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The best way to reduce harm is for the NHS to embrace wholeheartedly a culture of learning”.

Even apparently simple human errors almost always have multiple causes, many beyond the control of the individual who makes the mistake. Therefore, it makes no sense at all to punish a person who makes an error, still less to criminalise it. The same is true of system failures that derive from the same kind of multiple unintentional mistakes. Because human error is normal and, by definition, is unintended, well-intentioned people who make errors or are involved in systems that have failed around them need to be supported, not punished, so they will report their mistakes and the system defects they observe, such that all can learn from them.

Taken from: A Promise to Learn – A Commitment to Act, The National Advisory Group on the Safety of Patients in England, chaired by Don Berwick, August 2013
Introduction

NHS Dumfries and Galloway aims to provide high quality care that is safe, effective and person-centred. However, the NHS is a complex system and adverse events can occur that do, or could have, a major effect on the people involved. Each of these events should be regarded as an opportunity to learn and to improve in order to increase the safety of our healthcare system for everyone.

NHS Dumfries and Galloway’s approach to learning from adverse events is based on Learning from Adverse Events through Reporting and Review: A National Framework for NHS Scotland.

The principles outlined in this document are not new and build on our previous Strategy.

Implementation of this Framework is part of our Risk Management Strategy and our Quality Improvement Programme and, as such, local ownership is essential to test and implement improvements at a local level, recognising that each service or specialty has different needs and a greater understanding of how that change will impact on their service directly.

NHS Dumfries and Galloway has established a Risk Network chaired by the Patient Safety and Improvement Manager to draw together those with a responsibility for managing/co-ordinating risk in each of our Directorates – together with other staff who have particular specialised roles (e.g. Health and Safety Adviser, Risk Co-ordinator, Risk Project Officer).

NHS Dumfries and Galloway is committed to reviewing and updating this framework as the national programme develops.

Aims

The aims of this Framework are to:

- learn from adverse events locally and to make service improvements that enhance the safety of our healthcare system for everyone
- support NHS staff to manage adverse events in a timely and effective manner
- establish a standardised approach to adverse event management across the Board, including consistent definitions and the establishment of measures to monitor implementation
- ensure a consistent and co-ordinated approach to the identification, reporting and review of adverse events
- to allow best practice to be actively promoted across the Organisation
• present an approach that allows reflective review of events and can be adapted to different settings
• provide standardised resources to develop the skills, culture and systems required to effectively learn from adverse events

The standardised local approach seeks to ensure that, no matter where an adverse event occurs in Dumfries and Galloway:

• the affected person receives the same high quality response
• any staff involved are treated in a consistent manner
• the event is reviewed in a similar way
• learning is shared and implemented across the Organisation to improve the quality of services.

Scope

The approach is intended to cover all care and services provided by NHS Dumfries and Galloway, NHS Dumfries and Galloway employees and independent contractors and clinical and non-clinical events (including information governance,\(^1\) health and safety at work).

The scope will include all events that could have caused (or did result in) harm to people or groups of people.

\(^1\) Information Security Policy
Framework – Part 1: Definitions

What is an Adverse Event?

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

1.2 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 or adverse publicity

1.3 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

1.4 People are defined as:
   - service users
   - patients
   - members of staff
   - carers
   - family members
   - visitors

1.5 Groups of people include any functional grouping of individuals such as a Directorate/Specialty. In this way, adverse events that result in, for example, reputational harm or financial harm are included within the scope

Categorisation of Adverse Events

1.6 The following Categories should be used to group adverse events:
   - Category A – Circumstances or events that have the capacity to cause error/and or harm
   - Category B – An error that did not reach the patient or person
   - Category C – An error that reached the patient or person but did not cause harm
   - Category D – An error that reached the patient or person and required monitoring or intervention to confirm that it resulted in no harm to the patient or person
   - Category E – Temporary harm to the patient or person and required intervention
   - Category F – Temporary harm to the patient or person and required initial or prolonged hospitalisation
   - Category G – Permanent patient or person harm
   - Category H – Intervention required to sustain life
   - Category I – Patient or person death
Framework – Part 2: Overarching Principles

2.1 NHS Dumfries and Galloway draws on the 2020 Workforce Vision’s (Everyone Matters, 2020 Workforce Vision, June 2013) key values which are care and compassion, dignity and respect, openness, honesty and responsibility, quality and teamwork. The principles of the local approach to learning from adverse events support and build on these values.

- **Emphasis on Learning and Promoting Best Practice across NHS Dumfries and Galloway** – the system is focused on learning organisationally and makes extensive use of improvement methodology to test and implement the necessary changes. Near misses are reviewed regularly to promote learning and system improvements.
- **System Approach** – adverse events act as a ‘window’ on the healthcare system allowing a systems analysis. This is important to allow a reflection on the weaknesses of the system – or, in the case of near misses, the strengths and prevent future events.
- **Openness about Failures** – errors are identified, reported and managed in a timely manner and patients and their families are told what went wrong and why. Reviews of events happen frequently and quickly following their occurrence. We expect adverse event reporting to increase as we move to a more open culture.
- **Just Culture** – individuals are treated fairly. Organisational culture is based upon the values of trust, openness, equality and diversity which encourages and supports staff to recognise, report and learn from adverse events.
- **Positive Safety Culture** – avoidance, prevention and mitigation of risks is part of the Organisation’s approach and attitude to all its activities and is recognised at all levels of the Organisation. Decisions relating to the management of adverse events are risk based, informed and transparent to allow an appropriate level of scrutiny.
- **Personal, professional and organisational accountability** – everyone is responsible for taking action to prevent adverse events, including speaking up when they see practice than endangers safety, in line with the whistle blowing policy. Roles and responsibilities will be explicit and clearly accepted with individuals understanding when they may be held accountable for their actions. The principal accountability of all NHS care providers is to patients, their families and carers.
- **Teamwork** – everyone who works for NHS Dumfries and Galloway is an essential and equal member of the team and needs to be valued, treated well and empowered to work to the best of their ability. Teamwork is recognised as the best defence of system failures and is explicitly encouraged and fostered within a culture of trust, mutual respect and open communication.
Framework – Part 3: Managing an Adverse Event

3.1 The circumstances surrounding each Adverse Event will vary in terms of:
- levels of harm
- numbers of people involved
- risk exposure
- financial loss
- media interest
- the need to involve other stakeholders

3.2 Therefore, the response to each Adverse Event should be appropriate to its scale, scope and complexity. This section outlines steps to manage Adverse Events:

*Six Steps of Adverse Event Management* –
1. Risk Assessment and Prevention
2. Identification and Immediate Actions following an Adverse Event
3. Initial Reporting and Notification
4. Analysis and Categorisation
5. Review
6. Improvement Planning and Monitoring

3.3 NHS Dumfries and Galloway’s local procedures to support implementation of this process are shown in the following flow chart – with clear timescales outlined for each stage of the process
2. Identification and Immediate Actions following an Adverse Event

- Adverse Event occurs
  - Immediate Action:
    - Keep yourself safe
    - Raise the alarm for help from others (if applicable)
    - Make person(s)/area safe
    - Label and remove equipment involved
    - Report

3. Initial Reporting and Notification

- Report to local Reporting system (DATIX)

4. Analysis and Categorisation

- Categorise Adverse Event (‘A’ to ‘I’)
  - Category ‘A’ to ‘F’ will be reviewed at a Departmental level; Category ‘G’ to ‘I’ a nominated Lead Reviewer will be commissioned by Quality and Patient Safety Leadership Group
  - Categorisation can be reviewed/changed by relevant Manager – and, in the case of Category ‘G’ to ‘I’ final categorisation decision will be made by Quality and Patient Safety Leadership Group

5. Review

- Undertake Review – keeping patient, their family and staff members informed
- Identify any Service or Care issues and develop Action Plan
- Share Review Report and Action Plan with all involved in the Review process and, if applicable, with Quality and Patient Safety Leadership Group
- Quality and Patient Safety Leadership Group Review, Quality Assure and Closure of Review
- Share learning and implement Key Learning Points
- Implement Action Plan
- Six Month Review of status of Action Plan to Quality and Patient Safety Leadership Group following closure
Stage 1: Risk Assessment and Prevention

3.4 Adverse Event management is one part of effective risk management. Avoidance, prevention and reduction of risks should be the primary defence to prevent adverse events occurring. It is, therefore, important, that risk assessment and prevention is seen as the first step in effective Adverse Event management.

3.5 Risk assessments should identify the hazards present in the healthcare system, evaluate the likelihood of potential harm from that hazard occurring, evaluate the potential severity of that harm and evaluate the number of people that might be affected. Mitigating actions should then be put in place that are proportionate to the risk to prevent it occurring.

3.6 As part of an integrated Risk Management approach the governance structures for the management of adverse events are aligned to the Quality and Patient Safety Leadership Group.

Stage 2: Identification and Immediate Actions following an Adverse Event

3.7 In all instances, the first priority is to ensure the needs of individuals affected by the adverse event are attended to – including any urgent clinical care which may reduce the harmful impact. A safe environment should be re-established, all equipment or medication retained and isolated and relevant documentation copied and secured to preserve evidence and facilitate review and learning.

3.8 The first consideration following an adverse event is that the patient or person affected must be cared for, their (and other patients'/persons') health and welfare secured and further risk mitigated. The patient or person's family or carers/other staff involved must be similarly cared for and involved where a patient or person has died or suffered serious harm. Consideration must be given to their needs first. That means prioritising further treatment they may require – at all times showing compassion and understanding (even if simply making regular contact to keep them informed of the progress of reviews or improvement plan implementation.

3.9 The Institute for Healthcare Improvement (IHI) within their publication The Respectful Management of Serious Clinical Adverse Events (Second Edition) suggests that an adverse event does not necessarily break down the trust between patient and staff, however the way in which the Organisation responds after such events often does.
3.10 NHS Dumfries and Galloway has agreed what patients/persons and/or carers/families can expect to happen every time a Significant Adverse Event occurs. The Organisation is committed to ensuring that, when a Significant Adverse Event occurs, the immediate crisis will be managed effectively to:

- ensure the patient/person and their family are safe and supported
- staff members are safe and supported
- the Organisation learns from the event and ensures any required improvements are made.

Summary of Immediate Actions

- Ensure a safe environment is re-established as soon as possible
- Any urgent clinical care that may reduce the harmful impact of the event must be given immediately
- The needs of patients/persons and their families and carers should be met and support provided
- Colleagues should be informed and support secured from other professionals
- Any faulty medicine or equipment should be removed and labelled so as to prevent future use
- A timely and objective entry should be made in the patient’s clinical records
- Any actions to reduce the risk of recurrence should be taken immediately

Refer to SAE Document - Management of SAEs Supporting Guidance and Resources.pdf

Stage 3: Initial Reporting and Notification

3.11 When an adverse event (including near misses) occurs the NHS Dumfries and Galloway electronic adverse event reporting system (DATIX) must be used -


The types of information to be reported in the first instance include:

- incident date and time (when)
- the location of where the adverse event occurred (where)
- situation, i.e. description of the adverse event, background to what was happening before the event happened which may have contributed to it, assessment as to whether there were any triggers to the adverse event and if any measures had been put in place before it occurred and recommendation, i.e. what could be done to make the situation safe and prevent a recurrence (SBAR)
• personal details relating to the person/people affected by the adverse event (victim/injured party)
• details of anyone else involved in the adverse event (witness/other staff member etc)
• whether or not the patient has been informed that an adverse event has occurred involving them
• what type of adverse event it was, i.e. patient clinical, patient – non clinical, staff or other and details of the adverse event (e.g. patient fall on level ground)
• harm type/result – Category ‘A’ to ‘I’ classification
• details of person reporting the adverse event, including full name and all contact information

3.12 It is imperative that the person(s) reporting the adverse event reports on fact – not on opinion or assumptions. It is important that details are accurate and factual for any future review

3.13 The Adverse Event Reporting Form should be completed as soon as possible after the event – within 12 hours – unless there are exceptional reasons for delay (for example, the event was identified retrospectively following a complaint or claim). All adverse events should be reported – even if some time has passed since the event occurred. The DATIX electronic adverse event reporting system is automatically set up to notify relevant senior managers and clinical staff when an adverse event has been reported which involves their area/staff
3.14 The NHS Dumfries and Galloway notification and escalation procedures which should be followed after an adverse event are:

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Circumstances or events that have the capacity to cause error and/or harm</td>
</tr>
<tr>
<td>B</td>
<td>An error that did not reach the patient or person</td>
</tr>
<tr>
<td>C</td>
<td>An error that reached the patient or person but did not cause harm</td>
</tr>
<tr>
<td>D</td>
<td>An error that reached the patient or person and required monitoring or intervention to confirm that it resulted in no harm to the patient or person</td>
</tr>
<tr>
<td>E</td>
<td>Temporary harm to the patient or person and required intervention</td>
</tr>
<tr>
<td>F</td>
<td>Temporary harm to the patient or person and required initial or prolonged hospitalisation</td>
</tr>
<tr>
<td>G</td>
<td>Permanent patient or person harm</td>
</tr>
<tr>
<td>H</td>
<td>Intervention required to sustain life</td>
</tr>
<tr>
<td>I</td>
<td>Patient or person death</td>
</tr>
</tbody>
</table>

### Categories A to D

<table>
<thead>
<tr>
<th>Action</th>
<th>Issues Reported to/Monitored via</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Inform appropriate senior member of staff (Charge Nurse/Senior Charge Nurse/Team Leader)</td>
<td>• Directorate Risk Facilitators</td>
</tr>
<tr>
<td>• Report on DATIX</td>
<td>• Patient Safety and Improvement Team – Risk Coordinator</td>
</tr>
<tr>
<td>• Senior member of staff to commence investigation within three days</td>
<td>• Local Management Team, e.g. Hospital Management Board (HMB)</td>
</tr>
<tr>
<td>• Aim to complete investigation within 10 working days</td>
<td>• Healthcare Governance Committee (HGC)</td>
</tr>
<tr>
<td>• Senior member of staff to record action taken after investigation of DIF2</td>
<td>• Consider whether patient/family should be informed and/or involved</td>
</tr>
<tr>
<td>• Senior member of staff to close incident</td>
<td></td>
</tr>
<tr>
<td>• Feedback lessons learned to Reporter</td>
<td></td>
</tr>
</tbody>
</table>

### Categories E and F

<table>
<thead>
<tr>
<th>Action</th>
<th>Issues Reported to/Monitored via</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Inform appropriate senior member of staff</td>
<td>• Directorate Risk Facilitators</td>
</tr>
<tr>
<td>• Senior member of staff to commence investigation within three days (Senior Charge Nurse/Nurse Manager/Head of Department)</td>
<td>• Patient Safety and Improvement Team – Risk Coordinator</td>
</tr>
<tr>
<td>• Aim to complete investigation 4-6 weeks</td>
<td>• Local Management Team, e.g. Hospital Management Board (HMB)</td>
</tr>
<tr>
<td>• Record action taken after investigation on DIF2</td>
<td>• Healthcare Governance Committee (HGC)</td>
</tr>
<tr>
<td>• Nurse Manager/Senior Clinician or Department Head to close incident</td>
<td>• Patient/Family should be informed and/or involved</td>
</tr>
<tr>
<td>• Feedback lessons learned to Reporter and wider team</td>
<td></td>
</tr>
</tbody>
</table>

### Categories G to I

<table>
<thead>
<tr>
<th>Action</th>
<th>Issues Reported to/Monitored via</th>
</tr>
</thead>
<tbody>
<tr>
<td>Must be reported immediately and escalated to an on-call Manager to be actioned in accordance with NHS Dumfries and Galloway Board procedure</td>
<td>• Directorate Risk Facilitators</td>
</tr>
<tr>
<td>• General Manager/Duty Manager must ensure safety of patient/staff</td>
<td>• Directorate General Manager</td>
</tr>
<tr>
<td>• Inform Executive on call</td>
<td>• Medical Director (if appropriate)</td>
</tr>
<tr>
<td>• Prepare an SBAR for Associate Medical Director/Deputy Nurse Director</td>
<td>• Patient Safety and Improvement Team – Risk Coordinator</td>
</tr>
<tr>
<td>• Associate Director reviews and decides if Significant Adverse Event Review is required and reports to Executive Medical Director/Executive Nurse Director who will commission a Significant Adverse Event Review</td>
<td>• Quality and Patient Safety Leadership Group (QPSLG)</td>
</tr>
<tr>
<td>• Investigation to be completed within 3 months</td>
<td>• Healthcare Governance Committee (HGC)</td>
</tr>
<tr>
<td>• Lessons learned will be widely disseminated</td>
<td>• NHS Board</td>
</tr>
<tr>
<td></td>
<td>• Patient/Family should be informed and/or involved</td>
</tr>
</tbody>
</table>
3.15 Reporting to External Agencies – Specific events must be reported to external regulators at a National or UK level. These include:

- reporting to the Health and Safety Executive as set out in the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR)
- reporting all adverse events involving health, social care, estates and facilities equipment to the Incident Reporting and Investigation Centre (IRIC) within Health Facilities Scotland as set out in CEL43 (2009)
- reporting of significant adverse events relating to blood transfusion to the Medicines and Healthcare Products Regulatory Agency (MHRA) as required by the UK Blood Safety and Quality Regulations 2005 and the EU Blood Safety Directive
- reporting suicides of individuals in contact with Mental Health Services to Healthcare Improvement Scotland (HIS)
- reporting of deaths associated with medical or dental care to the Procurator Fiscal
- reporting to the UK wide national audits and inquiries
- reporting information governance adverse events to the Information Commissioner’s office
- reporting of Adverse Drug Reactions via the Yellow Card Scheme to the MHRA. This system has been expanded since July 2012 to include medication errors due to a change in the European Transposition of Pharmacovigilance legislation
- reporting of Ionising Radiation adverse events to the Warranted Inspector for IR(ME)R.

Summary of Reporting Actions:

- All adverse events should be recorded on local adverse event reporting systems as soon as possible after the event has occurred
- The adverse event should be reported to any external agencies as appropriate
Stage 4: Analysis and Categorisation

3.16 Following initial reporting of an adverse event or near miss the relevant Manager will assess the adverse event report to consider whether a more in-depth review of the event is required.

3.17 It is important that the level of review is proportionate to the severity of the adverse event. Adverse event reviews aim to establish the contributing factors – with a view to reducing the likelihood and/or impact of similar future events.

3.18 Every event should be reviewed – but the level of review will be determined from the category of the adverse event and the potential for learning (see below). Local mechanisms are in place to quality assure the categorisation of events and appropriate action will be taken should the original categorisation be inappropriate.

3.19 The decision to proceed or not to an adverse event review should be clearly documented. The decision as to whether a full review should take place will depend on the characteristics of the event, the patient or the clinical service, the outcome and the potential for learning. If an initial review of a near miss suggests that there could be defects or failures in systems and processes then this could trigger a more extensive review.

3.20 Information, communications, outcomes and associated actions should be centrally recorded and stored within the DATIX system so that an audit trail is evident.

Categorisation of Adverse Events

3.21 All Adverse events must be categorised. This supports the decision making processes to determine the level of review required (although other factors may also impact this decision).

3.22 The following categories should be used to classify the impact of the adverse event:

- Categories ‘A’ to ‘D’ – events that had the potential to cause harm but i) an error did not result, ii) an error did not reach the person or iii) an error reached the person but did not result in harm (near misses)
- Categories ‘E’ and ‘F’ – events that may have contributed to or resulted in temporary harm
- Categories ‘G’ to ‘I’ – events that may have contributed to or resulted in permanent harm
3.23 This categorisation is based on impact of harm. It is acknowledged that we are aiming to take a preventative rather than reactive approach and we should not wait for harm to occur before making improvements to the system. Therefore, NHS Dumfries and Galloway will increasingly focus our efforts on the analysis and review of events that did not result in harm – as these provide the most important learning and improvement opportunities.

3.24 This categorisation requires some initial assessment of the event – which is supported by various decision tools such as the NHS Dumfries and Galloway Risk Matrix - Risk Matrix.pdf (Appendix 1).

Levels of Review

3.25 The initial process of adverse event review and analysis should be essentially the same whatever the categorisation of the adverse event.

3.26 The category of the event will largely determine the level of review required – i.e. Category ‘G’ to ‘I’ events that result in permanent harm will require a more extensive review than Category ‘E’ and ‘F’ events that result in temporary harm. Trend and thematic analysis of events will identify if more detailed review of Category ‘A’ to ‘D’ and Category ‘E’ and ‘F’ events is required.

3.27 Consideration of the potential for learning from the event should also determine the level of review required. This aims to ensure that responses are not overly focussed on the impact or outcome of that particular event but are used to gain an insight on underlying weaknesses of the system. The following decision-making prompts may help to determine the potential for learning –

- is the outcome a known complication of the disease/treatment/process?
- has there been any breach or deviation in policy or procedure?
- are there unknowns surrounding the event?
- is there learning to be gained/would you do anything differently next time?
- is there concern regarding the event from the patient or family – or from management?

3.28 Response to a request for information or investigation following an adverse event must be treated as a priority as there must be no unnecessary delay before lessons are learned and processes and systems are made safer.

It is expected that all line managers with a responsibility for managing adverse events have in place a clearly defined process for ensuring effective response.
and action in their absence – using either peer colleagues or deputy staff. Except in rare circumstances it would not be expected that the response times would be breached because of the absence (either planned or unplanned) of line managers.

Summarisation of Categorisation Actions

- A discussion with appropriate individuals should take place about the categorisation of the adverse event and what level of review is required
- A senior member of staff should be designated as responsible for reporting and follow up of Category ‘G’ to ‘I’ adverse events within given timescales. They should also be responsible for ensuring relevant internal staff are informed of the event
- Decision making should be recorded on the DATIX adverse event system

Stage 5: Review

3.29 The purpose of the review is to determine what happened, how it happened, why it happened and whether there are learning points for the service or wider organisation. The Review will be just and fair and take a systems approach. If the Review Team considers that there are any issues about the performance of an individual member of staff this should be referred to the appropriate line manager and should not be part of the review

3.30 For Significant Adverse Events, a Lead Director or Senior Manager will be assigned to ensure a thorough and appropriate review is undertaken. The following should be established:

- Terms of Reference for the review should be established
- Review Team should be identified with a Lead Reviewer appointed and roles within the Team clearly defined (the Review Team should be sufficiently removed from the event and have no conflict of interest to be able to provide an objective view)
- the lead responsibility for establishing and meeting the communication requirements of patients (or their representatives) should be clarified with the Lead Reviewer
- staff and managers involved should be informed of the review and invited to contribute to the review process. Staff should be kept informed of progress throughout the review
- the support needs of staff involved in the adverse event must be considered
• DATIX electronic risk management systems should be maintained to ensure a comprehensive, accessible file of review documentation is maintained which should include (but not limited to):
  - adverse event report including the notification process (and documentation of decision to proceed to review)
  - any staff statements submitted as part of the review
  - all contact/communication with the patient/family/carer
  - any reports/documentated information provided to support review
  - details of any equipment involved in the adverse event, including location
  - final report and action plan (including sign-off sheet)

(NHS Dumfries and Galloway SAER Policy refers - Management of SAEs Supporting Guidance and Resources.pdf)

3.31 Adverse event reviews should use defined methodologies to ensure a structured and consistent approach to identifying the contributory factors, details of the care provided and if any lessons about that care could inform service improvement or reduce recurrence. A variety of tools such as cause and effect charts, fishbone diagrams and the ‘Five Whys’ Model can be used. At least one member of the Review Team should be trained in review methodologies and their application. Where this is not possible support from Patient Safety and Improvement Team should be sought.

3.32 For continuity a final report on DATIX should be completed and reviewed prior to the incident being closed. For Significant Adverse Event Reviews a formal Report will be produced and reviewed by Quality and Patient Safety Leadership Group. The Board should also offer to share this with the patient, family and/or carer.

3.33 The Board has processes in place for the review of Reports and recommendations through the Quality and Patient Safety Leadership Group – who will receive a copy of the final Report and will be responsible for approving the Report. The Review Team and all staff involved in the adverse event should receive a copy of the final Report.

Summary of Review Actions

• Adverse events should be reviewed using best practice investigative techniques and methodologies. Methodologies should be briefly, but clearly, set out in the review report
• Staff leading adverse event reviews should have up to date training and be competent in investigative methodologies, techniques and analysis, including human factors and report writing
For Significant Adverse Event Reviews in particular –

- The Review Team must be multidisciplinary and should include a professional with experience relevant to the event being reviewed
- The Review Team should be sufficiently removed from the event and have no conflict of interest (real or perceived) to be able to provide an objective view
- The roles and responsibilities of each member of the Review Team must be clear, including identifying a Lead Reviewer and should be documented
- Individuals involved in the adverse event (for example patients, family, carers, staff) must be involved and informed throughout the review process
- The scale, scope and timescale for the review must be agreed at the outset of the review process and documented in the Terms of Reference
- Reviews should seek to understand what happened, why it happened and recommend what systems or processes should be put in place to prevent future occurrence
- Reviews should be quality assured to ensure they are robust and demonstrate the use of investigative techniques

- Electronic adverse event system (DATIX) must be used to store all documentation to ensure a comprehensive, accessible, auditable file of review documentation is maintained

Stage 6: Improvement Planning and Monitoring

3.34 Classification ‘E’ and ‘F’ and ‘G’ to ‘I’ adverse event reviews must have an improvement plan developed in response to the findings and recommendations. For Significant Adverse Event Reviews the Quality and Patient Safety Leadership Group will clearly define who is responsible for developing the plan and who should be involved in the process. All actions should identify owners and timescales for completion. Final plans should be shared with those who reported and were involved in the original adverse event

3.35 Improvement Plans will be owned locally and reviewed no later than six months after closure of the adverse event. If a recommendation is not being progressed there should be a reason why this is the case recorded on the adverse event reporting system (DATIX). The Quality and Patient Safety Leadership Group have responsibility for monitoring implementation of improvement plans, ensuring completion within the agreed timescales and documenting rationale for exceptions

3.36 Arrangements are in place to share learning and improvements from adverse event reviews across services and the wider organisation. Reports relating to
thematic learning are collated over specific timeframes to assist and inform wider service and organisation improvement programmes

Summary of Improvement Planning and Monitoring Actions

- An agreed improvement plan should set out how each recommendation from a Review will be monitored, implemented, measured and shared. The plan will include responsible owners, timescales for delivery and review dates
- The outcome of the review and improvement plan will be shared with those who reported and were involved in the adverse event
- The organisation will monitor and review all Significant Adverse Event Reviews and seek assurances about learning and the embedding of improvement plans through regular thematic reviews
- Learning, improvements and best practice will be actively promoted and implemented locally
Framework – Part 4: Roles and Responsibilities

4.1 The Board is responsible for ensuring governance systems are in place with clear lines of accountability and clearly defined roles and responsibilities to support the effective management of adverse events

4.2 The Organisation ensures that effective arrangements are in place for reporting, recording, management, review and monitoring of all adverse events. They also ensure that robust systems are in place to learn from adverse event reports, review actions and identify themes or trends in order to make improvements to address risks

4.3 The Board’s adverse event management arrangements are as follows:

- *The Chief Executive* is accountable and responsible to the NHS Board for ensuring that policies and procedures are in place to ensure the effective reporting, recording, management, investigation and monitoring of all adverse events. In addition, the Chief Executive will ensure robust systems are in place to learn from adverse event reports and to ensure that actions to address the risk are reviewed. In practice, the Chief Executive will delegate this responsibility to the *Director of Nursing*

- *The Director of Nursing* is accountable and responsible to the Chief Executive for ensuring that policies and procedures are in place to ensure the effective reporting, recording, management and investigation and monitoring of all adverse events across NHS Dumfries and Galloway – in practice this is delegated to the *Patient Safety and Improvement Manager*

- *The Quality and Patient Safety Leadership Group* (which is chaired by *the Director of Nursing*) is responsible for ensuring that all Significant Adverse Events are commissioned, a Lead Reviewer appointed, a thorough review carried out, any actions/recommendations as a result of that investigation are taken forward and reviewed at least six months following closure of the report

- *The Healthcare Governance Committee* is responsible for assuring the Board that there are robust measures in place to record and manage adverse events and that learning and improvement have taken place to reduce the risk of recurrence of an adverse event

- It is the responsibility of all *Executive Directors* and *Managers* to ensure compliance with this Policy and its supporting procedures within their respective areas of responsibility

- It is the responsibility of every *Ward/Department Manager* and *Supervisor* to ensure compliance with this Policy and supporting procedures within their respective areas of responsibility and to make
staff aware of their responsibilities as part of the local induction programme

- There is a requirement for all staff to bring to the notice of their employers any staff workplace events, whether or not they result in injury or loss. Employees have a duty to co-operate with their employer to enable their employer to comply with their statutory duties. This includes participation in adverse event investigation at any level and attendance at any training delivered in support of this Policy as directed by Line Management. Any member of staff who has knowledge of a particular adverse event must initiate an adverse event report within 12 hours unless they know someone else has already done this.
Reviewing and Updating the Framework

NHS Dumfries and Galloway is committed to reviewing and updating this Framework every three years and sooner if the National Framework is updated

Concluding Comments

We know that NHS Dumfries and Galloway already provides excellent care and good practice is occurring relating to the management of adverse events. However, we also know that sometimes things go wrong. There are a number of challenges faced when implementing a consistent approach to learning from adverse events that improves the safety of our healthcare system for everyone that interacts with it and places the person at the centre of all decisions.

These challenges include:

- how and when to disclose information to patients, families and carers and how to involve them in the review process
- how to encourage staff to openly report adverse events without fear of personal consequence (although this does not mean that individuals should never be held to account for their actions)
- how we ensure adverse event reviews are proportionate and make best use of our resources
- how to translate learning into service improvements and actively promote this at an organisational level
- how we collate, analyse and learn from adverse events at a local level – and how we look to integrate other data (such as from complaints and claims) in order to inform improvements
- how we truly take a systems approach to analyse and learn from adverse events and move towards a preventative rather than reactive approach
- how we will know if the national approach to learning from adverse events results in changes that are improvements – as there is often a delay between making changes and seeing an effect.

The action points throughout this Document aim to support improvement work to address these challenges. This whole approach is underpinned by a just and positive safety culture which places people at the heart of everything we do.
Appendix 1: Risk Register Matrix

Central to the process is the Organisational Risk Register. All risks (including significant or frequently occurring adverse events and patient feedback) should be added to your Risk Register once they have been assessed and evaluated using the Risk Scoring Criteria undernoted. Risks which cannot be controlled locally (or which are considered High or Very High Risk) must be escalated to Director or General Manager level.

<table>
<thead>
<tr>
<th>Severity of Consequence</th>
<th>Likelihood of Occurrence (chance of event occurring within the next year)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Rare (little chance of occurrence)</td>
</tr>
<tr>
<td><strong>Negligible, e.g.</strong></td>
<td></td>
</tr>
<tr>
<td>• minor injury not requiring first aid</td>
<td></td>
</tr>
<tr>
<td>• unsatisfactory patient experience not directly related to patient care and readily resolvable</td>
<td></td>
</tr>
<tr>
<td>• partial loss of service</td>
<td></td>
</tr>
<tr>
<td>• financial impact less than £5k</td>
<td></td>
</tr>
<tr>
<td><strong>Minor, e.g.</strong></td>
<td></td>
</tr>
<tr>
<td>• minor temporary injury or illness, first aid treatment required</td>
<td></td>
</tr>
<tr>
<td>• unsatisfactory patient experience directly related to patient care – rapidly resolvable</td>
<td></td>
</tr>
<tr>
<td>• individual service objectives only partially achievable</td>
<td></td>
</tr>
<tr>
<td>• financial impact £5k-£50k</td>
<td></td>
</tr>
<tr>
<td><strong>Moderate, e.g.</strong></td>
<td></td>
</tr>
<tr>
<td>• significant injury or ill health requiring medical intervention – temporary incapacity</td>
<td></td>
</tr>
<tr>
<td>• patient outcome or experience below reasonable expectations in a number of areas</td>
<td></td>
</tr>
<tr>
<td>• unable to share service objectives without substantial additional costs or delays</td>
<td></td>
</tr>
<tr>
<td>• financial impact £50k-£500k</td>
<td></td>
</tr>
<tr>
<td><strong>Major, e.g.</strong></td>
<td></td>
</tr>
<tr>
<td>• single avoidable death or long term incapacity or disability</td>
<td></td>
</tr>
<tr>
<td>• significant impact on ability to deliver service objectives, service may have to be discontinued</td>
<td></td>
</tr>
<tr>
<td>• major financial loss £500k-£2.5m</td>
<td></td>
</tr>
<tr>
<td><strong>Extreme, e.g.</strong></td>
<td></td>
</tr>
<tr>
<td>• multiple or repeated avoidable fatalities or major permanent incapacity/disability</td>
<td></td>
</tr>
<tr>
<td>• sustained loss of service with serious impact on delivery of patient care, major contingency plans invoked</td>
<td></td>
</tr>
<tr>
<td>• corporate obligations not met</td>
<td></td>
</tr>
<tr>
<td>• severe financial loss £2.5m+</td>
<td></td>
</tr>
</tbody>
</table>

Low: No additional risk controls required. The person responsible shall document assurance that existing controls or contingency plans remain effective and ensure any weaknesses are addressed.

Medium: Further action shall be taken to reduce the risk but the cost of control should be proportionate. The person responsible shall ensure additional risk control measures are introduced within a defined timescale. Assurance that risk controls or contingency plans are effective shall be documented and evaluated by the relevant Head of Service and any weaknesses addressed.

High: Further action, possible urgent and requiring considerable resources, shall be taken to reduce the risk. Responsibility for introducing risk control measures within a set timescale shall be explicitly defined by the appropriate Director or General Manager and followed up through the performance review process. Assurance that risk controls or contingency plans are effective shall be documented and evaluated by the relevant Director or General Manager.

Very High: If confirmed to be unacceptable, the risk should be escalated immediately to Director level. An immediate action plan should be drawn up with Executive level leadership. If appropriate, suspension of the activity until the risk has been introduced should be considered. The risk and the action taken to reduce it to an acceptable level should be taken to the next available Board.

Appendix 2: NCC MERP Index for Categorising Medication Errors

NOT PROTECTIVELY MARKED
<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category A</td>
<td>Circumstances or events that have the capacity to cause error</td>
</tr>
<tr>
<td>Category B</td>
<td>An error occurred but the error did not reach the patient (an ‘error of omission’ <em>does</em> reach the patient)</td>
</tr>
<tr>
<td>Category C</td>
<td>An error occurred that reached the patient but did not cause patient harm</td>
</tr>
<tr>
<td>Category D</td>
<td>An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm</td>
</tr>
<tr>
<td>Category E</td>
<td>An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention</td>
</tr>
<tr>
<td>Category F</td>
<td>An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalisation</td>
</tr>
<tr>
<td>Category G</td>
<td>An error occurred that may have contributed to or resulted in permanent patient harm</td>
</tr>
<tr>
<td>Category H</td>
<td>An error occurred that required intervention necessary to sustain life</td>
</tr>
<tr>
<td>Category I</td>
<td>An error occurred that may have contributed to or resulted in the patient’s death</td>
</tr>
</tbody>
</table>

| No Error | Error, no harm | Error, harm | Error, death |

**Definitions**

- **Harm**: Impairment of the physical, emotional or psychological function or structure of the body and/or pain resulting therefrom
- **Monitoring**: To observe or record relevant physiological or psychological signs
- **Intervention**: May include change in therapy or active medical/surgical treatment
- **Intervention necessary to sustain life**: Includes cardiovascular and respiratory support (e.g. CPR, defibrillation, intubation etc)
Appendix 3: References

An Organisation with a Memory, Department of Health; 2000

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Serious Incident Framework, NHS England; 2013

Six Steps to Root Cause Analysis (3rd Edition), Maria Dineen May 2011