South Eastern Health and Social Care Trust

Policy Code: SET/H&S (05) 2020

South Eastern Health & Social Care Trust

Title:	Policy and Procedures for the Reporting and Management of Adverse Incidents			
Author(s):	Regional Working Group on Adverse Incidents			
Ownership:	South Eastern Health & Social Care Trust			
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1.0 INTRODUCTION/PURPOSE OF POLICY

1.1 Background

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 Health & Social Care Board (HSCB) hereinafter called ("the organisation").

1.2 Introduction

The manner in 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.

1.3 Purpose of policy

This policy provides guidance on the reporting and managing of adverse incidents which affect service users, staff and visitors to 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 statutory[1] 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.

1.4 Policy Aims and Objectives

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

[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.

improve 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 and identification of factors contributing to incidents to assist in implementation of service improvement and risk reduction strategies, thereby minimising risk to service users, staff and visitors and the organisation; and
- To support staff when mistakes happen and encourage staff to review and reflect on their practice post review of incidents.

1.5 Legislative Requirements

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

- Health & Safety at Work (NI) Order 1978;
- Management of Health and Safety at Work Regulations (Northern Ireland) 2000
- Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) 1997;
- Social Security Claims and Payments Regulations 1979; and
- The Public Interest Disclosure Act 1998.

2.0 SCOPE OF POLICY

2.1 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.

2.2 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 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;
- Policy on Mortality & Morbidity Guidance.

This policy also excludes the arrangements for reporting of Serious Adverse Incidents (including Never Events) and Child Deaths which are the subject of separate Trust policies.

3.0 ROLES AND RESPONSIBILITIES

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

3.2 **Chief Executive**: is the Accountable Officer for the organisation and is responsible for ensuring that it meets its statutory and legal requirements in respect of adverse incident reporting and management. He/she will ensure that the Trust adheres to, and responds appropriately to, circulars and guidance issued by the Department of Health (DoH) in respect of adverse incident management.

3.3 **Director of Human Resources & Corporate Affairs:** 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., Health & Social Care Board (HSCB), Heath & 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, Risk Management & Governance

3.4 **Director/s:** 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.

3.5 **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 an open, honest and just reporting culture and ensure that appropriate reviews are carried out.

3.6 **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.

3.7 Person/s who report an incident (Reporter):

The Reporter is responsible for reporting the incident using DatixWeb in line with Trust reporting criteria and timescales. Where DatixWeb is not in use in some areas within the Trust then the reporter must report using the designated reporting system in place at the time.

3.8 Person/s who review incidents (Reviewer):

The Reviewer is responsible for ensuring that incidents reported are 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.

3.9 Person/s who approve incidents (Approver):

The 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.

3.10 Medicines Governance Pharmacist (MGP):

The MGP is responsible for the expert review, quality assurance and identification of learning from reported medication incidents. In the event that an adverse medication related incident is categorised as a Serious Adverse Incident (SAI), 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 Northern Ireland Medicines Governance Team for identification of regional trends and identification of learning.

3.11 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.

3.12 Senior Information Risk Owner (SIRO):

SIRO is the lead Director for ensuring that 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.

4.0 KEY POLICY PRINCIPLES

4.1 Definitions

4.1.1 Adverse Incident: Any event or circumstances 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 service[2]. A suggested list of broad categories of adverse incidents to be reported is listed in Appendix 1, for guidance purposes.

4.1.2 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.

4.1.3 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 defined by the HSCB within "Procedure for the Reporting and Follow-up of Serious Adverse Incidents (SAI's), Oct 2016[4].

4.1.4 Service User[5]: This term refers to a patient, service user, family (of a service user and/or family of a victim), carer or nominated representative.

4.1.5 Untoward Events relating to Children in Need and Looked After Children: These are incidents aligned to delegated statutory functions and Departmental Guidance which should be reported to the HSCB Social Care and Children's Directorate.

4.1.6 Notifiable Events to the Regulation & Quality Improvement Authority: Registered providers and managers have a statutory requirement to notify RQIA of specified events that occur within Adult Services and Childrens' Services.

4.1.7 Data Breach: incidents relate to unauthorised or unlawful processing of personal data and/or accidental loss/provision or destruction of, or damage to, personal data.

4.1.8 Medication Incident: any preventable medication related event that could have or did lead to patient harm, loss or damage.[6]

4.2 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

[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
[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] Northern Ireland Medicines Governance Team

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.

4.3 Policy Principles

4.3.1 The organisation's approach to Adverse Incident Reporting and Management: An open, honest and just culture[7]

As part of its proactive approach to risk management, the organisation promotes an open, honest and just 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 an open, honest and just 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. 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.

All employees must be honest, open and truthful in all their dealings with patients/clients and the public, and organisational and personal interests

[7] *a just culture focuses on identifying and addressing systems issues that lead individuals to engage in unsafe behaviours, while maintaining individual accountability by establishing zero tolerance for reckless behaviour. Just organizations focus on identifying and correcting system imperfections, and pinpoint these defects as the most common cause of adverse events. Just culture distinguishes between human error (e.g., mistakes), at-risk behaviour (e.g., taking shortcuts), and reckless behaviour (e.g., ignoring required safety steps), in contrast to an overarching 'no-blame' approach" (Agency for Healthcare Research and Quality; Patient Safety Network 2016, US Department of Health).*

must never be allowed to outweigh the duty of openness, transparency and candour.

4.3.2 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 for eg, HSCB, RQIA and HSENI. 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.

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 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 HSCB.

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

4.3.3 Additional Internal reporting arrangements in respect of other incidents covered by this policy

Untoward Events relating to Children in Need and Looked After Children

The arrangements for the reporting of untoward events relating to children in need and looked after children are as outlined in the letter and amended attachments issued on 16 August 2010 (originally issued on 5 May 2005) by the Director of Social Care and Children, HSCB these include:-

- The admission of all children/young people under 18 years to adult mental health and learning disability facilities including placements made outside of Northern Ireland.

- Children from a looked after background who abscond or who are missing from care settings. This includes trafficked children, and unaccompanied asylum seeking children. In such cases Trusts should ensure that the Regional Protocol in respect of Children missing from Care/Home is adhered to and confirm such within the report to the HSCB. This will include prior notification to the HSCB in advance of any media coverage.

- Children who are from a looked after background who are admitted to the Juvenile Justice Centre, Young Offenders Centre or who have been detained in an custodial setting for a period exceeding 4 hours.

- Children/young people in placements outside of the regulated provision for 16-17 year olds.

Any of the above incidents which also meet the criteria for reporting as an SAI or Early Alert should be notified to the Risk Management Department as soon as possible in line with Trust procedures. These incidents should also be reported via DatixWeb.

Notifiable Events to the Regulation & Quality Improvement Authority

Trust Services which are regulated by RQIA should report the following types of incidents in relation to Adult and Childrens' Services in line with the updated guidance issued in July 2015.

These incidents include:

- Death – whether expected or unexpected;
- Accident – occurring in the service involving service users, staff or other persons where medical intervention was sought;
- Outbreak of infectious disease;
- Allegation of misconduct of staff;
- Incident involving the Police; and
- Any other event adversely affecting a service user – this may include, Failure of basic utility (electricity, gas, water etc); Fire at a premises; Significant damage to premises; Failure of any safety related equipment; Incident of any drug or alcohol misuse; Medication incident; Behavioural issue; Suicide/self-harm.

Children Services Only:

- Serious complaint regarding child protection; serious harm and/or exploitation of a child or young person;
- Child Protection Enquiry;
- Allegation of Serious Offence; and
- Sexual Exploitation.

Any of the above incidents which also meet the criteria for reporting as an SAI or Early Alert should be notified to the Risk Management Department as soon as possible in line with Trust procedures. These incidents should also be reported via Datixweb.

Reporting of Serious Data Breaches to the Information Commissioner (ICO)

Principle f. Article 5, General Data Protection Regulation 2018 requires that personal data shall be 'processed in a manner that ensures appropriate security of personal data, including protection against unauthorised or unlawful processing and against accident loss, destruction or damage, using

appropriate technical or organisational measures ('integrity and confidentiality').

An incident report should be submitted for all data breaches. The Head of Information Governance, in conjunction with the Director of HR and Corporate Affairs will then determine whether a data breach should be reported to the Information Commissioner's Office after considering the following:

- Potential detriment to individuals;
- Volume of data affected; and
- Sensitivity of data.

The ICO will assess the nature and seriousness of the data breach and the adequacy of any remedial action taken, and well 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 Head of Information Governance to facilitate onward reporting to the ICO if appropriate.

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.

Reporting of Adverse Incidents in Relation to Medical Devices, Non-Medical Equipment, Buildings and Plant to the Northern Ireland Adverse Incident Centre

The arrangements for the reporting of adverse incidents **relating to Medical Devices, Non-medical equipment, Buildings and Plant** as per the definition used by the Northern Ireland Adverse Incident Centre ie, *An adverse incident involving a medical device is defined as "an event, which causes, or has the potential to cause, unexpected or unwanted effects involving the safety of patients, users or other persons."* are as outlined in Policy on the Management of NI Central Alert System (NICAS) (including the reporting of incidents involving medical devices). All incidents should be reported/investigated using DatixWeb.

The aforementioned policy also includes arrangements for the reporting of Defective Medicinal Products and Food Incidents.

4.3.4 Operational Procedures for Reporting of Adverse Incidents

The process for reporting, recording and reviewing adverse incidents is detailed below and also included in diagrammatic format in Appendix 1. Key points to remember are listed below.

4.3.5 What to do when an adverse incident occurs – immediate actions

The injured person or damaged property should be assessed immediately to ascertain extent of injury/damage and identify emergency or urgent treatment/action required. The situation must be made safe. Communicate with the service user and their relatives/carers, as appropriate following an adverse event. Ensure appropriate discussion with the service user and/or relatives/carers and give consideration to any additional support which may be required. Refer to the organisation's Being Open Policy. Any equipment involved in the adverse incident, even if not directly implicated, should be removed from use and the following action taken:-

- Clearly label "Do Not Use" including a short description of the nature of the fault, if possible;
- Retain any related evidence such as packaging (for batch or serial numbers) or consumables/accessories (eg, giving sets for pumps etc);
- Decontaminate any device that can be decontaminated without destroying evidence and attach a decontamination certificate to that effect (refer to local Trust policy); and
- For medication – where packaging or labelling of a medicine is an issue, retain or photograph to facilitate further review and follow up with the pharmaceutical company, MHRA or relevant authority.

You must also follow **Trust policy** in relation to immediate actions to be taken when finding a person deceased following a suspected incident.

4.3.6 Who should report?

Any member of staff can report an adverse incident. It is the responsibility of **ALL** staff who are involved in, witness to, or become aware of an adverse incident, to ensure it is reported using the organisation's adverse incident reporting system. If the incident involves another area within the Trust, this area must be made aware of it and remedial actions agreed.

4.3.7 When to report?

It is important that all adverse incidents are reported as soon as possible and ideally within 24 hours of occurrence or becoming aware of the adverse incident. This supports effective review and timely learning, and ensures compliance with responsibilities for external reporting.

4.3.8 What types of incidents to report?

The incident reporting system will ensure that any event which meets the definition in section 4.1.1 involving service users, staff and visitors are reported promptly and action instigated, where necessary. Appendix 2 provides a list of broad categories of possible adverse incidents which may assist reporters. This is not an exhaustive list but gives a broad indication of the types of adverse incidents to be reported.

4.3.9 How to report?

All incidents should be reported using the organisation's adverse incident reporting system (DatixWeb).

In respect of incidents involving service users, please note that adverse incident reports are NOT health records and copies of any electronic reports (or paper forms) should NOT be filed in the service users' records. However, details of the incident (including the incident reference number, if available) that are relevant to the treatment and care being provided to the service user should be added separately within the service user's healthcare record.

4.3.10 Other Reporting Systems

Some departments have additional error and incident monitoring arrangements (e.g. Laboratories) as part of specific legal, accreditation or quality assurance framework requirements for these services. Staff using these systems must ensure that incidents which meet the organisation's definition of adverse incidents are also reported via the organisation's adverse incident reporting system.

4.3.11 Staff Support directly following an incident

The organisation recognises that it has a responsibility to support all staff following adverse incidents. All staff involved in an adverse incident will need an appropriate level of support consistent with the outcome of the incident. It is the line manager's responsibility to ensure that individuals are supported appropriately. Support can be provided by Occupational Health, Trade Unions and local staff care services (24 hour care line – Inspire Workplaces - free phone 0808 800 0002 Staff involved should be kept informed of the progress of reviews at intervals agreed with their manager.

In addition, individuals who have been absent from work may require additional support and supervision to aid confidence when returning to work. Staff involved in the incident should also be involved in Level 1 Reviews, where appropriate, with feedback provided in relation to Level 2 or 3 Reviews, when complete. Further guidance can be obtained via the Trust's policy on Supporting Staff involved in Incidents, Complaints, Claims & Coroners Inquests.

4.3.12 Arrangements for Incident Review & Grading

Deciding what to 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 more structured approach to its incident management.

Organisations should grade all incidents in 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).

In addition, it is important to complete the potential risk grading also using the Regional Risk Matrix (Impact Assessment Table/ Likelihood Descriptors) on DatixWeb [refer to guidance in Appendix 4 Datix User Guides on iConnect.

The Regional Risk Matrix is also used by a range of specialist advisers for grading of incidents. Not all incidents fit discreetly into individual categories within the matrix and therefore the grading/coding of incidents will be at the discretion of the relevant adviser.

4.3.13 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'***[8] 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

[8] Insert details re Regional Being Open policy

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.

4.3.14 Communication with the Media

All communications with the media should be co-ordinated by the Trust's Communications Department.

4.3.15 Debriefing of Staff after Adverse Incidents

Assistant Directors/ Senior Managers and Heads of Department should ensure that local procedures are 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 eg, 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.

4.3.16 Review, Monitoring and Analysis of Adverse Incident Statistics

The organisation has in place mechanisms for the review, monitoring and analysis of adverse incidents and produces reports for consideration and discussion locally at relevant governance related committees/sub committees and externally as required. Incident statistics should also be used with other sources of statistics to help inform the management of risks and effectiveness of actions taken following incident reviews, Quality Improvement projects and other quality and safety initiatives.

The Medicines Governance Pharmacist will lead on the multidisciplinary review, monitoring and analysis of medication related incidents and will link in with the Regional Medicines Governance Team in respect of the production of regional medication related governance reports.

4.3.17 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, eg, 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.

5.0 IMPLEMENTATION OF THE POLICY

5.1 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 intranet.

5.2 Resources

5.2.1 Training

Initial Adverse Incident Training is mandatory via Corporate Induction for all staff and appropriate additional training and guidance will be provided by Risk Management & Governance Directorate to ensure that all Trust employees understand their responsibilities under this policy and are able to effectively fulfil their obligations to report/manage adverse incidents. The organisation's training administration system 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.

5.3 Exceptions

There are no exceptions to this policy and to the organisation's commitment to learn from adverse incidents.

6.0 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

Risk Management & Governance Directorate in the light of best practice, changing legislation or new/updated policy guidance.

7.0 EVIDENCE BASE/REFERENCES

- 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.

8.0 CONSULTATION PROCESS

This policy was developed by the Regional Adverse Incident Work Group chaired by the Assistant Director, Risk Management & Governance, South Eastern Health & Social Care Trust. Consultation was completed via email with relevant Assistant Directors and staff within all organisations included in the working group.

9.0 APPENDICES

Appendix 1 – Incident reporting and review process flowchart
Appendix 2 – Examples of Adverse Incidents
Appendix 3 – Regional Risk Matrix
Appendix 4 – Guidance for Incident Review and Grading

10.0 EQUALITY STATEMENT

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. ☒

SIGNATORIES

Policy Name	Author Endorsement	Modified	Modified By
Policy and Procedures for the Reporting and Management of Adverse Incidents	Yes	27/08/2020 03:37 PM	Walker, Valerie

Policy Name	Approval	Modified	Modified By
Policy and Procedures for the Reporting and Management of Adverse Incidents	Endorsed	05/10/2020 03:58 PM	Weir, Myra

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

INCIDENT

IMMEDIATE ACTION

1. Make person(s) / area safe.
2. Obtain medical aid if required.
3. Inform manager on duty ASAP.
4. Complete an incident form.
5. Consider level of communication with the patient.
6. Consider level of review required and action accordingly. If incident meets SAI criteria, follow relevant procedures.

GREEN INCIDENT (LOW RISK)

Green incidents – Should normally be reviewed locally in the ward or department in which the event occurred. The investigative lead will normally be the Ward/Team/Departmental manager. It is the local team's responsibility to identify learning points, or safety improvement measures that are within the departments control and ensure that those safety measures identified that are not within the control of the department are appropriately communicated to the relevant Management Team for consideration.

Incident types frequently falling into this category should also be subject to aggregate analysis by the Ward/Team/Departmental Manager to identify any need for more targeted data collection. It is acceptable for the ward/departmental manager to close such incidents following review and recording of findings and lessons learned on Datix.

Review of this grade of incident should normally be completed and **closed within 5 working days**.

YELLOW INCIDENT (MEDIUM RISK)

Yellow Incidents – These should also be reviewed locally, as for Green Incidents, but reviewed by the **[Governance Manager/Clinical Manager/Senior Nurse/Senior Manager – note each organisation to insert relevant designations]** for that area. Again it is the local team's responsibility to identify learning points, or safety improvement measures within the departments control and ensure that those which are not, are appropriately communicated to the relevant Management Team for consideration. Frequently occurring events attracting this risk category should also undergo Trust-wide aggregate review to identify any need for more targeted data collection.

It is acceptable for the Ward/Team/Departmental Manager to close such incidents following review and proper recording of findings and lessons learned on Datix.

Review of this grade of incident should normally be completed and **closed within 4 weeks**.

AMBER INCIDENT (HIGH RISK)

Amber Incidents – These incidents should be subject to the appropriate level of review. The **[Governance Manager/Clinical Manager/Senior Nurse/Senior Manager – note each organisation to insert relevant designations]** should discuss with the relevant **Assistant Director/Co-Director**, who is going to take the lead. It is the responsibility of the relevant management team to ensure that all learning points and safety improvements are appropriately identified and those not within the control of the local management team are communicated to the relevant person/s and committee/s, whichever is the more appropriate.

Note – Improvement strategies arising out of this group of events should be monitored as part of the organisation's Governance arrangements.

Where necessary advice can be sought from the **[insert name of Department].**

Review of this grade of incident should normally be completed and **closed within 12 weeks**.

RED INCIDENT (EXTREME RISK)

Red Incidents – Where major (ie, long-term permanent harm/disability [physical/emotional injuries/trauma]) or tragic harm (ie, permanent harm/disability [physical/emotional trauma] or incident leading to death) has occurred the Chief Executive of the organisation (**or nominated Director and/or Assistant Director/Co-Director**), with the support and advice of the relevant Director/s and Governance lead(s), should appoint a team led by a trained facilitator in SEA/root cause analysis. All of the resulting reports and improvement strategies arising from these events should be monitored by the organisation's [insert name of Committee/sub-committee].

Review of this grade of incident should normally be completed and **closed within 12 weeks.**

Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1997 (RIDDOR)
Report all RIDDOR reportable Events to Risk Management Advisory Services.

Report all Medical Device Events to Medical Devices Manager.

Report all staff sickness precipitated by an accident at work to Occupational Health.

RIDDOR reportable events are:
Any fracture (not fingers or toes) | Amputations | Dislocation of Joint
Loss of sight | Chemical, hot burn to eye | Any electric shock requiring resuscitation | Hypothermia, or heat induced illness | Loss of consciousness – asphyxia | Acute illness caused by biological substance

If in doubt contact the Health &Safety Adviser

Open, Honest and Just Culture

This Trust welcomes knowledge of adverse events as an opportunity to learn for the benefit of our service users, staff and visitors. Unless there is clear evidence of flagrant malpractice, a complete disregard for the safety of others, maliciousness, intent to harm, theft or fraud the disciplinary policy will not be used for review purposes. Incidents will be investigated for the purposes of learning and change and staff are required to engage as active participants of this.

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 (ie, 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 – Regional Risk Matrix

DOMAIN	IMPACT (CONSEQUENCE) LEVELS [can be used for both actual and potential]				
	INSIGNIFICANT (1)	**MINOR (2)**	**MODERATE (3)**	**MAJOR (4)**	**CATASTROPHIC (5)**
PEOPLE *(Impact on the Health/Safety/Welfare of any person affected: e.g. Patient/Service User, Staff, Visitor, Contractor)*	• Near miss, no injury or harm.	• 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).	• 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.	• Long-term permanent harm/disability (physical/emotional injuries/trauma). • Increase in length of hospital stay/care provision by >14 days.	• Permanent harm/disability (physical/ emotional trauma) to more than one person. • Incident leading to death.
QUALITY & PROFESSIONAL STANDARDS/ GUIDELINES *(Meeting quality/ professional standards/ statutory functions/ responsibilities and Audit Inspections)*	• Minor non-compliance with internal standards, professional standards, policy or protocol. • Audit / Inspection – small number of recommendations which focus on minor quality improvements issues.	• Single failure to meet internal professional standard or follow protocol. • Audit/Inspection – recommendations can be addressed by low level management action.	• Repeated failure to meet internal professional standards or follow protocols. • Audit / Inspection – challenging recommendations that can be addressed by action plan.	• Repeated failure to meet regional/ national standards. • Repeated failure to meet professional standards or failure to meet statutory functions/ responsibilities. • Audit / Inspection – Critical Report.	• Gross failure to meet external/national standards. • Gross failure to meet professional standards or statutory functions/ responsibilities. • Audit / Inspection – Severely Critical Report.
REPUTATION *(Adverse publicity, enquiries from public representatives/media Legal/Statutory Requirements)*	• Local public/political concern. • Local press < 1day coverage. • Informal contact / Potential intervention by Enforcing Authority (e.g. HSENI/NIFRS).	• 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.	• Regional public/political concern. • Regional/National press < 3 days coverage. Significant effect on public confidence. • Improvement notice/failure to comply notice.	• 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 (eg, Ombudsman). • Major Public Enquiry.	• 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.
FINANCE, INFORMATION & ASSETS *(Protect assets of the organisation and avoid loss)*	• Commissioning costs (£) <1m. • Loss of assets due to damage to premises/property. • Loss – £1K to £10K. • Minor loss of non-personal information.	• 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	• 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	• 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	• 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
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. • No impact on public health social care. • Insignificant unmet need. • Minimal disruption to routine activities of staff and organisation.	• 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.	• 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.	• 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.	• 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.
ENVIRONMENTAL *(Air, Land, Water, Waste management)*	• Nuisance release.	• On site release contained by organisation.	• Moderate on site release contained by organisation. • Moderate off 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.

SET Risk Matrix – April 2013 (based on HSC Regional Risk Matrix - April 2013, updated June 2016) - Clean

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

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 **[refer to Datix User Guides available on iConnect also].** 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. Depending on the findings during review, the grade may need to be amended.

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.

For further details on how to do this refer to Datix User Guide and or Risk Management Advisory Services, Risk Management & Governance Directorate.