)</th>
<th>MINOR (2)</th>
<th>MODERATE (3)</th>
<th>MAJOR (4)</th>
<th>CATASTROPHIC (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PEOPLE</td>
<td>• Near miss, no injury or harm.</td>
<td>• Short-term injury/minor harm requiring first aid/medical treatment.</td>
<td>• Semi-permanent harm/disability (physical/mental injuries/trauma) (Recovery expected within one year).</td>
<td>• Long-term permanent harm/disability (physical/mental injuries/trauma).</td>
<td>• Permanent harm/disability (physical/mental trauma) to more than one person.</td>
</tr>
<tr>
<td>• Impact on the Health/Safety/Welfare of any person affected: e.g. Patient/Service User, Staff, Visitor, Contractor</td>
<td>• Minimal injury requiring no/ minimal intervention.</td>
<td>• Increase in length of hospital stay/care provision by 5-14 days.</td>
<td>• Increase in length of hospital stay/care provision by &gt;14 days.</td>
<td>• Increase in length of hospital stay/care provision by &gt;14 days.</td>
<td>• Increase in length of hospital stay/care provision by &gt;14 days.</td>
</tr>
<tr>
<td>• Interruption, problems with Service and Business Resources</td>
<td>• Non-permanent harm lasting less than one month (1-4 day extended stay).</td>
<td>• Emotional distress (recovery expected within days or weeks).</td>
<td>• Increased patient monitoring</td>
<td>• Increased patient monitoring</td>
<td>• Increased patient monitoring</td>
</tr>
<tr>
<td>• Protect assets of the organisation</td>
<td>• Informal contact / Potential intercession by Enforcing Authority</td>
<td>• Extended local press &lt; 7 day coverage with minor effect on public confidence.</td>
<td>• Commissioning costs (£) &lt;1m.</td>
<td>• Commissioning costs (£) &lt;1m.</td>
<td>• Commissioning costs (£) &gt;10m.</td>
</tr>
<tr>
<td>• Insignificant unmet need.</td>
<td>• Loss/ interruption or access to systems denied 8 – 24 hours resulting in minor damage to premises/property.</td>
<td>• Loss of or corruption of sensitive / business critical information.</td>
<td>• Loss – £10K to £100K.</td>
<td>• Loss – &gt; £2m.</td>
<td>• Loss – &gt; £2m.</td>
</tr>
<tr>
<td>• Minor off-compliance with internal standards, professional standards, policy or protocol.</td>
<td>• Loss of information.</td>
<td>• Impact on service contained with assistance, high financial loss</td>
<td>• Loss of information.</td>
<td>• Impact on service contained with assistance, high financial loss</td>
<td>• Impact on service contained with assistance, high financial loss</td>
</tr>
<tr>
<td>• Audit / Inspection – small number of recommendations which focus on minor quality improvements issues.</td>
<td>• Impact to service immediately contained, medium financial loss</td>
<td>• Impact on service contained with assistance, high financial loss</td>
<td>• Impact on service contained with assistance, high financial loss</td>
<td>• Impact on service contained with assistance, high financial loss</td>
<td>• Impact on service contained with assistance, high financial loss</td>
</tr>
</tbody>
</table>

#### REPUTATION

| • Local press < 7 day coverage. | • Extended local press < 7 day coverage with minor effect on public confidence. | • Regional/National press < 3 days coverage. | • Regional / National Media interest >3 days <7 days. | • Regional / National Media interest >3 days <7 days. | • Regional / National Media interest >3 days <7 days. |
| • Informal contact / Potential intervention by Enforcing Authority (e.g. HSENI/NIFRS). | • Advisory letter from enforcing authority/increased inspection by regulatory authority. | • Improvement notice/failure to comply notice. | • Improvement notice/failure to comply notice. | • Improvement notice/failure to comply notice. | • Improvement notice/failure to comply notice. |

#### FINANCE, INFORMATION & ASSETS

| (Protect assets of the organisation and avoid loss) | Commissioning costs (£) (£) 1m. | Commissioning costs (£) 1m – 2m. | Commissioning costs (£) 2m – 5m. | Commissioning costs (£) 5m – 10m. | Commissioning costs (£) >10m. |
| • Loss of assets due to damage to premises/property. | • Loss of assets due to minor damage to premises/property. | • Loss – £10K to £100K. | • Loss – £100K to £250K. | • Loss – £250K to £2m. | • Loss – £2m. |
| • Loss – £1K to £100K. | • Loss of information. | • Loss of information. | • Loss of information. | • Loss of information. | • Loss of information. |
| • Minor loss of non-personal information. | • Impact on service immediately contained, medium financial loss | • Impact on service contained with assistance, high financial loss | • Impact on service contained with assistance, high financial loss | • Impact on service contained with assistance, high financial loss | • Impact on service contained with assistance, high financial loss |

#### RESOURCES

| (Service and Business interruption, problems with service provision, including staffing (number and competence), premises and equipment) | Loss/ interruption < 8 hour resulting in insignificant damage or loss/impact on service. | Loss/ interruption < 8 hour resulting in insignificant damage or loss/impact on service. | Loss/ interruption 1-7 days resulting in moderate damage or loss/impact on service. | Loss/ interruption 8-31 days resulting in major damage or loss/impact on service. | Loss/ interruption >31 days resulting in catastrophic damage or loss/impact on service. |
| • No impact on public health social care. | • No impact on public health social care. | • No impact on public health social care. | • Moderate impact on public health and social care. | • Major impact on public health and social care. | • Catastrophic impact on public health and social care. |
| • Insignificant unmet need. | • Insignificant unmet need. | • Insignificant unmet need. | • Moderate unmet need. | • Major unmet need. | • Catastrophic unmet need. |
| • Minimal disruption to routine activities of staff and organisation. | • Minimal disruption to routine activities of staff and organisation. | • Minimal disruption to routine activities of staff and organisation. | • Moderate impact on staff, service delivery and organisation, rapidly absorbed. | • Major impact on staff, service delivery and organisation - absorbed with some formal intervention with other organisations. | • Catastrophic impact on staff, service delivery and organisation - absorbed with significant formal intervention with other organisations. |

#### ENVIRONMENTAL

| • On site release contained by organisation. | • Moderate on site release contained by organisation. | • Major release affecting minimal off-site area requiring external assistance (fire brigade, radiation, protection service etc). | • Toxic release affecting off-site with detrimental effect requiring outside assistance. | • Toxic release affecting off-site with detrimental effect requiring outside assistance. | • Toxic release affecting off-site with detrimental effect requiring outside assistance. |
### Risk Likelihood Scoring Table

<table>
<thead>
<tr>
<th>Likelihood Scoring Descriptors</th>
<th>Score</th>
<th>Frequency (How often might it/does it happen?)</th>
<th>Time framed Descriptions of Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Almost certain</td>
<td>5</td>
<td>Will undoubtedly happen/recur on a frequent basis</td>
<td>Expected to occur at least daily</td>
</tr>
<tr>
<td>Likely</td>
<td>4</td>
<td>Will probably happen/recur, but it is not a persisting issue/circumstances</td>
<td>Expected to occur at least weekly</td>
</tr>
<tr>
<td>Possible</td>
<td>3</td>
<td>Might happen or recur occasionally</td>
<td>Expected to occur at least monthly</td>
</tr>
<tr>
<td>Unlikely</td>
<td>2</td>
<td>Do not expect it to happen/recur but it may do so</td>
<td>Expected to occur at least annually</td>
</tr>
<tr>
<td>Rare</td>
<td>1</td>
<td>This will probably never happen/recur</td>
<td>Not expected to occur for years</td>
</tr>
</tbody>
</table>

### Impact (Consequence) Levels

<table>
<thead>
<tr>
<th>Likelihood Scoring Descriptors</th>
<th>Insignificant (1)</th>
<th>Minor (2)</th>
<th>Moderate (3)</th>
<th>Major (4)</th>
<th>Catastrophic (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Almost Certain (5)</td>
<td>Medium</td>
<td>Medium</td>
<td>High</td>
<td>Extreme</td>
<td>Extreme</td>
</tr>
<tr>
<td>Likely (4)</td>
<td>Low</td>
<td>Medium</td>
<td>Medium</td>
<td>High</td>
<td>Extreme</td>
</tr>
<tr>
<td>Possible (3)</td>
<td>Low</td>
<td>Low</td>
<td>Medium</td>
<td>High</td>
<td>Extreme</td>
</tr>
<tr>
<td>Unlikely (2)</td>
<td>Low</td>
<td>Low</td>
<td>Medium</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Rare (1)</td>
<td>Low</td>
<td>Low</td>
<td>Medium</td>
<td>High</td>
<td>High</td>
</tr>
</tbody>
</table>
ROOT CAUSE ANALYSIS – A BRIEF GUIDE

Root Cause Analysis (RCA) is a retrospective review of an incident undertaken in order to identify:

- **What** happened?
- **How** did it happen?
- **Why** did it happen?

The analysis is then used to identify areas for change, recommendations and sustainable solutions, to help minimise the reoccurrence of the incident type in the future. RCA can also be used to investigate complaints and claims. Root Cause Analysis will usually be carried out by a team of senior staff unconnected with the incident. Once the membership and Terms of Reference of the investigation team have been agreed, the following steps should be taken:

**STAGE ONE - Identify the problem, gather and map the information**

<table>
<thead>
<tr>
<th>Gather information on what happened and how the incident was detected from:</th>
</tr>
</thead>
<tbody>
<tr>
<td>The people involved or who witnessed the incident – the patient or their relatives should be asked to contribute where appropriate.</td>
</tr>
<tr>
<td>The place or environment where the incident occurred</td>
</tr>
<tr>
<td>The equipment or moving parts of objectives involved in the event</td>
</tr>
<tr>
<td>The paperwork relating to the event (records, policies, procedures)</td>
</tr>
<tr>
<td>The widely held beliefs about the normal working processes, team relationships and adequacy of leadership in the workplace</td>
</tr>
</tbody>
</table>

**What are the Contributory Factors?**

- Staff Attitude
- Staff knowledge, skills, competency, experience
- The culture of the area
- How poor practice is exposed and dealt with
- Lack of reflective practice
- Lack of audit culture
- Poor leadership/absent leadership

**RCA Tools and Techniques to gather information:**

- Brainstorming
- Statements – ask staff involved to prepare written statements
- Timeline of events – a chronological list of events leading up to the incident and key actions taken following the incident. Timelines can be simple (date/time of each event) or developed into more complex tabular timelines, recording more than just the basic facts (e.g. care/service delivery problems or good practice). Refer to records and/or statements and other evidence when preparing a timeline and develop as more information becomes available.
- Time/Person grid – a table mapping the whereabouts of staff involved against dates and times
Appendix F

STAGE TWO – Analysing the information and making sense of the contributory factors

RCA Tools and Techniques to analyse the information:-

- Fishbone (or Ishikawa) Diagram – used to identify contributory factors such as
  - Patient factors
  - Individual (staff) factors
  - Task factors
  - Communication Factors
  - Team Factors
  - Education & Training Factors
  - Equipment and Resources Factors
  - Working Condition Factors
  - Organisation and Strategic Factors

- Five Whys – questions each identified primary cause of a problem and to identify whether it is a symptom, an influencing factor or a root cause. A series of questions (usually up to five) are asked to get to the real reason why something was done a certain way.

- Barrier Analysis – establishes what barriers (defences or controls) should have been in place to prevent the incident, or could be installed to increase system safety. You should consider:
  - Physical barriers (e.g. locks/controlled access/guards),
  - Natural barriers (i.e. barriers of distance, time or replacement)
  - Human action barriers (e.g. control/restraint of clients/patients)
  - Administrative barriers (e.g. protocols, procedures, supervision and training, two people signing for controlled drugs)

- Change Analysis – enables you to make a comparison between a process when it works well and the same process when it has not worked so well.

STAGE THREE – Recommendations

When formulating recommendations you should consider:-

- Who agrees the recommendations and actions? The recommendations should be agreed by relevant clinicians/Service Managers/Assistant Director and Director. This is particularly important when submitting a Serious Adverse Incident investigation report to the HSCB.

- Who implements and resources a recommended solution? Solutions should be implemented by the appropriate manager with responsibility for the service area.

- Who needs to know about recommendations and action plans? Ensure those who are required to implement recommendations are informed of timescales for implementation and that action plans are monitored. Also ensure that relevant staff are informed of any changes to policies, procedures, new equipment, and provided with training as appropriate. Don’t forget to advise the patient and/or their family of the outcome of the investigation.

Source: National Patient Safety Agency. For further information on Root Cause Analysis please visit [http://www.nrls.npsa.nhs.uk/resources/rca-conditions/](http://www.nrls.npsa.nhs.uk/resources/rca-conditions/)