

Policy and Procedures for the Reporting and Management of Adverse Incidents

Version 2.0 2023

Lead Policy Author & Job Title:	Caroline Doyle, Interim Assistant Director of Clinical & Social Care Governance
Directorate responsible for document:	Medical Directorate
Issue Date:	19 December 2023
Review Date:	19 December 2025



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Policy Checklist

Policy name:	Policy and Procedures for the Reporting and Management of Adverse Incidents, Version 2.0
Lead Policy Author & Job Title:	Caroline Doyle, Interim Assistant Director of Clinical and Social Care Governance
Director responsible for Policy:	Dr Stephen Austin, Medical Director
Directorate responsible for Policy:	Medical
Equality Screened by:	Caroline Doyle, Interim Assistant Director of Clinical and Social Care Governance
Trade Union consultation?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Policy Implementation Plan included?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date approved by Policy Scrutiny Committee:	19 December 2023
Date approved by SLT:	Revised policy - SLT approval not applicable
Policy circulated to:	All Directors and Assistant Directors for sharing amongst teams within Directorates All Governance Coordinators
Policy uploaded to:	Sharepoint

Version Control

Version:	Version 2.0		
Supersedes:	Southern Health and Social Care Trust Incident Management Procedure (2014 working draft)		
Version History			
Version	Notes on revisions/modifications and who document was circulated or presented to	Date	Lead Policy Author
Version 2.0 2023 Draft	Circulated to Policy Scrutiny Committee and SLT for comment	19/12/2023	Caroline Doyle, Interim ADCSCG
Version 1.0 2014 Working Draft		01/10/2014	Margaret Marshall, ADSCG

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1.0 Introduction

Arising out of the recommendations of the Regional Learning System Project Report (August 2015), it was agreed to develop a regional policy on the reporting and management of adverse incidents to be used by all Health & Social Care Trusts, the Northern Ireland Ambulance Service (NIAS) and the Strategic Planning & Performance Group (SPPG) hereinafter called (“the organisation”).

The following document has been developed in accordance with the Southern Health and Social Care Trust’s (SHSCT) Key Principles for Policy development.

1.1 Purpose and Aims

The manner by which an organisation manages and learns from adverse incidents is one of the key markers of success in relation to risk management, corporate and clinical and social care governance standards. Consistent identification, monitoring and review of incidents is central to the organisation’s strategic and operational processes to ensure it can achieve its vision for safe and effective care.

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 do occur it is important to identify causes to ensure that lessons are learned to prevent recurrence.

The organisation is committed to an open, honest and just culture and reporting of adverse incidents is encouraged so that the organisation can learn from incidents and take actions including changes in practice to reduce the risk of recurrence. It also will ensure that staff learn and are supported in making changes to their practice, post incidents, as required.

1.2 Objectives of this Policy

This policy provides guidance on the reporting and management of adverse incidents which affect service users, staff and visitors on its premises or have an impact on the organisation, its reputation or its legal duty of care. It will also enable a robust and systematic approach to the management of adverse incidents that will be consistently applied across the organisation ensuring that it meets all relevant statutory¹ or mandatory responsibilities and reporting requirements, thereby safeguarding the wellbeing of service users, staff and visitors.

It has been developed to ensure organisational wide learning takes place within a structured framework and that any lessons learned are disseminated widely throughout the organisation and to external agencies, as appropriate.

Adverse incident management systems assist organisations to ensure that systems are in place to secure service user, staff and visitor safety, ensure internal accountability and safeguard the organisation’s assets and reputation. Learning from adverse incidents enables the organisation to proactively reduce risk and improve

¹ Health & Safety at Work Order 1978, Management of Health and Safety at Work Regulations (Northern Ireland) 2000 and the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (Northern Ireland) 1997.

services. It recognises that most incidents occur because of problems with systems rather than individuals but may also on occasions be multifactorial in nature.

The objectives of this policy are: -

- To promote and provide a unified regional organisational wide system for the reporting, recording, review and analysis of all adverse incidents;
- To improve the safety and quality of care through reporting, analysing and learning from incidents involving service users, staff and visitors (including contractors);
- To comply with relevant legislation and standards relating to the reporting of incidents;
- To ensure all adverse incidents are dealt with appropriately and in a timely and consistent manner;
- To provide a means of analysing trends in incidents within teams and the Trust Clinical and Social Care Governance (CSCG) structures;
- Identification of factors contributing to incidents to assist in implementation of learning, service improvement and risk reduction strategies, thereby minimising risk to service users, staff and visitors and the organisation; and
- To support staff when things do not go as planned and encourage staff to review and reflect on their practice post review of incidents.

1.3 Policy Statement

The Trust is committed to providing the best possible services for its service users, staff and visitors. It recognises that adverse incidents will occur and that it is important to identify causes to ensure that lessons are learnt to prevent recurrence. It is, therefore, essential that a responsive and effective incident recording, reporting and management system is in place to achieve this aim. Where learning from such adverse incidents is identified, the necessary changes should be put in place to improve practice.

2.0 Policy Principles

2.1 Definitions

Adverse Incident: Any event or circumstance that could have or did lead to harm, loss or damage to people, property, environment or reputation arising during the course of the business of a HSC organisation/Special Agency or commissioned service². A suggested list of broad categories of adverse incidents to be reported is listed in Appendix 1 for guidance purposes.

Harm is defined as: “injury (physical or psychological), disease, suffering, disability or death”.³ In most instances, harm can be considered to be unexpected if it is not related to the natural cause of the patient’s/client’s illness or underlying condition.

Serious Adverse Incident (SAI): is an adverse incident that must be reported to the Health and Social Care Board (HSCB) because it meets at least one of the criteria as

² HSCB Policy and Procedure for the reporting and follow up of Serious Adverse Incidents, November 2016

³ Doing Less Harm, NHS, National Patient Safety Agency 2001

defined by the HSCB within “Procedure for the Reporting and Follow-up of Serious Adverse Incidents (SAIs), Oct 2016⁴.

Service User⁵: this term refers to a patient, service user, family (of a service user and/or family of a victim), carer or nominated representative.

2.2 The organisation’s approach to Adverse Incident Reporting and Management: A just and learning culture⁶

As part of its proactive approach to risk management, the organisation promotes a just and learning culture in which errors or service failures can be admitted, reported and discussed without fear of reprisal. This will enable lessons to be identified and allow active learning to take place and the necessary changes made or reflected in policies, procedures and practices.

All staff must report and manage adverse incidents according to this policy (and any related operational procedures) for adverse incident reporting. Crucial to the effectiveness of adverse incident reporting and management is the organisation’s commitment to the promotion of a just and learning culture where all staff can participate in reporting adverse incidents. Staff are encouraged to report incidents and to look critically at their own actions and those of their teams, to ensure the organisation can provide quality services for our service users, staff and visitors.

Ultimately, the organisation wants to encourage staff to report areas of concern and to foster a positive ethos around reporting. Trust staff work within complex systems in which many factors influence events and outcomes. The principles of a just and learning culture will be applied to determine the most appropriate response when things do not go as planned. It is important that learning takes place to prevent a reoccurrence of an adverse incident rather than adopting a punitive approach. Staff who make a prompt and honest report in relation to an adverse incident should not expect to be subject to disciplinary action except under the following circumstances: -

- A breach of law;
- Wilful or gross carelessness or professional misconduct;
- Repeated breaches of Trust policy and procedure;
- Where, in the view of the Trust, and/or any professional registration body, the action causing the incident is far removed from acceptable practice; or
- Where there is failure to report a serious incident in which a member of staff was involved or about which they were aware.

Completion of an adverse incident report does not discharge staff of their duty of care and their risk management responsibility. There should be timely and appropriate follow-up of adverse incidents. Where preventative measures and/or procedural changes are identified these should be put in place to minimise the risk of the adverse incident recurring.

⁴ HSCB Policy and Procedure for the reporting and follow up of Serious Adverse Incidents, November 2016

⁵ As per the draft Statement of what you should expect in relation to a Serious Adverse Incident Review, January 2019

⁶ *a just culture considers wider systemic issues where things go wrong, enabling professionals and those operating the system to learn without fear of retribution. “...generally in a just culture inadvertent human error, freely admitted, is not normally subject to sanction to encourage reporting of safety issues. In a just culture investigators principally attempt to understand why failings occurred and how the system led to sub-optimal behaviours. However a just culture also holds people appropriately to account where there is evidence of gross negligence or deliberate acts’.* (NHS England, A Just Culture Guide; Professor Sir Norman Williams’s Review into Gross Negligence Manslaughter in Healthcare report, June 2018).

All employees must be honest, open and truthful in all their dealings with patients/clients and the public, and organisational and personal interests must never be allowed to outweigh the duty of openness, transparency and candour.

2.3 External reporting arrangements in respect of other incidents not covered by this policy

Depending on the nature of the adverse incident the organisation may be required to report relevant details to other statutory agencies and external bodies e.g. HSCB, RQIA, HSENI, UKAS (United Kingdom Accreditation Service). Staff should ensure that they are aware of their local reporting requirements to other statutory agencies and external bodies as per their local policy/procedures. These incidents must also be recorded on the organisation's incident reporting system.

2.4 External reporting arrangements in respect of Independent Service Providers (ISPs) and Contractors

With regard to Independent Service Providers (ISPs) and contractors, they will be required under their contractual arrangements to maintain a system of reporting and recording of adverse incidents related to service users referred to them by the Trust for assessment, treatment or care. ISPs are also required to submit monitoring information to the organisation as required. Both adverse incidents and SAIs are discussed at contract meetings between Trusts and ISPs. As per the HSCB (now SPPG) procedure for reporting SAIs (November 2016), the Trust will decide whether an ISP adverse incident meets the criteria for reporting as a SAI and is, therefore, responsible for reporting the SAI to the SPPG.

This policy does not cover the arrangements for the reporting of Early Alerts to the Department of Health as this is the subject of separate guidance/policy.

3.0 Scope of Policy

This policy covers all areas of the organisation's business and applies to all incidents involving service users, staff and visitors, as well as those incidents where individuals are not affected. It also includes contractors, students, volunteers and bank and agency staff or locums and any others to whom the organisation owes a duty of care.

This policy excludes detailed arrangements in respect of the following areas which are covered by separate regionally agreed policies:

- Policy on the reporting of Early Alerts;
- Policy of Being Open;
- Policy on Raising Concerns;
- Policy on Reporting of Adverse Incidents under RIDDOR Regulations;
- Policy on Supporting Staff involved in Incidents, Complaints, Claims and Coroners Inquests;

- Policy on Liaison and Effective Communications with PSNI and HSENI when investigating Patient Safety Incidents involving Unexpected Death and Serious Untoward Harm; and
- Policy on Mortality & Morbidity Guidance.

4.0 Responsibilities

Trust Board is responsible for ensuring that a robust system is in place for reporting and management of adverse incidents and will receive regular management reports on this subject matter.

Chief Executive is the responsible Officer for the Trust's statutory duty of quality and is required to drive the delivery of the Trust's corporate priorities, particularly the priority to provide safe, high quality care. Through the overview of this Trust Policy and Procedure, the Chief Executive will seek to embed the Trust's value of all staff being open and honest and acting with integrity and candour.

The Executive Medical Director is the lead Director responsible for the reporting and management of adverse incidents within the Trust. He/she will ensure that systems, policies and procedures are developed and implemented on an organisational basis including the onward reporting of relevant incidents to external agencies for e.g., Strategic Planning & Performance Group (SPPG), Health & Safety Executive for Northern Ireland (HSENI) and the Regulation, Quality Improvement Authority (RQIA). On a daily basis this function is delegated to the Assistant Director of Clinical and Social Care Governance.

Directors and Divisional Medical Directors are responsible for ensuring that the Trust's policy on adverse incident reporting and management is widely disseminated, promoted and implemented within their areas of responsibility.

Assistant Directors/ and Clinical Directors are responsible and accountable to their respective Directors for ensuring that this policy and any associated procedures are effectively implemented within their areas of responsibility. They should also promote a just and learning reporting culture and ensure that appropriate reviews are carried out.

Senior Managers, Heads of Departments/Services are responsible for:

- ensuring that this policy and associated procedures are effectively implemented across their area of responsibility;
- promoting an open, honest and just reporting culture;
- ensuring that staff are appropriately trained in the reporting and management of adverse incidents;
- ensuring that appropriate review of adverse incidents is carried out; and
- reviewing, approving and/or escalation of incidents via DatixWeb.

Person/s who report an incident (Reporter) is responsible for reporting the incident using DatixWeb in line with Trust reporting criteria and timescales.

Person/s who review incidents (Reviewer) is responsible for ensuring that incidents are reported in line with Trust reporting policies and procedures and the content of the report is appropriate. They will also be responsible for initiating any relevant reviews within agreed Trust timeframes. On completion of this process they are responsible for moving the incident to 'awaiting final approval' stage.

Person/s who approve incidents (Approver) is responsible for ensuring the incident reporting and review process have been followed and that all information and/or actions contained within the report and review have been acted upon appropriately prior to agreeing 'final approval' and closure of the incident within agreed Trust timeframes.

Medicines Governance Pharmacist (MGP) is responsible for the expert review, quality assurance and identification of learning from reported medication incidents. In the event an adverse incident is categorised as a Serious Adverse Incident, the MGP should be involved in the review. He /she is also responsible for submission of HSC Trust medication incident data for regional analysis by the Medicines Governance Teams.

All staff have a responsibility to:

- ensure the safety of individuals involved (service users, visitors and staff), the environment and equipment;
- avoid putting themselves and others in situations of danger;
- ensure their line manager/s and/or person in charge of the area is informed of the incident;
- record and report all adverse incidents using the organisation's reporting systems as soon as possible and ideally within 24 hours of the occurrence or becoming aware of the adverse incident; and
- co-operate with any review process including the provision of witness statements, if appropriate.

Senior Information Risk Owner (SIRO) is the lead Director for ensuring Information Governance (IG) incidents are reported and appropriately managed including reporting to Information Commissioner's Office, if necessary. He/she (or nominee) will provide advice and support to managers in respect of IG incidents, as appropriate.

5.0 Legislative Compliance, Relevant Policies, Procedures and Guidance

The key legislative reporting requirements for organisations in respect of adverse incidents are as follows:

- Health & Safety at Work (NI) Order 1978;
- Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) 1997;
- Social Security Claims and Payments Regulations 1979; and
- The Public Interest Disclosure Act 1998.

6.0 Implementation of Policy

6.1 Learning and Feedback

Learning from adverse incidents can only take place when they are reported and investigated in a positive, open and structured way. Where learning from such adverse incidents is identified the organisation will ensure that the necessary changes will be put in place to improve practice. Where learning from incidents is relevant to other areas across the organisation, and/or externally, the learning should be shared as per current organisational arrangements, e.g. established sub committees and groups.

Feedback to staff is vital in respect of incidents they report. Managers should ensure it occurs in their respective areas. This can be on a one to one basis or feedback can be given to all staff at regular Incident, Staff or Assurance / Governance Meetings.

6.1 Dissemination

This policy covers all areas of the organisation's business and applies to all incidents involving service users, staff and visitors, as well as those incidents where individuals are not affected. It also includes contractors, students, volunteers and bank and agency staff or locums and any others to whom the organisation owes a duty of care. All staff employed by the Trust should be provided with access to this policy. The latest version of this policy (and related documents) is available on the Trust's Sharepoint.

6.2 Resources

6.2.1 Training

Adverse Incident Training is **mandatory** for all staff and appropriate training and guidance will be provided to ensure that all Trust employees understand their responsibilities under this policy and are able to effectively fulfil their obligations to report adverse incidents. The organisation's training administration system, LearnHSCNI, should be used appropriately to record staff training. Senior Managers/Heads of Departments are responsible for ensuring that training on Incident Reporting is covered in local Directorate induction programmes.

7.0 Monitoring

An audit of the policy will be undertaken post implementation to ensure adherence to the principles and procedures outlined in this policy document. Changes will be made to the policy, as required. This policy will be reviewed on a regular basis by the Assistant Director of Clinical and Social Care Governance in the light of best practice, changing legislation or new/updated policy guidance.

8 .0 Sources of Advice & Further Information

- Health & Safety at Work (Northern Ireland) Order 1978;
- Management of Health & Safety at Work Regulations (Northern Ireland) 2000;
- Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1997;
- HSCB Procedure for the Reporting and Follow up of Serious Adverse Incidents, November 2016;
- Six steps to Root Cause Analysis, 2002, Consequence UK Limited;
- National Patient Safety Agency;
- Seven Steps to Patient Safety (2004); and
- Being Open, Patient Safety Alert, November 2009.

9.0 APPENDICES

<i>Appendix 1</i>	<i>Process for Reporting and managing an Adverse Incident</i>
<i>Appendix 2</i>	<i>Examples of Adverse Incidents that should be reported</i>
<i>Appendix 3</i>	<i>Regional Risk Matrix</i>
<i>Appendix 4</i>	<i>Guidance for Incident Review and Grading</i>

10.0 Equality & Human Rights Considerations

In line with duties under the equality legislation (Section 75 of the Northern Ireland Act 1998), Targeting Social Need Initiative, Disability discrimination and the Human Rights Act 1998, an initial screening exercise to ascertain if this policy should be subject to a full impact assessment has been carried out. The outcome of the Equality screening for this policy is:

- Major impact**
- Minor impact**
- No impact.**



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Operational Procedure for the Reporting and Management of Adverse Incidents

1.0 Purpose of procedure

This procedure sets out the organisation's processes for reporting, recording, reviewing and communication with service users and staff following an adverse incident.

2.0 What to do when an adverse incident occurs – immediate action

- The extent of injuries/damages to person(s) or property should be ascertained, and a determination made regarding the need for emergency or urgent treatment / action. For patient / client care related incidents, contact the relevant medical team to assess where required;
- Appropriate obvious treatment / actions should be taken to minimise the likelihood of the incident recurring;
- Any equipment involved in the incident should be removed from use and clearly labeled, "Do not use", until appropriate checks can be carried out. Do not dispose of equipment involved in an incident;
- **The service user/patient/client and/or their family/or carers** should be informed, as soon as possible of the incident and of any treatment that may be necessary taking into consideration any consent issues and referring to the Trust's "Being Open" policy;
- Any incident involving a patient or client, and the action taken, should be recorded in their healthcare record;
- If the incident is major or catastrophic and requires an immediate action plan to prevent further harm the line manager (if out of hours, the Senior Out of Hours Manager) should be informed;
- For incidents requiring further in-depth investigation e.g. SAIs/Internal Root Cause Analysis (RCA's) / Reviews, patient/client records should be returned as soon as is practical to the Directorate Governance Coordinator to ensure all recorded information is available for review. Retrospective notes are permitted as long as these are clearly marked as being made in retrospect;
- Where appropriate and where it would be beneficial to assist in the investigation of the incident, photographs should be taken and retained as evidence – this is particularly useful in Health and Safety type incidents or where damage had occurred to property;
- CCTV footage should be sourced, and a copy made for all cases which would be subject to PSNI investigation;
- Security staff and/or the PSNI should be informed where appropriate;
- Consideration should also be given to the need to activate site-based emergency / contingency plans if necessary (in line with current emergency procedures).

3.0 Reporting an Incident:

Appendix 1 – sets out the process for reporting and managing an adverse incident.

Appendix 2 - sets out some examples of incidents that should be reported via the Trust's DATIX incident management system

Where: All incidents must be recorded electronically via the Datix Web based form (IR1 form) which can be accessed as follows from the Trust intranet site. **(Trust intranet/ useful links/ other useful links and scroll down to click on 'Datix Web')**

By Whom: This form must be completed by all staff who are involved in or have witnessed an incident, or by the person the incident has been reported to.

When: All incidents should be reported via the electronic reporting form (IR1 form), no later than the end of the working shift or day during which it occurred, **or** its occurrence became known.

How: Information concerning the incident must be accurate, complete and factual. The description of the incident should not contain opinions, conclusions, subjective or speculative statements. The following instructions should be followed when filling in the electronic incident form. *See Hyperlink below:*

http://vsrintranet/SHSCT/documents/DatixWebIR1FormUserGuidance_000.pdf

Incidents given an initial severity rating of major or catastrophic (as a minimum) will automatically be triggered to the appropriate Head of Service/Team Manager and relevant Assistant Director in an email via Datix Web.

In circumstances where the incident is considered as a potential Serious Adverse Incident (SAI), immediate telephone contact should be made to the relevant Head of Service/ Line Manager or Out of Hours Manager if appropriate. They will notify the appropriate Director, Assistant Director/Divisional Medical Director and Clinical and Social Care Governance Coordinator at the earliest opportunity. The incident will then be reviewed by the latter group against the HSCB SAI criteria and the DHSSPS Early Alert criteria. The appropriate Director should brief the Chief Executive on incidents that occur that meet the SAI criteria.

4.0 Procedure for Reviewing, Grading and Monitoring Adverse Incidents:

All incidents are to be reviewed on a weekly basis by the service area's Incident Review Teams. The purpose of the Incident Review Team is to undertake a local assessment / review of the incident in a timely manner. This review should include:

- Quality assure the information submitted via the Datix system and the initial severity rating given to the incident. Where the review team believes the

severity rating should be changed – the incident reporter should be contacted, and this should be discussed and agreed

- Calculate the actual and potential risk rating for the incident using the Risk Grading Matrix and impact Table (Appendix 3)
- Consider the need for additional internal and /or external reporting e.g. RIDDOR, NIAIC, HSCB, RQIA, UKAS, Vulnerable Adults (PVA), Fire.
- If the incident is also an adult safeguarding review (this will be recorded on Datix) then the Incident Review team should link with the adult safeguarding Designated Officer (DO) for that incident.
- Develop and agree learning and action plans as appropriate. All **moderate**, **major** and **catastrophic** incidents reported will require a time bound action plan which **must** include relevant learning points. This learning should be communicated and actioned within teams
- Feedback the outcome of the review of **moderate, major and catastrophic** incidents to the incident reporter.
- Inform the appropriate Assistant Director of any immediate learning which could minimise the risk of further reoccurrence of the incident
- Escalate any barriers to implementation of action plans relating to incidents to the appropriate Head of Service and the Assistant Director
- Close all incidents following completion of the review process

N.B: The Medicines Governance Pharmacist will lead on the multidisciplinary review, monitoring and analysis of medication related incidents and will link with the Regional Medicines Governance Team to inform the content of regional medication related governance reports.

4.0 Deciding what to review

Appendix 4 – Sets out guidance for Adverse Incident Review

Many organisations typically report thousands of incidents each year. It is therefore unrealistic to suggest that all incidents should be reviewed to the same degree, or at the same level, within the organisation. Furthermore, the outcome of an incident, including a ‘near miss’, at the time of occurrence is sometimes a poor indicator of the level of review required. The application of a simple risk assessment process to incidents at the time of occurrence can enable the organisation to implement a structured approach to its incident management.

5.0 Communication with Service Users and/or relatives (for incidents resulting in moderate to catastrophic harm incidents)

The lead member of staff responsible for the treatment and/or care will retain the responsibility for communicating with the service user 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.

Harming a service user can have devastating emotional and physical consequences for the individuals, their families and carers, and can be distressing for the

professionals involved. ***‘Being Open’***⁷ is a set of principles that health and social care staff should use when offering an explanation and apologising to service users and/or their carers when harm has resulted from an incident. **“Saying sorry is not an admission of liability”**.

‘Being Open’ involves:

- acknowledging, apologising and explaining when things go wrong.
- keeping service users and carers fully informed when an incident has occurred.
- conducting a thorough review into the incident and reassuring service users, their families and carers that lessons learned will help prevent the incident reoccurring.
- providing support for those involved to cope with the physical and psychological consequences of what happened; and
- recognising that direct and/or indirect involvement in incidents can be distressing for health and social care staff. Permission will be given to seek emotional support.

The organisation is committed to improving the safety and quality of the care we deliver to the public. Our ***‘Being Open’*** policy expresses this commitment to provide open and honest communication between health and social care staff and a service user (and/or their family and carers) when they have suffered harm as a result of their treatment. It is based on published guidance by the National Patient Safety Agency (NPSA) and also complies with step 5 of *‘Seven Steps to Patient Safety’*.

Further guidance on communicating with service users and their relatives is available in the Being Open and/or Serious Adverse Incident Policy.

6.0 Debriefing of Staff after Adverse Incidents

Assistant Directors/ Senior Managers and Heads of Department should ensure that local procedures and training is in place for the debriefing of staff after incidents. Agreed timescales for debriefing should be specified. The Line Manager should ensure that the staff member has access to appropriate help immediately post incident as necessary e.g., referral for medical opinion in case of assault, counselling etc. Line managers should, where appropriate, seek medical advice as to whether it is advisable for the staff member to return to (or stay in) the workplace.

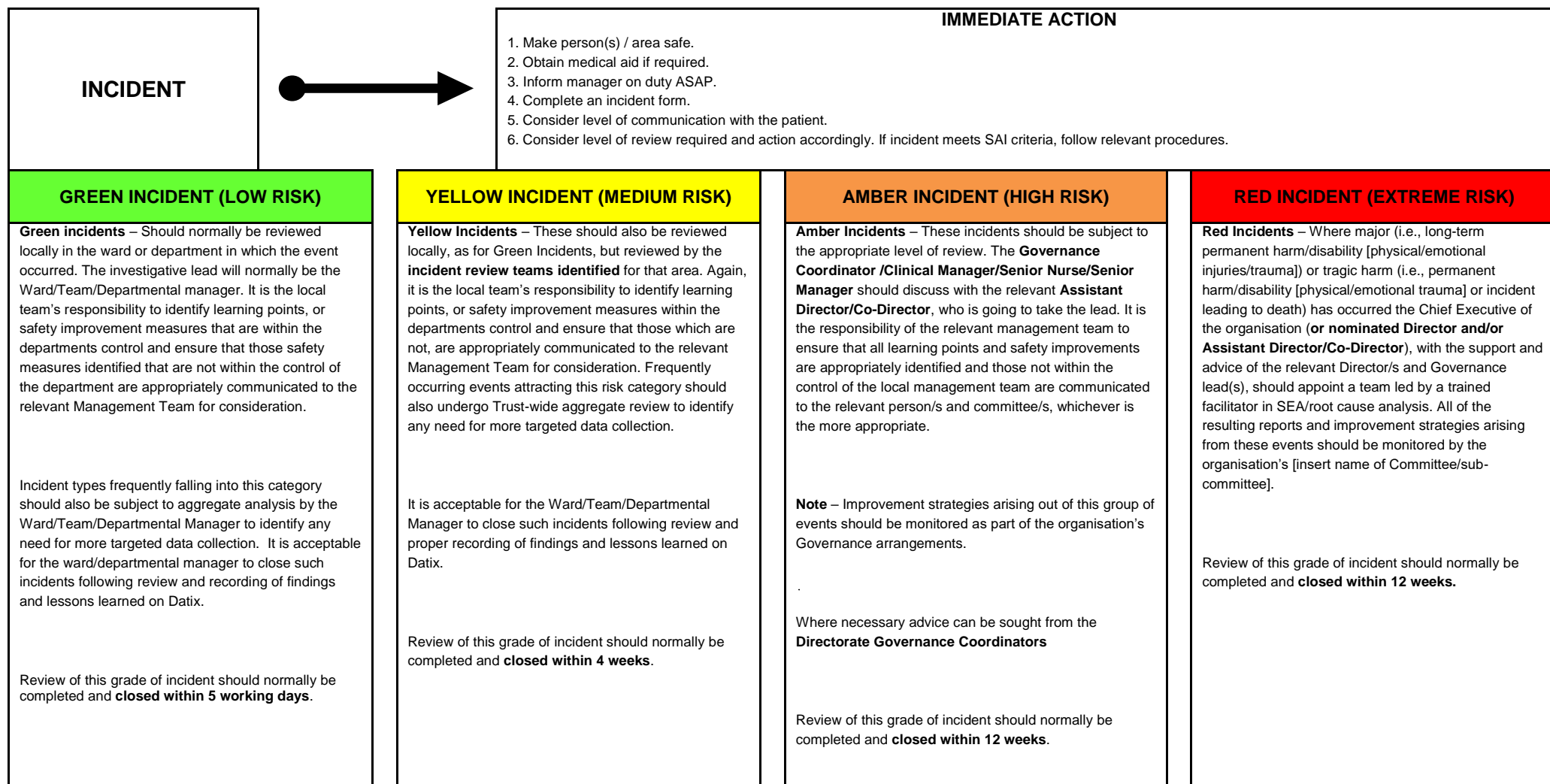
In the case of assaults, line managers should discuss with the staff member whether or not they wish the police to be involved. Line managers should make staff aware of the availability of the services of Occupational Health Services and other staff care services.

It should be standard practice at all debriefing sessions with staff to consider the contributing factors, which may have led to an incident. This should assist staff in reviewing practice and updating care plans, risk assessments etc. in order to minimise the risk of recurrence. Details of debriefing offered/arranged should be documented and retained in the staff member’s local personnel file.

7.0 Communication with the Media

All communications with the media regarding Adverse Incidents should be coordinated by the Trust's Communication Team.

Appendix 1 – Process for Reporting and Managing an Adverse Incident (Including level of Incident review based on potential risk grading)



Appendix 2 – Examples of Adverse Incidents that should be reported

Broad categories of possible adverse incidents are shown below and may assist reporters. This list is not comprehensive but gives a broad indication of what should be reported

- Abusive, violent, disruptive, challenging or self-harming behaviour
- Delays or difficulties during appointments, admissions, transfers or discharges
- Accidents e.g. falls, medical sharps injuries, manual handling, exposure to hazardous substance, burn or scalds
- Cardiac arrests involving CPR and/or Defib
- Issues with clinical investigations, scans, x-rays, lab tests etc.
- Communication breakdowns between staff and/or with service users, issues with consent and confidentiality
- Diagnosis, missed or delayed
- Financial loss to the Trust
- Infrastructure or Resources (staffing, facilities, environment) – for example, unsafe environment, waste issues, misuse, failure or theft of IT equipment or systems, lack of facilities, equipment or supplies, inadequate staffing levels
- Infection control issues, pressure sores, fluid maintenance, pain management, any other issues relating to implementation of care or ongoing monitoring / review
- Labour or delivery adverse incidents
- Medical device/equipment related Incidents – any preventable equipment related event that could have or did lead to patient harm, loss or damage. Includes incidents related to training, servicing, disposal, storage, and suitability as well as failure of the equipment itself
- Medication incident (i.e., any preventable medication related event that could have or did lead to patient harm, loss or damage).
- Patient Information issues e.g. records, documents, test results, scans. This may also include any breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise processed.
- Treatment, procedure – any adverse incident immediately before, during or immediately after
- Security – for example, fires and fire risks, theft or damage to personal property, premises or vehicles, intruders or break-ins

Appendix 3(Table 1) Regional Risk Matrix - IMPACT (CONSEQUENCE) LEVELS [can be used for both actual and potential]

DOMAIN	Appendix 3(Table 1) Regional Risk Matrix - IMPACT (CONSEQUENCE) LEVELS [can be used for both actual and potential]				
	INSIGNIFICANT (1)	MINOR (2)	MODERATE (3)	MAJOR (4)	CATASTROPHIC (5)
<p>PEOPLE</p> <p><i>(Impact on the Health/Safety/Welfare of any person affected: e.g. Patient/Service User, Staff, Visitor, Contractor)</i></p>	<ul style="list-style-type: none"> Near miss, no injury or harm. 	<ul style="list-style-type: none"> Short-term injury/minor harm requiring first aid/medical treatment. Any patient safety incident that required extra observation or minor treatment e.g. first aid. Non-permanent harm lasting less than one month. Admission to hospital for observation or extended stay (1-4 days duration). Emotional distress (recovery expected within days or weeks). 	<ul style="list-style-type: none"> Semi-permanent harm/disability (physical/emotional injuries/trauma) (Recovery expected within one year). Admission/readmission to hospital or extended length of hospital stay/care provision (5-14 days). Any patient safety incident that resulted in a moderate increase in treatment e.g. surgery required. 	<ul style="list-style-type: none"> Long-term permanent harm/disability (physical/emotional injuries/trauma). Increase in length of hospital stay/care provision by >14 days. 	<ul style="list-style-type: none"> Permanent harm/disability (physical/ emotional trauma) to more than one person. Incident leading to death.
<p>QUALITY & PROFESSIONAL STANDARDS/ GUIDELINES</p> <p><i>(Meeting quality/ professional standards/ statutory functions/ responsibilities and Audit Inspections)</i></p>	<ul style="list-style-type: none"> Minor non-compliance with internal standards, professional standards, policy or protocol. Audit / Inspection – small number of recommendations which focus on minor quality improvements issues. 	<ul style="list-style-type: none"> Single failure to meet internal professional standard or follow protocol. Audit/Inspection – recommendations can be addressed by low level management action. 	<ul style="list-style-type: none"> Repeated failure to meet internal professional standards or follow protocols. Audit / Inspection – challenging recommendations that can be addressed by action plan. 	<ul style="list-style-type: none"> Repeated failure to meet regional/ national standards. Repeated failure to meet professional standards or failure to meet statutory functions/ responsibilities. Audit / Inspection – Critical Report. 	<ul style="list-style-type: none"> Gross failure to meet external/national standards. Gross failure to meet professional standards or statutory functions/ responsibilities. Audit / Inspection – Severely Critical Report.
<p>REPUTATION</p> <p><i>(Adverse publicity, enquiries from public representatives/media Legal/Statutory Requirements)</i></p>	<ul style="list-style-type: none"> Local public/political concern. Local press < 1day coverage. Informal contact / Potential intervention by Enforcing Authority (e.g. HSENI/NIFRS). 	<ul style="list-style-type: none"> Local public/political concern. Extended local press < 7-day coverage with minor effect on public confidence. Advisory letter from enforcing authority/increased inspection by regulatory authority. 	<ul style="list-style-type: none"> Regional public/political concern. Regional/National press < 3 days coverage. Significant effect on public confidence. Improvement notice/failure to comply notice. 	<ul style="list-style-type: none"> MLA concern (Questions in Assembly). Regional / National Media interest > 3 days < 7days. Public confidence in the organisation undermined. Criminal Prosecution. Prohibition Notice. Executive Officer dismissed. External Investigation or Independent Review (e.g., Ombudsman). Major Public Enquiry. 	<ul style="list-style-type: none"> Full Public Enquiry/Critical PAC Hearing. Regional and National adverse media publicity > 7 days. Criminal prosecution – Corporate Manslaughter Act. Executive Officer fined or imprisoned. Judicial Review/Public Enquiry.
<p>FINANCE, INFORMATION & ASSETS</p> <p><i>(Protect assets of the organisation and avoid loss)</i></p>	<ul style="list-style-type: none"> Commissioning costs (£) <1m. Loss of assets due to damage to premises/property. Loss – £1K to £10K. Minor loss of non-personal information. 	<ul style="list-style-type: none"> Commissioning costs (£) 1m – 2m. Loss of assets due to minor damage to premises/ property. Loss – £10K to £100K. Loss of information. Impact to service immediately containable, medium financial loss 	<ul style="list-style-type: none"> Commissioning costs (£) 2m – 5m. Loss of assets due to moderate damage to premises/ property. Loss – £100K to £250K. Loss of or unauthorised access to sensitive / business critical information Impact on service contained with assistance, high financial loss 	<ul style="list-style-type: none"> Commissioning costs (£) 5m – 10m. Loss of assets due to major damage to premises/property. Loss – £250K to £2m. Loss of or corruption of sensitive / business critical information. Loss of ability to provide services, major financial loss 	<ul style="list-style-type: none"> Commissioning costs (£) > 10m. Loss of assets due to severe organisation wide damage to property/premises. Loss – > £2m. Permanent loss of or corruption of sensitive/business critical information. Collapse of service, huge financial loss
<p>RESOURCES</p> <p><i>(Service and Business interruption, problems with service provision, including staffing (number and competence), premises and equipment)</i></p>	<ul style="list-style-type: none"> Loss/ interruption < 8 hour resulting in insignificant damage or loss/impact on service. No impact on public health social care. Insignificant unmet need. Minimal disruption to routine activities of staff and organisation. 	<ul style="list-style-type: none"> Loss/interruption or access to systems denied 8 – 24 hours resulting in minor damage or loss/ impact on service. Short term impact on public health social care. Minor unmet need. Minor impact on staff, service delivery and organisation, rapidly absorbed. 	<ul style="list-style-type: none"> Loss/ interruption 1-7 days resulting in moderate damage or loss/impact on service. Moderate impact on public health and social care. Moderate unmet need. Moderate impact on staff, service delivery and organisation absorbed with significant level of intervention. Access to systems denied and incident expected to last more than 1 day. 	<ul style="list-style-type: none"> Loss/ interruption 8-31 days resulting in major damage or loss/impact on service. Major impact on public health and social care. Major unmet need. Major impact on staff, service delivery and organisation - absorbed with some formal intervention with other organisations. 	<ul style="list-style-type: none"> Loss/ interruption >31 days resulting in catastrophic damage or loss/impact on service. Catastrophic impact on public health and social care. Catastrophic unmet need. Catastrophic impact on staff, service delivery and organisation - absorbed with significant formal intervention with other organisations.

Appendix 3 table 2 - Risk Likelihood Scoring Table

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

Risk Matrix/Consequence (Severity Levels)

Likelihood Scoring Descriptors	Insignificant (1)	Minor (2)	Moderate (3)	Major (4)	Catastrophic (5)
Almost Certain (5)	Medium	Medium	High	Extreme	Extreme
Likely (4)	Low	Medium	Medium	High	Extreme
Possible (3)	Low	Low	Medium	High	Extreme
Unlikely (2)	Low	Low	Medium	High	High
Rare (1)	Low	Low	Medium	High	High

Appendix 4 – Guidance for Incident Review & Grading

This section is a general guide to the review of incidents. **It is recognised that each organisation will have different organisational arrangements and therefore it is acceptable to replace this appendix with local arrangements provided they are based on the undernoted principles.**

Deciding what to review

Organisations should grade all incidents on DatixWeb for actual impact at the time of reporting the incident. This is usually completed by the reporter of the incident using the Regional Risk Matrix (Impact Assessment Table) (see Appendix 3). The Reviewer/Approver should complete the potential risk grading also using the Regional Risk Matrix (Impact Assessment Table /Likelihood Descriptors) on Datix Web **The** following steps should be used:

- **Step 1** – grade the adverse incident according to the **actual impact/ severity** to the individual and/or organisation.
- **Step 2** – determine the **potential impact/consequence** and **likelihood** of reoccurrence; and
- **Step 3** – calculate overall risk rating (i.e. Red [Extreme Risk], Amber [High Risk], Yellow [Medium Risk] or Green [Low Risk]).

The organisation's on-line reporting system allows staff to input this information directly into the electronic system.

Step 1 – What is the actual impact/severity of the event?

Use the Impact Assessment Table at Appendix 3 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/guidelines, Reputation, Finance, Information & Assets, Resources or Environmental issues.

If two or more domains (see Appendix 3) 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: Insignificant, Minor, Moderate, Major or Catastrophic. This information should be recorded within the "Actual Impact/Severity" field within Datix.

Step 2 – Assessment of potential future risk

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 visitors, 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 the following factors: -

- **Potential Impact/Severity/Consequence** – 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 Impact Table in the Risk Matrix). You should also consider the **most likely or typical impact** for that type of incident.
- **Likelihood** – consider how likely it is that the event will occur again? This can be done by considering the likelihood table (Table 1) at Appendix 3.

Grading of potential future risks following incidents helps to inform the extent of review required and the level at which review should be conducted. Grading should be based on best judgement taking into consideration all facts known about the incident at the time of occurrence.

Action required based on the Incident Grading

The Table in Appendix 1 details the actions required with regard to the level of review based on the potential risk grading.