ADVERSE EVENT MANAGEMENT POLICY

(Incident management)

In preparation for national reporting, terminology has been standardised: event/adverse event is the terminology now used meaning incident.

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Chief Executive

Employee Director

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1. **Introduction**

    NHS Borders is committed to the delivery of effective, safe, and person-centred care and ensuring there will be no avoidable injury or harm to people or adverse impact on the organisation resulting from the delivery of healthcare or any event/incident. In line with the Scottish Government “The Healthcare Quality Strategy for NHS Scotland” (2010)\(^1\), Staff Governance Standards 4th Edition (2012) and Health & Safety Legislation, The personal health, safety and wellbeing of patients, their family and carers, staff and members of the public will be achieved through the provision of an appropriate, clean and safe environment.

    The systematic recording, management, learning, sharing knowledge and understanding of all adverse events and near misses is a holistic approach core to the scrutiny, analysis and management of risk.

    In preparation for the national reporting terminology has been standardised: event/adverse event is the terminology now used meaning incident.

2. **Definitions**

    In line with definitions provided by Health Improvement Scotland Learning from adverse events through reporting and review: A national framework for NHS Scotland Sept 2013 NHS Borders subscribes to the following:

2.1 **Adverse Event**

    An adverse event is defined as an event that could have caused, or did result in, harm to people, groups of people and/or an organisation.

2.1.1 **People are defined as:**

    - Service users
    - Patients
    - Members of the public
    - Members of staff (including volunteers)
    - Carers
    - Family members, and
    - Visitors

2.2 **Harm**

    Harm is defined as an outcome with a negative effect. Harm to a person or groups of people may result from worsening of a medical condition, the inherent risk of an investigation or treatment, system failure, provider performance issues, service disruption, financial loss, environmental harm or adverse publicity/reputational harm.

    All harm is not avoidable, for example the worsening of a medical condition or the inherent risk of treatment. However, it is often not possible to determine if the harm caused was avoidable until a review is carried out.
2.3 Near Miss
Is an event that potentially could have resulted in an adverse outcome or harm but due to action taken or a fortunate break in the chain of events, harm was averted.

2.4 Significant Adverse Event (SAE)
An SAE can be described as an unexpected or avoidable event that could have resulted, or did result in, unnecessary serious harm or death of a patient, staff, visitor or member of the public (Healthcare Improvement Scotland (HIS), 2012) or an increase in organisational liabilities. This includes events which have resulted in a major or extreme adverse outcome as defined within the risk matrix. In addition this includes NHS Borders unexpected and preventable events outlined in section 7 or any event deemed by the organisation as being significant.

This will include any other event, such as a significant near miss or an identified adverse trend that any member of the Board Executive Team, Clinical Board Management Teams and Heads of Support Services agree warrant review.

2.5 Categorisation of Events
HIS has defined events into categories that will help determine the level of review.

- **Category 1:** Events that may have contributed to or resulted in permanent harm, for example death, intervention required to sustain life, severe financial loss (> £1M), ongoing national adverse publicity (likely to be graded as major/extreme)
- **Category 2:** Events that may have contributed to or resulted in temporary harm, for example initial or prolonged treatment, intervention or monitoring required, temporary loss of service, significant financial loss, adverse local publicity (likely to be graded moderate/minor)
- **Category 3:** Events that had the potential to cause harm but i) an error did not result, ii) an error did not reach the person iii) an error reached the person but did not result in harm (Near Miss). (Likely to be graded as negligible/near miss.) These results can occur either by timely intervention or due to good fortune.

2.6 Significant Adverse Event Review (SAER)
This is a process that uses templates and checklists to review a SAE.

2.6.1 Initial Review
When an adverse event occurs, defined as requiring a review, the first decisions for the sponsor and appointed reviewers are: What is the proportionate response and what level of review is required? This process is termed “the initial review”. This initial review will take the form of the sponsor and appointed reviewers collecting immediate evidence, reviewing the impact and seriousness of the event, analysing data, determining the level of potential learning and making a decision on what level of review is required. Initial review will determine whether a comprehensive review, concise review or management review is required.
2.6.2 Comprehensive Review
This is the most in-depth type of review, gathering evidence and reviewing all details of the event. Significant lapses identified within the initial review are investigated plus other types of lapses and all lines of enquiry are followed. This review will utilise root cause analysis methodology to its fullest.

2.6.3 Concise Review
This review focuses on the significant lapses/concerns identified within the initial review. It will utilise the appropriate tools of root cause analysis to ensure contributing factors are identified for the significant lapses.

2.7 Management Review
This is a local review deemed necessary by the senior management of the clinical board/directorate. This review may be undertaken by a local manager or an appointed manager. Review methodology will be used as appropriate.

2.8 Further Inquiries
This requires all first approvers to review events recorded on Datix system to identify contributing factors and further actions. It may require first approvers to ask questions of staff as to how the event occurred and what further actions would minimise recurrence. This is a minimal review and is required for all events.

2.9 Independent Review
An independent review may be commissioned by the Board Executive Team, this will consist of a non NHS Borders (independent) individual/s being appointed to act as the lead reviewer or review team.

2.10 Root Cause
The fundamental reason(s) why an event occurred.

2.11 Improvement Action Plan
A time bound plan setting out the steps to prevent an event recurring and clear responsibility for implementing the action.

3. Aims
NHS Borders will take all reasonably practicable steps, to minimise and manage risk with the overall objective of protecting patients, staff, visitors and members of the public by minimising organisational liability. The primary concern is the provision of a safe environment together with working practices and policies that take into account risks. Adverse event recording and management is a core element of this process. The process is depicted in appendix 1.

The purpose of this policy is to:
• prevent adverse events occurring through proactive risk assessment
maximise safety to patients, family, carers, staff, and members of the public
ensure all adverse events are reported, reviewed and lessons learned to ensure effective risk management in accordance with legal and national standards
define adverse event management responsibilities of NHS Borders staff
minimise organisational risk and liabilities in accordance with risk management strategies
identify the systems, procedures and guidance that will support the implementation of NHS Borders Adverse Event Recording & Management Operational Procedure
ensure an active and planned approach to engaging with key stakeholders particularly patients, family, carers, staff, partner agencies and members of the public affected by any adverse event
ensure a “Just Culture” where individuals are accountable and treated fairly. NHS Borders’ culture is based on values of trust, openness, equality and diversity which encourages and supports staff to recognise, report and learn from adverse events

4. Scope and Range
The policy applies to all employees of NHS Borders and includes bank staff, and volunteers. In addition the policy applies to locum/agency/honorary contract staff and contractors.

General Practitioners (GPs) will be able to access the Datix incident recording system for the purpose of reporting clinical adverse events that originate from NHS Borders healthcare activities. When using the system, GPs will be expected to comply with this policy.

Where other agencies contract or deliver services on behalf of NHS Borders, incidents regarding interface issues should be notified to NHS Borders.

At this time the organisation will be using a phased approach to the inclusion of independent contractors including community pharmacists, optometrists, and general dental practitioners into adverse event reporting.

NHS Borders staff working with a healthcare partner such as Scottish Borders Council must report and manage events within the scope of this policy. Healthcare partners are not included within the scope of this policy but must notify NHS Borders of any adverse event that affects our organisation.

5. Being Open and Fair
NHS Borders will demonstrate transparency and openness to patients, families, carers, members of the public, staff and partner agencies affected by an adverse event.

Reviews will be conducted openly and fairly. The purpose of a review is to identify underlying causes or system failures which led to an event occurring. NHS Borders is committed to a “Just Culture” in creating “an environment where learning and accountability are fairly and constructively balanced” (Dekker, 2012). The Board has a non punitive approach to human error and aims to learn from mistakes.
however, appropriate Human Resources policies and procedures will apply where gross negligence of duty has occurred.

Staff are entitled to support throughout the adverse event review process. This can be provided from the Occupational Health Service, professional, specialist advisers or staff side organisations.

If at any point during an adverse event review a professional or conduct issue is identified that could have an impact on patient care in the immediate future, the staff member identifying the issue should discuss it immediately with the appropriate line manager in line with NHS Borders policy involving the relevant appropriate professional lead.

The National Patient Safety Agency ‘Incident Decision Tree’ is a helpful tool to use to ensure a fair approach to individual accountability. This will be available in the Significant Adverse Event Review Tool Kit on the intranet.

6. Roles and Responsibilities

6.1 Borders NHS Board Members
Agree robust governance systems that capture risks relating to adverse event management and learning systems. Seek assurance through these systems that the policy is being implemented effectively and fairly.

6.2 The Chief Executive as Accountable Officer is responsible for:
- supporting through effective leadership a positive safety culture
- providing a safe environment for patients, family, carers, staff, healthcare partners and members of the public
- creating a culture to support staff to safely express any concerns and for these to be listened to, discussed and acted on as appropriate
- ensuring compliance with the policy
- ensuring all staff are skilled and trained in adverse event management
- ensuring appropriate engagement and information sharing with patients, family, carers, staff, partner agencies and members of the public
- providing resources to ensure effective implementation of this policy
- ensuring the risk management processes are used effectively to proactively identify risks and minimise the likelihood and outcomes of adverse events occurring
- ensuring that reviews are monitored and learning is shared throughout the organisation and out with the organisation as appropriate

6.3 Directors/Associate Directors/General Managers/Heads of Support Services
- will act as review sponsors commissioning the appropriate level of review
- ensure that adverse events are reviewed and managed at the Clinical Board Healthcare and Integrated Care Governance Groups and Support Directorates/Services Governance Groups
- will establish a local system that ensures events are managed and monitored within approved timescales
• ensure that learning from SAERs are shared locally and across the organisation, improvement actions are completed in agreed timescales
• will report exceptions to the Healthcare Governance Steering Group

6.4 **Line Managers** are responsible for:
• ensuring staff who have been involved in an event are informed, engaged and supported
• ensuring employees comply with all NHS Borders Adverse Event Management policies and procedures and the Risk Management Policy
• ensuring preventative measures and processes are followed, to effectively undertake risk assessment, identify potential harm and manage risks to an acceptable level. The aim is to decrease/eliminate the likelihood of an event occurring and/or the level of harm. ensuring an SAE is escalated as per the NHS Borders Adverse Event Management Reporting / Escalation Procedure (Appendix 2)
• monitoring events to ensure they have been fully reported, contributing factors identified and corrective actions to minimise reoccurrence taken
• approving events on Datix within 10 working days, where the line manager has been identified as either a first or final approver
• escalating events of particular concern to the next level of management
• identifying and reviewing events potentially reportable under RIDDOR and other specialist reporting – refer to section 10
• informing the topic specialists on any updates made to potentially reportable events
• adding identified risks where appropriate to the risk register

6.5 **All Employees** have a responsibility to:
• assist in identifying preventative measures through proactive risk assessment

Where an event has occurred:
• make the situation safe to prevent further injury/loss providing that it is safe to do so. If they cannot make the area safe summon further assistance.
• report the event to their line manager
• retain any information/data or evidence that could be used in a review e.g.
  o equipment/devices or machinery
  o packaging which could identify batch numbers
  o CCTV
• always check with a manager before clearing up the scene of a significant adverse event
• ensure it is reported onto Datix as soon as possible but within 24 hours of it occurring. If the event is an SAE it should be recorded as soon as situation is made safe and emergency communication is complete
• ensure, where the event involves a patient, that the details are recorded in the patient’s health records and includes the Datix Reference Number
• record details of any information given to or received from the patient, family, carers, staff, partner agencies and members of the public in the patient’s health record and/or Datix Event Form
• participate in and contribute to event reviews as required to ensure lessons are learned and future risk of recurrence is reduced
comply with NHS Borders Adverse Event Management policy and procedures as well as their own codes of professional conduct where applicable
undertake training as appropriate to their role on the implementation and management of all NHS Borders Adverse Event Management Policy, procedures and any local protocols
as an exception ensure that retrospective reporting of staff work related injuries are recorded on Datix within 4 weeks of the date of the event
use learning and reflection from adverse events in profession revalidation and appraisal

6.6 Clinical Board Healthcare and Integrated Care Governance Groups and Support Directorates/Services Governance Groups are responsible for providing assurance to NHS Borders Board:

that the NHS Borders Adverse Event Management policies and procedures, the Risk Management Policy have been implemented and compliance is monitored by the Clinical Board/Support Directorate/Service
Preventative measures and processes are in place to effectively undertake risk assessment, identify potential harm and manage risks to an acceptable level. The aim to decrease/eliminate the likelihood of an event occurring and/or the level of harm.
that actions contained within improvement plans have been completed
data is regularly analysed to identify trends requiring further review
Identify possible learning opportunities within their own area and departments.
contribute to organisational learning by sharing and adopting lessons learnt
report exceptions to the Healthcare Governance Steering Group

6.7 Occupational Health and Safety Forum is responsible for:

monitoring event reviews and improvement/action plans (including significant adverse events) for occupational health and safety events.
receiving NHS Borders event report statistics/trends, using learning to inform training and policy going forward
disseminating learning from health and safety incidents via the forum

6.8 Healthcare Governance Steering Group is responsible for monitoring organisational wide learning relating to healthcare governance matters including adverse events.

fostering a culture of learning, openness and transparency encouraging staff, patients and the public to feedback and raise issues
seeking assurance from Clinical Boards and Support Directorates that they have effective local systems and procedures in place for healthcare governance including adverse event management
oversight of themes and risks reported by clinical boards/support services and organisational groups
promoting an active partnership approach within NHS Borders with staff, patients, key stakeholders and other organisations to enhance the quality of service provided and support the delivery of person centred, safe and effective healthcare

Healthcare Governance Structures are depicted in appendix 3
7. **Adverse Event Review**

All adverse events require reviewing and monitoring as described below.

7.1 **Level of Review** - see appendix 4

The level of review will be initially determined by final approver (risk owner) but authorised by senior manager/director reflecting the severity of the actual/adverse outcome, whether it is defined as a SAE or has significant issues that would impact on patient/staff/organisational safety.

Incidents should be managed and reviewed in line with:

1. **SAER** - all events graded as having an outcome of major or extreme or are deemed significant enough to review through the SAER process. Other events that have a lower graded outcome may warrant a review due to significant issues being identified that can impact on corporate objectives (please refer to table below).

   Clinical Governance and Quality will oversee the appointment of the Sponsor, appointment of the Sponsor will be authorised by a Director. (initial, comprehensive and concise)

2. **Local Management Review** - events that have outcomes or potential outcomes that could have significant local impacts or have significant safety issues will require a management review. These may be events that are recognised through trend analysis, systemic/process issues, recurring hazards/safety issues, failures in communication, transitions as examples

3. **Further Inquiries** - this is the identification of contributing factors at local levels. This will be facilitated by the Datix reporting system all events will require this level of local scrutiny.

   For Significant Adverse Event Review process see appendix 5
While not all inclusive, the table below lists events that must be reviewed using NHS Borders SAER Process.

<table>
<thead>
<tr>
<th>NHS Borders unacceptable and preventable events</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical events that should never happen</strong></td>
</tr>
<tr>
<td>Surgery performed on the wrong body part</td>
</tr>
<tr>
<td>Surgery performed on the wrong patient</td>
</tr>
<tr>
<td>Wrong procedure performed on a patient</td>
</tr>
<tr>
<td>Unintended retention of a foreign object after surgery or a procedure</td>
</tr>
<tr>
<td>Unexpected anaesthetic, intra-operative or immediate post operative death</td>
</tr>
<tr>
<td>Medication error - wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, wrong route of administration, or medication not given</td>
</tr>
<tr>
<td>Death or severe harm as a result of the inadvertent transfusion of ABO incompatible blood</td>
</tr>
<tr>
<td>Unexpected significant hypo or hyperglycaemia occurring in the secondary healthcare environment</td>
</tr>
<tr>
<td>Severe Illness or death caused by HAI [including surgical site infection]</td>
</tr>
<tr>
<td>Grade 3 and 4 pressure ulcers acquired in hospital</td>
</tr>
<tr>
<td>Unexpected or avoidable death from sepsis</td>
</tr>
<tr>
<td>Venous thrombo–embolus acquired in hospital where prophylaxis was indicated and appropriate but not given</td>
</tr>
<tr>
<td>Death of patient after an inpatient fall</td>
</tr>
<tr>
<td>Maternal death</td>
</tr>
<tr>
<td>Intra-partum stillbirth or unexpected early neonatal death (0-7 days)</td>
</tr>
<tr>
<td>Patient suicide whilst under the care of our mental health services or seen by mental health services in the last 12 months</td>
</tr>
<tr>
<td>Death or serious injury to others whilst under the care of mental health services</td>
</tr>
<tr>
<td>In the normal course of treatment/investigation the opportunity to recognising cancer/life limiting condition is missed and results in inappropriate intervention</td>
</tr>
<tr>
<td>Death or significant harm of a child or vulnerable adult due to physical neglect or intentional harm</td>
</tr>
<tr>
<td>Death or serious harm from the administration of the wrong treatment following patient misidentification</td>
</tr>
<tr>
<td><strong>Environmental events that have caused or have the potential to cause death, significant harm or required intervention to save life</strong></td>
</tr>
<tr>
<td>A window restrictor that ensures the opening can be no more than 100mm has been overcome/or fails and allows the window to open past the safety margin</td>
</tr>
<tr>
<td>Entrapment by bed rail</td>
</tr>
<tr>
<td>Severe scalding of patient</td>
</tr>
<tr>
<td>Inhalation of toxic substances/organisms - including legionella</td>
</tr>
<tr>
<td><strong>Information Governance: significant release of personal/corporate data</strong></td>
</tr>
<tr>
<td>A large number of people affected or small numbers of people affected with significant impact of their mental/physical well being. Any event that would be required to be reported to Information Commissioner Office</td>
</tr>
</tbody>
</table>
Further information regarding significant adverse events that would require SAER can be found in publications such as The Department Of Health ‘Never Events’ List 2012-13 http://www.baccn.org.uk/news/120420_1.pdf

7.1.1 Exceptions
It is accepted that there may be exceptions to SAERs and in such cases, judgement will be applied. These exceptions must be presented (using the SAER exception form) by the relevant final approver and authorised by one of the following:
- General Manager/Associate Nursing Director/Associate Medical Director/Head of Support Service
- Member of the Board Executive Team (Directors)

The Board Executive Team (BET) may also decide to commission an independent review which may involve external reviewers. The BET will appoint the:
- Review Sponsor.
- Lead Reviewer.
- Review Team members.

The BET are responsible for ensuring the operational team are kept fully up to date with developments.

8. Risk Management (RM)
This policy is an integral component of the risk management process. Risk associated with adverse event management shall be managed through the organisation’s full risk management framework and supporting processes. The risk management process that includes adverse event management is explained further in Appendix 6.

9. Governance
The Healthcare Governance Steering Group will oversee the governance of this policy reporting to the appropriate organisational governance groups any weaknesses identified. The Steering Group will escalate issues to the Clinical Executive Operational Group/Strategy Group for onward consideration at BET and/or Audit Committee and ultimately the Health Board. (as per appendix 3)

Clinical Boards/Integrated Boards/Directorate Governance Groups will gain assurances that:
- this policy is being implemented
- improvement action plans are implemented and monitored
- learning plans have been generated and shared within their Clinical Board/Directorate and as appropriate throughout the organisation
- learning plans have been submitted to the Clinical Governance & Quality Team for collation

Please refer to information governance policies when implementing this policy.
9.1 **Data Protection**
All NHS Borders employees have a contractual responsibility to maintain confidentiality of information.

9.1.2 **Personal Information**
Review reports may contain personal information that can identify patients and individual members of staff. Under the Data Protection Act 1998, NHS Borders has a legal duty to protect all personal information.

Before authorising the release of any reports managers must ensure they have received permission to release personal information or have edited any personally identifiable information.

Guidance on disclosure of confidential information from SAE can be found in the Review Process Guidance on the intranet.

9.2 **Performance Monitoring**
Clinical Boards and Support Services will have adverse event management included in the organisational performance reviews. Identified actions will be included within scorecards.

9.3 **Audit**
The implementation of the policy will be audited through an agreed audit plan by:
- The Clinical Governance and Quality Team
- The Risk Health and Safety Team.
Specific audits of subjects arising from adverse event management will be arranged as necessary. Specialist advisers will also carry out audits as necessary.

All audit reports will be submitted to the Healthcare Governance Steering Group in the first instance for onward reporting to the Clinical Executive Operational Group and the Audit Committee.

10. **Specialist Reporting**

10.1 **Suicides & Homicide in Mental Health**
In the case of suicide or homicide the NHS Borders SAER Process will be used in conjunction with the NHS Borders Suicide Review Process, which details the reporting requirements to Healthcare Improvement Scotland.

10.2 **Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR)**
RIDDOR requires that certain events and occupational diseases are reported to the Health & Safety Executive (HSE) as the enforcing authority. These regulations apply to staff, patients and anyone else who may connected to our undertaking. The Risk, Health and Safety Team oversee the reporting of these events.
• RIDDOR requires reportable incidents to be reported to the HSE by the quickest practicable means.
• Deaths, major incidents and stipulated occurrences must be reported to the HSE as soon as possible.
• Staff who are absent from work, due to a work related incident, for more than 7 days must be reported to the HSE within 5 days of reaching the seventh day of absence.

If notifiable incidents are not reported or are over the reporting deadlines, the organisation or the Reporting Officer may be at risk of prosecution. Staff are therefore required to ensure all incidents are reported within 24 hours. If the event is a significant adverse event it should be reported as soon as possible.

Please refer to the RIDDOR Reporting Guidelines which are available on the NHS Borders intranet. [http://intranet/resource.asp?uid=20245](http://intranet/resource.asp?uid=20245)

10.3 Other Reporting
A number of services/departments may be required to report to external organisations or regulatory bodies e.g. Blood Transfusion incidents, when reportable events occur topic specialists will require information in a timely manner. For more information regarding this please refer to the NHS Borders Adverse Event Recording & Management Operational Procedure.

In the case of child protection the NHS Borders SAER Process will be used in conjunction with the Child Protection Committee multi-agency practice review and/or Significant Case Review process.

11. Specialist Support

11.1 Caldicott Guardian
The role of Caldicott Guardian sits with the Joint Director of Public Health. Where access to further clinical information is required, advice must be sought from the Medical Director or the Caldicott Guardian.

11.2 Accountable Officer for Controlled Drugs
Within NHS Borders this role sits with the Director of Pharmacy. All events involving controlled drugs must be reported via Datix and reviewed. The processes and requirements are outlined in the NHS Borders Adverse Event Recording & Management Operational Procedure.

11.3 Specialist Advisers - see appendix 7
NHS Borders has many specialists to support managers in minimising risks for example: Preventions and Management of Aggression and Violence Team; Occupational Health Service; Infection Control; Blood Transfusion; Fraud Officer; Risk, Health and Safety; Clinical Governance and Quality; Fire Safety Adviser; Estates; Resilience Manager. Staff and managers are expected to engage the appropriate specialist adviser as required.
12. **Policy Review**  
This policy will be reviewed and updated 2 yearly.

13. **Legislation**  
NHS Borders has a variety of legal duties of relevance to adverse event reporting and management.

This legislation includes:
- Health and Safety at Work Act 1974
- Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR)
- Management of Health and Safety at Work Regulations 1999
- Data Protection Act 1998
- Social Security (Claims and Payments) Regulations 1979
- Freedom of Information Act (Scotland) 2002
- Contingency Act 2004 (Scottish Regulations 2005)
- Medicine Act 1968 (subsequent amendments)
- Misuse of Drugs Act 1971
- Civil Contingencies Act 2004 (Contingency Planning) (Scotland) Regulations 2005

14. **References**
[http://www.scotland.gov.uk/Publications/2012/06/9560](http://www.scotland.gov.uk/Publications/2012/06/9560)
3. Health and Safety Legislation, Health and Safety Executive  

11. Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995


13. Management of Health and Safety at Work Regulations 1999


15. Freedom of Information Act (Scotland) 2002


Appendix 1 – Flow Chart of actions to be taken to effectively manage adverse events

- Immediate actions following an adverse event
  - Adverse event occurs
  - Make person/s area safe and attend to any medical requirements
  - Implement any immediate operational actions to reduce risk of recurrences e.g. removal of trip hazard or faulty equipment

- Initial reporting and notification
  - Report to local reporting systems
  - Escalated as per protocol
  - Reporting and escalation diagram

- Manage and monitor event
  - Final Approver monitors event & management actions, finally approves event
  - Does event meet criteria for a review? If yes take next step

- Review
  - Establish appropriate review as per protocol
    - Initial review
    - SAER
    - Management review
  - Undertake appropriate review keeping patient, their family and staff members informed

- Improvement planning and monitoring of outcomes/lessons learnt
  - Develop action plan
  - Implement actions/solutions and lessons learned
  - Evaluate & refinement of actions taken
  - Governance mechanism quality assurance and closure of the review
  - Local Healthcare Governance Group
  - Healthcare Governance Steering Group
Appendix 2 - Significant Adverse Event – Reporting/ Escalation Procedure

ADVERSE EVENT (AE) OCCURS
Any AE that has caused a major injury/death to an individual or has had an adverse effect on the delivery of healthcare or resulted in significant loss.

Person reporting AE
Alerts Line Manager

Line Manager escalates as appropriate

OUT OF HOURS COMMUNICATION PROCESS
To the On Call Manager or Hospital Bleep holder (night only), or equivalent

On Call Manager

Ensures relatives contacted if appropriate

OUT OF HOURS COMMUNICATION PROCESS

Medical Director
Director of Nursing
Chief Operating Officer

Chief Executive

NHS Board

IN HOURS COMMUNICATION PROCESS

Operational Manager/ Service Manager

Heads of Service/ Clinical Head of Service

As required:
Clinical Governance & Quality
Risk, Health & Safety
Communication Team

Associate Director of Nursing/
Associate Medical Director/ General Manager

Medical Director/ Director of Nursing & Midwifery/ Chief Operating Officer/ Director of Support Service

Chief Executive

NHS Board
<table>
<thead>
<tr>
<th>Level of Review</th>
<th>CATEGORY 1 ADVERSE EVENT</th>
<th>CATEGORY 2 ADVERSE EVENT</th>
<th>CATEGORY 3 ADVERSE EVENT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Level of Review</strong></td>
<td>Significant Adverse Event Review</td>
<td>Management Review</td>
<td>Further Inquiry</td>
</tr>
<tr>
<td>All events graded as having an outcome of major or extreme or are deemed significant enough to review through the SAER process. Other events that have a lower graded outcome may warrant a review due to significant issues being identified that can impact on corporate objectives.</td>
<td>Adverse events that have significant impacts at local level/clinical board level should be considered for a management review. Likely to be graded moderate or minor but not exclusively.</td>
<td>All events will have contributing factors determined and recorded on Datix. This is a minimal review in which managers are satisfying themselves they know why an event happened.</td>
<td></td>
</tr>
<tr>
<td><strong>Level of authority (Decision making)</strong></td>
<td>BET/ Associate Medical Director/ Associate Director of Nursing or General Manager or Head of Service will authorize exceptions. Risk, Health and Safety Team will coordinate appointment of a Sponsor and Reviewers in accordance with SAER process.</td>
<td>Associate Medical Director/ Associate Director of Nursing/General Manager/Clinical Service lead/Clinical Service Manager may decide a management review is required and who will lead.</td>
<td>All Approvers and Deputies will undertake as part of normal Datix management.</td>
</tr>
<tr>
<td><strong>Review process</strong></td>
<td>Initial Review will be undertaken to determine whether adverse event requires a comprehensive review (all lapses investigated), a concise review (focus on identified significant lapses) or a management review (local managers take ownership of review process).</td>
<td>Initial Review will be undertaken to determine whether event requires a comprehensive review (all lapses investigated) or a concise review (focus on identified significant lapses). Appointed manager takes ownership of review process.</td>
<td>Approvers will satisfy themselves that contributing factors have been identified by staff discussion, observations, looking at policies/practices, circumstances.</td>
</tr>
<tr>
<td><strong>Review Team</strong></td>
<td>Sponsor agree terms of reference and supported by Reviewer/s will determine whether they will suffice as the Review Team or whether other stakeholders are required. Review Team conduct the review as agreed.</td>
<td>Lead Reviewer will decide on team members based on the type of adverse event and potential risks associated with it.</td>
<td>A Team is not necessary however if the Approver feels that there is benefit then they make arrangements as required on a short life basis.</td>
</tr>
<tr>
<td><strong>Improvement Action Plan</strong></td>
<td>Clinical Board/Directorate develop Improvement Plan and identify Lessons Learnt see Appendices in the Significant Adverse Event Review Process.</td>
<td>Complete improvement/Action plan (see Appendices in the Significant Adverse Event Review Process)</td>
<td>Notes may be entered into Datix.</td>
</tr>
</tbody>
</table>
| **Time-scale / Key Performance** | • Sponsors/Reviewers appointed within 24 hrs  
• Initial review completed 1 week  
• Comprehensive/Concise review completed, report with recommendation within 8 weeks  
• Clinical Board/Directorate develop improvement plan & lesson learnt within 2 weeks  
• Improvement plan timescales set as appropriate | • Manager appointed to oversee review process - 24hrs  
• Lead reviewer appointed if required within 48hrs  
• Initial review completed 1 week  
• Comprehensive/Concise review completed, action plan & lessons learnt developed within 5 weeks  
• Improvement plan timescales set as appropriate | Operational Manager to have monitored event details and improvement actions approving within 10 days of being reported. Initiate a risk assessment if appropriate. |
Appendix 5 - Significant Adverse Event Review Process

Adverse event occurs as defined in policy as a significant adverse event (SAE)

Clinical Board/Directorate carry out initial assessment and decide whether exception applies and what review is appropriate

Decision on one of the following as appropriate

Management review process

SAER

Exception form applies completed and stored on Datix

Sponsor and reviewer(s) appointed

Initial review (lapses identified)

Sponsor decides type of review (terms of reference defined) supported by reviewer(s)

Concise review (focused on significant lapses identified in initial review)

Comprehensive review (all lapses)

Composition of review team

Sponsor/reviewer(s) & other identified stakeholders form team

Sponsor/reviewer(s) & other identified stakeholders form team

Review

Conclusions, recommendations, solutions and report

Clinical Board/Directorate develop action plan

Lessons Learned

Disseminated throughout organisation

Report to CG&Q including lessons learned

Implementing action/solutions and lessons learned

Changes in practice

Evaluation of changes

Clinical Board/Directorate/Healthcare Governance Group

Healthcare Governance Steering Group
Appendix 6 – Reactive & Proactive Risk Management

**RISK MANAGEMENT OF ADVERSE EVENTS**

**REACTIVE RISK MANAGEMENT**

- Event or Near Miss takes place
- Member of staff reports event
- Datix Form
- Near Miss
- Consequence x likelihood gives risk level of event
  - Event sent to first approver and final approver and any changes necessary made
- If requires SAER/ Mngt Review
  - Review report
  - Lessons learnt
  - Risk assessment
  - Risk added to risk register if appropriate
  - Action plan

**PROACTIVE RISK MANAGEMENT**

- Risk Assessment
  - Risk Register
  - Tolerate risk
  - Manage risk
  - Transfer risk
  - Terminate risk
  - Action plan developed
  - Line Managers/ Risk Owners Complete Action Plan as appropriate
  - Implement action plan
  - Monitor risk against risk appetite
  - within risk appetite
  - Out with Risk appetite
    - Local HCG Group
    - Clinical Board Directory
    - HCGSG
    - Escalates as required to health board

**REVIEW AND MONITOR**
## Appendix 7 – Topic Specialists

<table>
<thead>
<tr>
<th>Topic</th>
<th>Contact Details</th>
<th>Email Address</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Blood Transfusion</strong></td>
<td>01896 826248</td>
<td><a href="mailto:Labs.transfusion@borders.scot.nhs.uk">Labs.transfusion@borders.scot.nhs.uk</a></td>
</tr>
<tr>
<td><strong>Child Protection</strong></td>
<td>In hours - 01896 664580</td>
<td><a href="mailto:Child.Protection@borders.scot.nhs.uk">Child.Protection@borders.scot.nhs.uk</a></td>
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<tr>
<td></td>
<td>Out of hours - 01896 752111</td>
<td></td>
</tr>
<tr>
<td></td>
<td>See website for more information</td>
<td></td>
</tr>
<tr>
<td><strong>Clinical Governance &amp; Quality</strong></td>
<td>01896 826072</td>
<td><a href="mailto:clinicalgovernance@borders.scot.nhs.uk">clinicalgovernance@borders.scot.nhs.uk</a></td>
</tr>
<tr>
<td><strong>Copyright</strong></td>
<td>01896 825520</td>
<td></td>
</tr>
<tr>
<td><strong>Data Protection</strong></td>
<td>01573 227 914</td>
<td><a href="mailto:data_protection_office@borders.scot.nhs.uk">data_protection_office@borders.scot.nhs.uk</a></td>
</tr>
<tr>
<td><strong>Discharge Liaison</strong></td>
<td>01896 826557</td>
<td><a href="mailto:discharge@borders.scot.nhs.uk">discharge@borders.scot.nhs.uk</a></td>
</tr>
<tr>
<td><strong>Estates</strong></td>
<td>01896 826363</td>
<td><a href="mailto:estates.helpdesk@borders.scot.nhs.uk">estates.helpdesk@borders.scot.nhs.uk</a></td>
</tr>
<tr>
<td><strong>Fire Advisor</strong></td>
<td>01896 826373</td>
<td></td>
</tr>
<tr>
<td><strong>Infection Control</strong></td>
<td>01896 826262</td>
<td><a href="mailto:Infection.control@borders.scot.nhs.uk">Infection.control@borders.scot.nhs.uk</a></td>
</tr>
<tr>
<td><strong>Medical Electronics</strong></td>
<td>01896 826310</td>
<td><a href="mailto:Medical.electronics@borders.scot.nhs.uk">Medical.electronics@borders.scot.nhs.uk</a></td>
</tr>
<tr>
<td><strong>Medical Records</strong></td>
<td>01896 826501</td>
<td></td>
</tr>
<tr>
<td><strong>Moving &amp; Handling</strong></td>
<td>01896 827628</td>
<td><a href="mailto:ohs.admin@borders.scot.nhs.uk">ohs.admin@borders.scot.nhs.uk</a></td>
</tr>
<tr>
<td><strong>Occupational Health</strong></td>
<td>01896 825982</td>
<td><a href="mailto:ohs.admin@borders.scot.nhs.uk">ohs.admin@borders.scot.nhs.uk</a></td>
</tr>
<tr>
<td><strong>Pharmacy</strong></td>
<td>01896 826609</td>
<td><a href="mailto:pharmacy.datix@borders.scot.nhs.uk">pharmacy.datix@borders.scot.nhs.uk</a></td>
</tr>
<tr>
<td><strong>Prevention and Management of Violence and Aggression (PMAV)</strong></td>
<td>01896 825532</td>
<td><a href="mailto:pmav@borders.scot.nhs.uk">pmav@borders.scot.nhs.uk</a></td>
</tr>
<tr>
<td><strong>Resilience</strong></td>
<td>01896 825513</td>
<td></td>
</tr>
<tr>
<td><strong>Risk, Health &amp; Safety</strong></td>
<td>01896 828250</td>
<td>Riskhealth&amp;<a href="mailto:safetyteam@borders.scot.nhs.uk">safetyteam@borders.scot.nhs.uk</a></td>
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