



Learning from Adverse Events through Reporting and Review Policy

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HRPOL002

NHS SHETLAND DOCUMENT DEVELOPMENT COVERSHEET

Name of document	Learning from Adverse Events through Reporting and Review Policy		
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Author	Clinical Governance & Risk Lead		
Executive Lead	Director of Human Resources & Support Services		

Proposed groups to present document to:		
Risk Management Group (RMG)	Area Clinical Forum (ACF) via JGG and Consultants Group	Hospital Management Team (HMT)
Health and Safety Committee	Clinical Care and Professional Governance Committee (CCPGC)	
Joint Governance Group (JGG)	Area Partnership Forum (APF)	

DATE	VERSION	GROUP	REASON	OUTCOME
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29 September 2016 sent email	1.1	Health and Safety Committee (via email)	C/S	PRO
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Examples of reasons for Presenting to the group	Examples of outcomes following meeting
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<ul style="list-style-type: none"> General comments/suggestions (C/S) 	<ul style="list-style-type: none"> For minor revisions (e.g. format/layout) – no need to re-submit to group (MR)
<ul style="list-style-type: none"> For information only (FIO) 	<ul style="list-style-type: none"> Recommend proceeding to next stage (PRO)

DATE	RECORD OF CHANGES MADE TO DOCUMENT
22 nd September 2016	RMG members – minor wording changes to scope of policy and paragraph for Executive Summary from Chief Executive.
29 th September 2016	Article in team brief and on intranet. No changes noted through team brief.
28 th November 2016	Slight rewording of Director of Pharmacy roles and responsibilities. Presentation of document to ACF in September 2016 added to document development coversheet.
08 th October 2018	Reference to Duty of Candour in line with revisions made to interim national framework including adding to the responsibilities of the Medical Director, “Lead Executive Manager for the Duty of Candour process”.
06 th November 2018	Changed the updated medical director responsibility from “Lead Executive Manager” to “Executive Director” as suggested at the JGG meeting 6 th November 2018.
02 nd October 2019	Policy was reviewed as part of the 3 year review. Minor changes made including updating HIS framework reference to 3 rd edition, July 2018, updated medical director to designated executive director with responsibility for risk from director of HR and support services, updated section 8 communication arrangements.
18 th November 2019	Pg 7, section 2 - ‘Overarching Principles Guide’ and pg 12, section 6 – roles and responsibilities - Managers , included reference and link to ‘A Just Culture Guide’.
07 th February 2020	Page 6 – following update to HIS framework, updated reference from 3 rd edition, July 2018 to 4 th edition, December 2019 (no other changes required to policy – only the procedure)

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1. Executive Summary

It is internationally recognised that between 10–25% of episodes of healthcare (in general hospital, community hospital and general practice) are associated with an adverse event¹.

It is important that there are robust and reliable processes in place to effectively manage adverse events, and that lessons learned are shared widely and used to support improvements in care and service delivery. This has been highlighted by the National Patient Safety Agency (NPSA) in their organisational reports which state “Organisations that report more incidents usually have a better and more effective safety culture. You can’t learn and improve if you don’t know what the problems are”.

Healthcare Improvement Scotland (HIS) have developed a national approach which provides a framework to support standardised processes for managing adverse events across all care settings in Scotland. This policy is based on the national framework and includes the definitions and principles outlined within the HIS document². The roles and responsibilities for the management of adverse events in NHS Shetland are clearly defined within this policy reflecting the national framework. There are a number of procedural and guidance documents which detail how the six stages of adverse event management are to be implemented within NHS Shetland (detailed in section 7).

This policy replaces the Adverse Event (Identification, Reporting, Review and Learning) Policy – May 2014 (HRSSPOL002).

As we all know and understand healthcare is high risk and we therefore accept that adverse events will happen. Healthcare in Shetland is no different in this. However, what we must do is learn from these events and ensure that wherever it is possible, action is taken so that similar events do not happen in the future.

This policy sets out our commitment and approach to reporting and learning from adverse events so that we provides ever safer services for our patients.

In commending the policy, I would emphasise that the single most important aspect to this is a commitment, from us all, to supporting a safety culture based on openness, constructive challenge, trust and respect.

Chief Executive

2. Overarching Principles

The principles of the national approach to learning from adverse events support and build on the key values of care and compassion; dignity and respect; openness, honesty and

¹ The Health Foundation (2011). Evidence scan: Levels of Harm
www.health.org.uk/publications/levels-of-harm/

² Healthcare Improvement Scotland (HIS) publication Learning from adverse events through reporting and review: A national framework for NHS Scotland (4th Edition December 2019)

responsibility, quality, and teamwork. These are listed below and have been adopted for use by NHS Shetland:-

- **Emphasis on learning and promoting best practice across Scotland** – the system is focused on learning, locally and nationally, 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 care 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, service users 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 that endangers safety, in line with the organisation’s 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 care providers is to patients, service users, their families and carers

In order to support consistent, constructive and fair evaluation of the actions of staff involved in patient safety incidents, the Board will use [‘A Just Culture Guide’](#). This guide which is supported by the General Medical Council (GMC), Nursing and Midwifery Council (NMC) and Royal College of Nursing can be used where an investigation begins to suggest a concern about an individual action. It can also be used by all parties to explain how they will respond to incidents and as a reference point for organisational human resources and adverse event procedures. In addition it can be used as a communication tool to help staff, patients and families understand how the appropriate response to a member of staff involved in the incident can and should differ according to the circumstances in which an error was made.

- **Teamwork** – everyone who works for Scotland’s care system 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

3. Introduction

Health and Social Care services in Scotland aim to provide high quality care that is safe, effective and person-centred. This is a complex system and adverse events 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 care system for everyone. Disclosure of adverse events (including near misses) is a professional duty of all NHS Shetland staff members.

The HIS document, 'Learning from adverse events through reporting and review, a national framework for Scotland (3rd edition) – July 2018' is intended to provide an overarching approach developed from best practice to enable care providers to effectively manage adverse events.

NHS boards are responsible and accountable for effectively managing adverse events. CEL(2013)20³ sets out the expectation that NHS Boards adopt this framework to improve their local approaches to handling adverse events. This policy and associated documents have been developed in line with the national framework. They describe the management system within NHS Shetland for reporting, reviewing and learning from all types of adverse events utilising an integrated adverse event reporting system. This includes clinical events involving patients, families, staff and carers (including health and safety, accidents or incidents) and non-clinical events (including information governance and finance). The organisation fully supports an open and fair culture and is committed to implementing the improvements identified to support a greater level of safety.

4. Scope of the Policy

This policy, based on the national framework, covers all care provided by NHS Shetland, including NHS services provided on behalf of the Integration Joint Board or jointly with Shetland Islands Council (SIC) including:

- Acute care and managed community services
- Primary care (GP practices, dental practices, community pharmacies and optometrists)
- Social care
- Employees and independent contractors,

and relates to

- Clinical and non-clinical events (including information governance, health and safety at work, adverse publicity and finance)

The scope includes all events that could have contributed or did result in, harm to people or groups of people. This includes harm to patients and service users, as well as harm to staff. Duty of Candour will apply to specific events or incidents that have resulted in death or harm. The Scottish Government has published guidance which has been locally adopted.

If the adverse event is primarily a health related issue then it will be reported via the NHS Shetland adverse event reporting system. If it is primarily a social care issue then this will be reported using the SIC system and if the issue is joint then the relevant managers will agree how to review the adverse event.

³ The national approach to learning from adverse events – Letter (CEL 2013_20) to NHS Boards (www.sehd.scot.nhs.uk/mels/CEL2013_20.pdf)

NHS Shetland recognises that staff must comply with their own professional code of conduct in respect to adverse events.

5. Definitions

The definitions below have been taken from the national framework and will be used by NHS Shetland.

An **adverse event** is defined as **an event that could have caused (“a near miss”), or did result in, harm to people or groups of people.**

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

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 and often areas for improvement are identified even when harm is not avoidable. Clinicians should consider any deterioration carefully and consider undertaking adverse event review processes if they think that clinical deterioration may have been due to *avoidable* factors.

People are defined as:

- Service users
- Patients
- Members of staff
- Carers
- Family members, and
- Visitors

Groups of people include any functional grouping of individuals such as an organisation. In this way, adverse events that result in, for example, reputational harm or financial harm are included within the scope of the national approach.

6. Roles and Responsibilities

The roles and responsibilities for the management of adverse events in NHS Shetland are detailed below:-

The Board

The Board has three core roles in relation to safety:

- **Formulating strategy:** clear vision and purpose that puts quality and safety at its heart including strategic aims for safety – ‘Will care be safe in the future?’
- **Ensuring accountability:** for delivering the strategy, for seeking assurance that systems are robust, and for the organisation operating with openness, transparency and candour
- **Shaping culture:** modelling and promoting values and standards of conduct for everyone

The Board should seek assurance that systems in place support the effective management of adverse events as outlined in this policy and through monitoring locally developed

measures. The Board will be kept informed of serious and ongoing issues and recognise the links between staffing, quality outcomes and safety.

Risk Management Group

The RMG are responsible for:-

- Ensuring implementation of the procedure for managing significant adverse events (which includes the role of the Clinical Risk Advisory Team (CRAT))
- Ensuring information on adverse events is used to inform the risk process
- Monitoring implementation of this policy

Clinical, Care and Professional Governance Committee (CCPGC)

The Clinical Care and Professional Governance Committee is responsible for:-

- Demonstrating leadership behaviours and actions that support a positive safety culture and commitment to being open
- 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
- Ensuring preventative measures and processes are in place to effectively undertake risk assessment, identify potential harm and manage risks to an acceptable level. The aim being to minimise the likelihood of an event occurring and/or the level of harm
- Ensuring actions contained within improvement plans have been completed and contribute to organisational learning by sharing and adopting key learning points
- Monitoring implementation of this policy via the quarterly adverse event report
- Approving this policy and any changes that may need to be made to the policy in future

Joint Governance Group (JGG)

The Joint Governance Group is responsible for:-

- Monitoring compliance with this policy
- Approving changes to the procedures and guidance documents

Local groups with responsibility for clinical governance and risk management

Local groups with a responsibility for clinical governance and risk management are responsible for:-

- Ensuring a culture of openness and safety in the team
- Reviewing all adverse events within the team
- Documenting learning and actions taken

Chief Executive, Executive Directors and Non-executive Directors

The chief executive, executive directors non-executive directors are responsible for:-

- Demonstrating leadership behaviours and actions that support a positive safety culture and commitment to being open
- Creating a culture to support staff to safely express concerns and for these to be listened to, discussed and acted on as appropriate

Chief Executive

The chief executive is also responsible for:-

- Ensuring robust and effective policies and procedures for adverse event management and meeting Duty of Candour requirements
- Ensuring effective systems are in place for reporting, learning and improvement
- Delegation of roles and responsibilities to executive team members

Executive Directors

The executive directors are also responsible for:-

- Delegated responsibilities from the chief executive
- A role in determining the level of review of adverse events
- Ensuring compliance within their directorates with the adverse event policy and procedures including Duty of Candour requirements
- Engaging with patients, service users and families, including through Duty of Candour processes
- Ensuring staff are supported and attend the training outlined in this policy
- Ensuring actions are implemented and improvements are made within their directorates

Individual executive director responsibilities are as follows:-

- **Director of Finance** - is the Board lead for finance and accountable to the chief executive for adverse events arising from all financial activities and data protection. The director of finance is responsible for the management and review of adverse events and feedback arising from Board financial activities and data protection
- **Medical Director** - carries specific responsibilities for all matters pertaining to professional conduct of medical staff and will provide expert advice where required. The medical director is also the Caldicott Guardian and has responsibility for ensuring the protection and use of patient identifiable information, which may be used during the adverse event and feedback reporting process. The medical director is also the Executive Director for the Duty of Candour process. The medical director is the designated Executive Director with responsibility for risk. The medical director also has responsibility for approving operational changes proposed by the clinical governance and risk lead
- **Director of Nursing and Acute Services** - carries specific responsibilities for all matters pertaining to professional conduct of nursing staff and Allied Health Professionals (AHPs) staff and will provide expert advice where required
- **Director of Pharmacy** - is responsible for ensuring that there are processes in place for the review of drug related adverse events, directs Medication Safety work and is the Accountable Officer for Controlled Drugs

Non-executive Directors

The non-executive directors are also responsible for:-

- Challenging executives and seek assurance that effective systems for reporting, managing, reviewing, learning and improving from adverse events are in place and working well within the organisation
- To ask:
 - Has care been safe in the past?
 - Is care safe today?
 - Are our systems and processes reliable?
 - Are we responding and improving?
 - Will care be safe in the future?

Clinical Governance and Risk Lead

The clinical governance and risk lead is responsible for:

- Administration of Datix
- Supporting reviews into, and monitoring, risk related issues
- Maintaining guidance for staff via the intranet
- Reviewing and updating the adverse events policy
- Making operational changes to the adverse events management system in consultation with the medical director

Health and Safety Lead

The health and safety lead is responsible for:

- Formulating and developing health and safety policy
- Supporting NHS Shetland in ensuring that appropriate action is taken as a result of Health and Safety adverse event reporting
- Advising and overseeing the management of adverse events relating to Health and Safety
- Ensuring any RIDDOR reportable adverse events are reported to the Health and Safety Executive within the appropriate timeframe

Directorate Management Teams

The directorate management teams are responsible for:

- Demonstrating behaviours and actions that support a positive safety culture and commitment to being open
- Setting an example and encouraging openness and honesty in reporting adverse events. Clinical leaders should actively foster a culture of learning and improvement
- Ensuring compliance with adverse event and Duty of Candour policies and procedures
- Reviewing and managing adverse events
- Progression of improvement plans and follow-up
- Dissemination of learning points (using the learning summaries where appropriate) and support to turn learning into action
- Engagement with patients, service users and families
- Supporting staff

Managers

Managers have a responsibility for:

- Demonstrating behaviours and actions that support a positive safety culture and commitment to being open
- Ensuring staff awareness and compliance with policies and procedures
- Managing adverse events including review, using '[A Just Culture Guide](#)' where appropriate, progress of actions, dissemination of learning points using the learning summary template where appropriate and implementation of improvement actions
- Engaging with patients, service users and families including through Duty of Candour processes
- Engaging with and supporting staff including referral to occupational health, counselling and other services as required
- Cascading learning and enabling conversations in teams

Staff

All staff have a responsibility for:

- Demonstrating behaviours and actions that support a positive safety culture and commitment to being open
- Maintaining a safe environment, safe systems of work and take proactive measures to reduce the risk of an adverse event occurring
- Attending training
- Reporting adverse events including near misses on the Datix system
- Following policy and procedures including adhering to timescales
- Participating fully in reviews and Duty of Candour processes
- Understanding learning points and implement recommended improvement actions
- Engaging with patients, service users, families and carers

Occupational Health Service

The occupational health service is responsible for:

- Supporting staff providing confidential care should this be required following an adverse event/feedback
- Reminding staff of their responsibility to report adverse events when they attend the Occupational Health Service e.g. following sharps injury

7. Managing an Adverse Event

The circumstances surrounding each adverse event will vary in terms of:

- Levels of harm
- Numbers of people involved
- Risk exposure
- Financial loss
- Media interest, and
- The need to involve other stakeholders

The response to each adverse event, therefore, should be proportionate to its scale, scope and complexity and opportunity for learning.

There are 6 stages of adverse event management as defined in the national framework. The stages are described in detail in the adverse event procedures and guidance documents which support the implementation of this policy. The six stages of adverse event management include:-

1. Risk assessment and prevention
2. Identification and immediate actions following an adverse event, including consideration of Duty of Candour
3. Initial reporting and notification
4. Assessment and categorisation, including consideration of Duty of Candour
5. Review and analysis
6. Improvement planning and monitoring

In addition there are a number of other documents which define the arrangements within NHS Shetland for adverse event management including:-

- Learning from Adverse Events Through Reporting and Review Procedure
- Procedure for Managing Significant Adverse Events and the Role of the Clinical Risk Advisory Team (CRAT)
- Sudden death process
- Multi board review guidance

8. Communication Arrangements

The approved policy will be included on NHS Shetland intranet and internet and an article will be included in team brief.

The Board has a training and development programme which includes induction, refresher and management bundles. These cover the adverse event reporting process and its management. Awareness sessions will also continue to be delivered where required to support implementation of this policy.

9. Measuring and Monitoring

The implementation of this policy will be monitored by the Risk Management Group (RMG) and the Clinical Care and Professional Governance Committee (CCPGC). The adverse event quarterly report will include the following local measures which have been identified in the national framework to support the measurement and monitoring strategy for this policy.

The measures supporting implementation of the national framework and this local adverse event policy include:-

- Compliance with timescales for completion of reviews
- Documentation of completion of Duty of Candour processes and any other engagement with patient, service user and family/carer
- Development of improvement plans following reviews
- Compliance with dates set in improvement plans for completion of actions
- Production of learning summaries from review reports for sharing locally
- Sharing of learning summaries nationally via the community of practice
- Percentage of how many adverse events have caused harm to patients, service users or staff (such as events graded as Category 1 and 2) out of the total number of adverse events

In addition the following measures will also be used to demonstrate supporting learning and improvement from adverse events:-

- Patient safety walk-rounds
- Top themes and trends in adverse events
 - By number
 - By harm/impact (as per definitions for Category 1, 2 and 3 events)
- Safety culture and climate surveys
- Surveys of patient, service user and family or carer involvement and engagement with adverse event review processes
- Evaluation of effectiveness of actions implemented following reviews

The Scottish Patient Safety Programme (SPSP) also has measures of harm for each of its programmes of work which NHS Shetland participate in. This will contribute valuable information to identify areas for improvement.

An annual review focusing on the quality of report content will also be undertaken using a set of criteria including guidance from HIS.

Monitoring of the use and usability of the adverse event management system will also be put in place including review of numbers and departments reporting and feedback from users on the adverse event report forms.

10. Equality and Diversity Impact Assessment (EDIA)

This policy is a suite of documents developed to support the Board's Risk Management Strategy by giving more detail about the process of reporting and reviewing adverse events. The EDIA carried out as part of the Risk Management Strategy recognises that in complying with the Health and Safety at Work etc Act 1974 and subordinate legislation the Board meets its duty of care towards not just employees but others who may be affected by its activities e.g. patients, visitors, members of the public, contractors and delivery personnel.

Additionally, the strategy recognises the statutory requirement to give special consideration to other groups including night workers, lone workers and workers with disabilities.

As the strategy also makes clear, the promotion of a just and open culture is regarded as an essential component of an effective risk management system.

The impact of the Risk Management Strategy and supporting documents has been assessed as positive in relation to equality and diversity.