Management of adverse events

Review Report | NHS Dumfries & Galloway

April 2013
Healthcare Improvement Scotland is committed to equality. We have assessed the review process for likely impact on equality protected characteristics as defined by age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, and sexual orientation (Equality Act 2010). You can request a copy of the equality impact assessment report from the Healthcare Improvement Scotland Equality and Diversity Officer on 0141 225 6999 or email contactpublicinvolvement.his@nhs.net
Contents

Executive summary 4
1 Introduction 8
2 NHS Dumfries & Galloway's adverse event management policies and procedures 10
3 Detailed review findings 13
Appendix 1 – Details of review team 25
Executive summary

In June 2012, Healthcare Improvement Scotland published a report called: *The Management of Significant Adverse Events in NHS Ayrshire & Arran* (2012). The report provides an in-depth analysis of NHS Ayrshire & Arran’s adverse event management system and outlines a number of recommendations and issues that the NHS board should act on. The report also contains recommendations for other NHS boards in Scotland and learning points for NHSScotland as a whole.

Immediately following the publication of our report, the Cabinet Secretary for Health, Wellbeing and Cities Strategy asked Healthcare Improvement Scotland to carry out a rolling programme of reviews across NHS boards starting in autumn 2012.

Our reviews focus on the six key recommendations for NHS boards (numbers 18–23) from the NHS Ayrshire & Arran report. The purpose of the reviews is to assess how investigation of adverse events is being used by NHS boards to drive learning and improvement in order to reduce the risk of these events occurring again.

What we found

Our review of NHS Dumfries & Galloway’s governance arrangements and processes for managing adverse events involved:

- an analysis of evidence provided by the NHS board, and
- a visit to NHS Dumfries & Galloway on Friday 22 February 2013.

In 2008, NHS Dumfries & Galloway installed and customised the Datix incident reporting software for the management of adverse events. In April 2012, the NHS board reviewed its processes and moved from a risk-based classification of incidents to a harm-based classification using the Institute for Healthcare Improvement global trigger tool categories. This new system was developed in consultation with staff at both clinical and partnership forums. The NHS board reported that this has simplified the incident reporting and approval process.

In response to the NHS Ayrshire & Arran report and recommendations, NHS Dumfries & Galloway has further reviewed its processes. The NHS board has revised its adverse incident management and learning policy and has created a comprehensive suite of documentation to support the management of adverse events. This includes the following:

- adverse incident policy statement
- management of significant adverse events procedure, and
- process for reporting and management of an adverse incident – quick reference guide.

At the time of our review, the NHS board was at the final approval stage for the revised documentation and had started rolling out these systems across the NHS board. We saw a commitment to a culture that supports learning and continuous improvement to increase the quality and safety of healthcare across the NHS board.

We noted the following areas of good practice within NHS Dumfries & Galloway:

- wide-ranging staff engagement, particularly in reporting incidents and the use of Datix
• evidence of good relationships and communication between senior management, members of significant adverse event review teams and staff involved in incidents
• involvement of staff in redesigning the incident reporting form to be more user friendly, and
• a recently simplified governance structure which aims to improve Board assurance.

We noted that the NHS board has undertaken substantial work to improve the significant adverse events process, underpinned by positive and committed leadership structures. This includes work on patient and family involvement, document control, and sharing learning across the organisation.

However, this is currently in the implementation stages and has not yet been embedded. Challenges remain in ensuring that the new systems and procedures are consistently applied and used across the NHS board. NHS Dumfries & Galloway has already identified this and there are plans to evaluate the new system. The recommendations identified below aim to support the NHS board’s improvement activity.

Recommendations

We expect NHS Dumfries & Galloway to continue to implement recommendations 18–23 from the NHS Ayrshire & Arran report. We have also identified the following associated recommendations to improve how the NHS board manages adverse events.

Engaging with stakeholders

Recommendation 18 from the NHS Ayrshire & Arran report

NHS boards should ensure that they are taking an active and planned approach to engaging with key stakeholders particularly the patients, family and carers affected by a significant adverse event.

NHS Dumfries & Galloway’s active and planned approach to engaging with key stakeholders affected by a significant adverse event, should:

1 implement a consistent process for involving patients, families and carers in the adverse event review process
2 demonstrate a formal process for documenting patient, family or carer engagement or providing a rationale if there was no involvement, and
3 ensure a consistent process for staff involvement in the adverse event review process, including feedback, action planning and drafting recommendations.
Staff knowledge and training

Recommendation 19 from the NHS Ayrshire & Arran report
NHS boards should ensure that their staff are trained and have suitable knowledge and understanding to be involved and contribute to the full management of significant adverse events including the implementation of actions relating to learning, change and improvement.

To support staff knowledge and training, NHS Dumfries & Galloway should:

4 demonstrate a systematic and organisation-wide approach to formal staff training, and
5 ensure staff involved in the management of significant adverse events have a clear understanding of root cause analysis methodologies.

Roles and responsibilities

Recommendation 20 from the NHS Ayrshire & Arran report
NHS boards should ensure that all members of staff have a clear understanding of their roles and responsibilities regarding significant adverse events and that clear lines of accountability are defined and reflective of the organisation’s governance structure.

To ensure clear functions and roles, NHS Dumfries & Galloway should:

6 ensure staff are clear about the process and responsibilities for carrying out a review and that a consistent approach is applied throughout the NHS board, and
7 embed the new governance arrangements and subsequently evaluate them to ensure that they are fulfilling their aims.

Information management

Recommendation 21 from the NHS Ayrshire & Arran report
NHS boards should ensure that their document control and related information systems are suitably integrated and robust to provide a complete audit trail of significant adverse event management from the incident occurring to evidencing change and improvement. These systems should also allow NHS boards to undertake ongoing thematic learning from significant adverse events.

To support its information management processes, NHS Dumfries & Galloway should:

8 ensure there is a consistent process for staff to capture and store all documentation relating to each stage of the adverse event process in the Datix system.

Risk-based, informed and transparent decision-making

Recommendation 22 from the NHS Ayrshire & Arran report
NHS boards should ensure that the decisions related to the management of significant adverse events are risk based, informed and transparent to allow appropriate level of scrutiny and assurance.

To support a risk-based, informed and transparent approach, NHS Dumfries & Galloway should:

9 implement its suite of documentation to ensure consistency of the adverse events review process across the NHS board, in particular, documenting the decision-making to escalate or re-grade incidents.

Timely management, learning, dissemination and implementation

Recommendation 23 from the NHS Ayrshire & Arran report

NHS boards should ensure that the management of significant adverse events is completed in a timely manner and that the thematic learning is appropriately disseminated and acted upon throughout the organisation.

To improve timely management, learning and dissemination following adverse events, NHS Dumfries & Galloway should:

10 demonstrate that the timescales for various stages of the adverse incident management process are met in line with the policy

11 ensure there is a consistent process for developing and monitoring action plans and outcomes, and

12 ensure lessons learned are captured and shared across the organisation, and develop a system to quality assure that learning has been shared with a focus on making improvements.

We have asked the NHS board to develop an improvement plan to address the identified recommendations.

We would like to thank NHS Dumfries & Galloway and in particular all staff at Dumfries & Galloway Royal Infirmary for their assistance during the review.
1 Introduction

1.1.1 An adverse event 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, visitors or members of the public. Reviewing and managing these events should help NHS boards learn how to reduce the risk of them happening again.

1.1.2 We published a report in June 2012 called: The Management of Significant Adverse Events in NHS Ayrshire & Arran. The report focuses on NHS Ayrshire & Arran’s adverse event management system but also contains recommendations for other NHS boards in Scotland and learning points for NHSScotland as a whole.

1.1.3 Immediately following the publication of our report, the Cabinet Secretary for Health, Wellbeing and Cities Strategy asked us to:

- develop a national approach to learning from adverse events, and
- carry out a rolling programme of reviews across NHS boards starting in autumn 2012.

The review process

1.1.4 Reviewing NHS boards’ governance arrangements and processes for managing adverse events helps us to identify whether appropriate learning and improvement is taking place to reduce the risk of events happening again.

1.1.5 Our reviews focus on the six key recommendations (18–23) for NHS boards from the NHS Ayrshire & Arran report (2012) to provide assurance that NHS boards are effectively managing adverse events. We measure NHS boards against the recommendations within the NHS Ayrshire & Arran report and against their own policies.

1.1.6 The review process has two key phases:

- pre-visit analysis, and
- the review visit.

Pre-visit analysis

1.1.7 We reviewed information provided by NHS Dumfries & Galloway in advance of the visit. This included:

- policies and procedures for adverse event management
- governance and reporting arrangements
- an assessment of the NHS board’s current and future planned approach following the recommendations of the NHS Ayrshire & Arran report
- a list of 15 recorded significant adverse events over the past 18 months, and
- details of four specific significant adverse event reviews.
1.1.8 Of the 15 recorded significant adverse events, we selected four cases for detailed review. We did this by reviewing the high level summary of each case, taking into account the location and specialty of the event and the level of investigation.

Review visit

1.1.9 The review visit took place on Friday 22 February 2013. The review team was made up of a number of individuals with relevant specialist knowledge from across Scotland (see Appendix 1 for membership of the review team).

1.1.10 During the visit, we had discussions with a range of staff from senior management to frontline operational staff to assess how adverse events are managed in practice.

1.1.11 We discussed the initial findings of our report with NHS Dumfries & Galloway’s chief executive on 15 March 2013.

Improvement plan

1.1.12 We expect NHS Dumfries & Galloway to continue to implement recommendations 18-23 from the NHS Ayrshire & Arran report and to implement the specific recommendations within this report. It is important that the recommendations are carefully considered and a detailed improvement plan developed, with appropriate timescales, ownership, accountability and measures incorporated.

1.1.13 We have asked NHS Dumfries & Galloway to keep us updated as the improvement plan progresses and to notify us when it has been agreed by local governance structures. This will inform the development of the national approach to learning from adverse events.
2 NHS Dumfries & Galloway’s adverse event management policies and procedures

2.1.1 NHS Dumfries & Galloway provides health services for a population of 148,000 within a large geographical area of about 2,400 square miles. The NHS board employs around 4,500 staff from a wide range of professional and support occupations, excluding GPs and dentists.

2.1.2 Dumfries & Galloway Royal Infirmary is the main acute hospital for the region. Galloway Community Hospital, in the west of the region, is a community hospital with accident and emergency and maternity provision, and carries out a range of elective services. Eight cottage hospitals also provide services such as minor injuries units. Midpark Hospital provides inpatient facilities for patients requiring acute mental health support.

2.1.3 NHS Dumfries & Galloway sets out a commitment to an open and honest culture and the just and fair treatment of staff in its adverse incident management and learning policy.

Policy for managing adverse events

2.1.4 NHS Dumfries & Galloway has the following policies, procedures and guidance in place for the management of adverse events:

- adverse incident management and learning draft policy
- adverse incident policy statement
- management of significant adverse events procedure, and
- process for reporting and management of an adverse incident – quick reference guide.

Adverse event definitions

2.1.5 The adverse incident management and learning draft policy (version 3, issue date December 2012) hereafter referred to as the policy, defines an incident as:

“[Anything] that causes (or has the potential to cause) unwanted effects involving the safety of patients, users, staff and other persons – or which results in loss or damage. Such incidents would include (amongst other examples) loss, harm, injury arising from unexpected hazards or physical/verbal abuse.”

2.1.6 Before April 2012, NHS Dumfries & Galloway graded incidents using the NHSScotland Risk Matrix, based on the level of severity of the incident. In April 2012, the NHS board changed the categorisation to use patient harm as the main indicator for adverse events and adopted the IHI global trigger tool categories:

- 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
• Category E: Temporary harm to the patient or person and required intervention
• Category F: Temporary harm to the patient 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

However, the NHS board continues to use the NHSScotland Risk Matrix to measure residual risk following an incident.

2.1.7 The NHS board has categorised a significant adverse incident as categories G, H or I.

2.1.8 During the 18-month period between January 2011 and July 2012, there were 5,689 adverse incidents. The NHS board categorised one of these as category G and 15 of these as H or I. Twelve of the 15 incidents have been subject to an investigation or a review. The remaining three cases were not reviewed as the individuals died of natural causes.

2.1.9 NHS Dumfries & Galloway has identified the top five themes for adverse events as:
• sudden deterioration or collapse
• treatment or procedure
• diagnosis failed or delayed
• medical devices and equipment, and
• non compliance with policy or protocol.

Governance arrangements

2.1.10 At the time of our review, NHS Dumfries & Galloway had recently undertaken a review of governance arrangements to ensure ongoing effective systems of assurance for significant adverse events reviews. The NHS board told us that the governance systems have been agreed and the revised policies will be approved and in place at the beginning of March 2013.

2.1.11 The chief executive has responsibility to ensure that robust systems are in place to learn from adverse incident reports and to ensure that actions to address the risk are reviewed. In practice, the chief executive delegates this responsibility to the executive nurse director, who attends the healthcare governance committee and is a member of the board management team.

2.1.12 Under the previous governance arrangements, all incidents of categories G, H and I were reported to the following positions and groups:
• directorate risk facilitators
• directorate general manager
2.1.13 The NHS board told us that the streamlined process will increase transparency and accountability and strengthen the significant adverse events process. The NHS board also told us that there are plans to evaluate this process after one year through internal audit and a review of quality and patient safety leadership group reports.

2.1.14 Figure 1 outlines the new governance arrangements in place for the management of adverse events.

**Figure 1: NHS Dumfries & Galloway’s governance structure**
3 Detailed review findings

3.1 Engaging with stakeholders

NHS boards should ensure that they are taking an active and planned approach to engaging with key stakeholders, particularly the patients, family and carers affected by a significant adverse event.

Patient, family and carers involvement

3.1.1 The policy provides guidance on ensuring the immediate safety of patients following an incident, and guidance on involving patients, family and carers in adverse event reviews.

3.1.2 The policy states that:

“Patients (where appropriate – their relatives and carers) will be informed of all adverse incidents that have affected them or their care. Patient’s relatives will be given the opportunity to discuss the incident with appropriate staff members and where the incident is significant they will be involved in and kept up to date on the investigation. This must include incidents that the patient may otherwise be unaware of, such as medication errors. At all stages in this process patients/and or relatives are at liberty to make a complaint.

“The organisation recognises that there may be occasions where it is not in the patient’s interest to be advised about an adverse incident. In such circumstances, the organisation with consent will seek advice before taking such a decision.”

3.1.3 The adverse incident policy statement outlines the principles of patient engagement. The management of significant adverse events procedure also details the process, responsible staff and resources available to involve patients in the complete review process. This includes the initial incident and notification, agreeing objectives of the review and an NHS board key contact. The procedure sets out the following commitment to patients and families:

• “We will keep you informed of our actions from the time that the adverse event happens through to the point when we have identified the learning and improvements to be made;
• We will communicate with you respectfully and honestly, in a way that compassionately acknowledges and recognises the emotional impact of the adverse event on you and your family;
• We will support you by providing a consistent named contact person;
• We will work with you to involve you in the review process, taking account of your preferences and providing you with the opportunity to share details of your experiences with staff to support their learning; and
• We will provide you with a sincere and honest apology for identified failings.”

3.1.4 Of the four cases selected for detailed review, we did not find a consistent process for involving patients, families and carers in the incident investigation. In two cases, clinical staff engaged with patient’s families to varying degrees. One involved a consultant writing to the family to detail the findings of the incident review report. The other
involved communication to discuss the review, process and outcomes. The patient’s next of kin also received a copy of the final report and correspondence showed them to be happy with the communication.

3.1.5 In the four cases, there was no evidence of a formal process for documenting patient, family or carer engagement or providing a rationale if there was no involvement. We did note that when an incident is reported on the Datix risk management system, there is a question in the incident reporting form that asks if the patient has been informed of the adverse event. The form also contains a field to record if the patient has been involved in the review process.

3.1.6 However, we noted that the NHS board has plans to introduce a checklist that sets out the process of managing a significant adverse event review, including staff and patient involvement. The NHS board also provided a recently developed significant adverse event review family evaluation questionnaire. The NHS board intends that this forms part of a suite of documentation that is completed during a review. This will ensure there is a consistent process for involving patients, families and carers in the incident investigation.

**Staff involvement**

3.1.7 Every staff member of NHS Dumfries & Galloway can report incidents through the Datix risk management system. The policy contains guidance for the engagement of staff in reporting incidents.

3.1.8 The adverse event policy statement sets out the following commitments for staff:

“When a Significant Adverse Event occurs the event will be managed effectively to ensure that:

- staff members are safe and supported;
- the organisation appropriately reviews what happened in an open, fair and thorough way, within defined timelines; and
- learns from the event and implements any required improvement.”

3.1.9 The significant adverse event review process, outlined as part of the management of significant adverse events procedure, states that a staff member’s line manager or the duty manager at the time of the incident is responsible for assessing and addressing staff support needs. At the time of our review, the NHS board also reported that there are opportunities for self or management referrals to occupational health services, if necessary.

3.1.10 The majority of staff spoken with during the review told us that they felt supported through the review process, were adequately informed on how reviews were progressing and knew where to get support. The exception to this was where a member of staff reported an incident outwith their normal working area and was not informed during or after the review. In this case, the staff member requested feedback and this was supplied. The Datix incident reporting form does include a question asking whether the reporter of the incident has received feedback and the rationale documented if not.
3.1.11 The procedure also contains a checklist for managing a significant adverse event review. This documents staff involvement in the review process and includes staff communication preferences, timelines for contact throughout the review and formal feedback.

3.1.12 However, the policy and supporting documentation does not detail if staff are involved in or contribute to the development of recommendations and action plans resulting from the investigations. Section 3 of the policy outlines that line managers are responsible for feeding back learning to staff involved in incidents and that:

“The Risk Coordinator will ensure that all the learning from adverse incidents is shared with all relevant people when this is wider than the investigating team.”

3.1.13 All four cases selected for detailed review showed evidence of staff involvement in the review process, through written staff statements. Learning recommendations were included as part of the subsequent reports. However, there was no evidence to suggest that staff were involved in the drafting of these or that they were feedback appropriately. Documentation provided for one of the cases also demonstrated that a copy of the report was sent to the reporting member of staff for comment and sign off before it was finalised.

3.1.14 The NHS board provided a recently developed significant adverse event review staff evaluation questionnaire. This will be used following a review to evaluate staff involvement and ensure there is a consistent process for involving staff in the adverse event process.

**Recommendations**

NHS Dumfries & Galloway’s active and planned approach to engaging with key stakeholders, particularly the patients, family and carers affected by a significant adverse event, should:

1. implement a consistent process for involving patients, families and carers in the adverse event review process
2. demonstrate a formal process for documenting patient, family or carer engagement or providing a rationale if there was no involvement, and
3. ensure a consistent process for staff involvement in the adverse event review process, including feedback, action planning and drafting recommendations.

### 3.2 Staff knowledge and training

NHS boards should ensure that their staff are trained and have suitable knowledge and understanding to be involved and contribute to the full management of significant adverse events including the implementation of actions relating to learning, change and improvement.

3.2.1 The policy states that NHS Dumfries & Galloway has delivered risk management training for staff since 2005 including:

- Datix
- incident management training
• incident investigation tools
• understanding human factors
• risk systems, and
• using the policy.

3.2.2 The senior management and risk management team reported that the NHS board provides all staff, including junior doctors on rotational placements, with an introduction to risk management training as part of formal induction when joining the organisation.

3.2.3 Staff spoken with during the review told us they had received mixed levels of training on Datix. This training ranged from formal comprehensive training, to key information disseminated through line management or other team members, to no training. However, all staff told us that they were aware of the revision to the Datix incident reporting form and that they could access guidance on the NHS board Intranet homepage. The NHS board has commissioned training on its new policy which will begin to be rolled out at the end of April following final approval of the suite of documents in March.

3.2.4 Staff spoke highly of the support provided by the risk management team. The risk management team had given guidance on the updated Datix incident reporting form at team meetings, and were available for further guidance and support when required.

3.2.5 Staff involved in significant adverse event investigations also told us that they had received mixed levels of investigation training. Some staff confirmed that they had attended specific training courses, whereas other staff told us that they learned on the job and created their own method of working within the scope of the investigation brief. In all of the cases selected for detailed review, staff told us that the risk management team provided support and guidance during the adverse event review process.

3.2.6 However, we noted that the NHS board has plans to deliver further training for those staff members taking part in a significant adverse event investigation. This is to include training on:

• routine investigation
• significant adverse event investigation
• human factors, and
• involving families when things go wrong.

3.2.7 The NHS board also told us that there are plans to identify a cohort of staff to receive root cause analysis training.
Recommendations
To support staff knowledge and training, NHS Dumfries & Galloway should:

4 demonstrate a systematic and organisation-wide approach to formal staff training, and
5 ensure staff involved in the management of significant adverse events have a clear understanding of root cause analysis methodologies.

3.3 Roles and responsibilities

NHS boards should ensure that all members of staff have a clear understanding of their roles and responsibilities regarding significant adverse events and that clear lines of accountability are defined and reflective of the organisations governance structure.

3.3.1 The adverse incident policy statement outlines the general roles and responsibilities of staff, departments and committees. It states that any staff member can complete a Datix incident reporting form, unless they are aware that this has already been done by another member of staff. Every ward or departmental manager and supervisor is responsible for ensuring staff are aware of, and comply with, the policy and that appropriate investigation, reflection and learning happens within their team.

3.3.2 Each directorate has responsibility for reviewing and managing incidents and ensuring that actions are progressed and lessons learned are disseminated. Directorate management boards receive and discuss incident reports to ensure that residual risk and learning is highlighted and actions progressed.

3.3.3 The chief executive is accountable and responsible to the Board for ensuring that policies and procedures are in place to ensure the effective reporting, recording, management, investigation and monitoring of all incidents. The executive nurse director has delegated lead from the chief executive for clinical governance and risk management. The healthcare governance committee has delegated responsibility on behalf of the Board for assurance on risk and incident management.

3.3.4 Under the new policy, the executive nurse director and medical director commission significant adverse event investigations. They are responsible for appointing a lead reviewer, technical support and establishing the remit of the investigation. This will ensure there is a balance between organisational, staff and patient or family needs.

3.3.5 Most staff spoken with during our review were clear of their responsibilities for reporting incidents and knew where to access support if necessary. However, some staff were less clear about the process and responsibilities for carrying out a review. In one case, the lead reviewer told us that they had developed their own system for undertaking investigations. The NHS board told us that each directorate has key contacts who provide support for significant adverse events reporting, management and investigation.

3.3.6 The NHS board told us it intends to move from a three stage to a two stage approval process. In this new process, low level events (categorised A–F) are initially investigated by local teams. These can be escalated to a full significant adverse event review if
deemed appropriate by either a risk triage group or senior management recommendation.

3.3.7 In the revised process, the associate nurse director or associate medical director conducts an initial review for all G–I incidents and makes recommendations for action. The executive medical and nursing directors then use this information to decide whether to progress to a full review and the general manager is informed of the result.

3.3.8 The NHS board has recently developed a management of significant adverse events procedure which sets out how the review team’s roles and responsibilities will work in practice. This includes the following staff:

- lead reviewer
- technical lead
- investigation co-ordinator
- family contact person, and
- staff contact person.

3.3.9 The NHS board intends that this forms part of a suite of documentation that will help inform a review. This will ensure there is a consistent process for all incident investigations.

3.3.10 Significant adverse event review reports are discussed at acute directorate risk group meetings, directorate management boards, and the quality and patient safety leadership group, which is a sub-group of the healthcare governance committee. The Board has delegated responsibility for assurance on risk and incident management to the healthcare governance committee, which will receive formal reports in the form of minutes and adverse event assurance reports from the quality and patient safety leadership group.

3.3.11 The quality and patient safety leadership group will meet weekly from March 2013 to review significant adverse events and will also carry out 3-month and 6-month reviews of actions. All significant adverse events are escalated for discussion at this group. In addition, the NHS board management team is now receiving monthly significant adverse incident reports with 3 and 6-month follow-up reports on actions.

**Recommendations**

To ensure clear functions and roles, NHS Dumfries & Galloway should:

6 ensure staff are clear about the process and responsibilities for carrying out a review and that a consistent approach is applied throughout the NHS board, and

7 embed the new governance arrangements and subsequently evaluate them to ensure that they are fulfilling their aims.
3.4 Information management

NHS boards should ensure that their document control and related information systems are suitably integrated and robust to provide a complete audit trail of significant adverse event management from the incident occurring to evidencing change and improvement. These systems should also allow NHS boards to undertake ongoing thematic learning from significant adverse events.

3.4.1 NHS Dumfries & Galloway uses the Datix risk management system to report incidents. The policy explains using Datix to report incidents, and the timescales and roles involved in this.

3.4.2 During our review, the NHS board demonstrated use of the Datix system. The NHS board has adapted the system in response to staff feedback and they reported that the incident reporting form is now easier to use and contains a Situation, Background, Action, Recommendation (SBAR) format as part of the initial reporting form. This streamlines the process and reduces duplication during the investigation.

3.4.3 The pre-visit evidence provided by the NHS board states that Datix has the capability to hold all documentation relating to adverse incidents. Investigations are documented and action plans embedded or attached to the Datix record. All correspondence relating to a record is contained in the incident file and follow-up reports are attached when and if required.

3.4.4 The NHS board demonstrated that documentation had been attached to the Datix record for all four cases selected for detailed review. However, the information attached to the records was not consistent and there was no record of review team paperwork.

3.4.5 During our review, staff told us that in some cases all information was stored in the Datix record. However, in others, most correspondence was saved in electronic files. Where this was the case, staff also told us that there were plans to attach this to the Datix record.

3.4.6 Staff also told us of different methods used to obtain staff statements in two different cases. Of the four cases selected for detailed review, review team documentation was also inconsistent. The NHS board submitted no documentation about the review team and their responsibilities for three of the cases. In one case, more detailed documentation was provided.

3.4.7 The NHS board has identified this as an area for improvement and has redesigned adverse events review paperwork to ensure consistent processes and documentation is used across the NHS board. This paperwork is part of a suite of documentation that will be completed during a review. The revised policy also states that all supporting documentation will be digitally scanned and retained by the incident reporting system and kept along with the incident record in accordance with requirements of the Data Protection Act.

3.4.8 The policy is clear how information should be shared within the governance structure and the policy details how external requests for information relating to an adverse incident investigation would be managed by the risk coordinator. The policy also details how feedback should be offered to the person reporting the incident by the person leading the investigation. This should be recorded on Datix and disseminated through
3.4.9 In three of the four cases selected for detailed review, staff told us that they were well informed about progress with the review and had received copies of the report findings and recommendations. Staff spoken with in one case told us that they were unsure of the process for feedback on progress of the review. However, they also told us that they felt appropriately empowered to ask for feedback and information was then provided.

**Recommendations**

To support its information management processes, NHS Dumfries & Galloway should:

8 ensure there is a consistent process for staff to capture and store all documentation relating to each stage of the adverse event process in the Datix system.

### 3.5 Risk-based, informed and transparent decision-making

**NHS boards should ensure that the decisions related to the management of significant adverse events are risk based, informed and transparent to allow appropriate level of scrutiny and assurance.**

#### Identification, notification and initial event reporting

3.5.1 The policy outlines that staff must report all incidents and near misses through the Datix system within 12 hours of an adverse event happening. The Datix incident reporting form should be completed by the person delivering the care or treatment during the incident or by the staff member who was the first to identify the incident.

3.5.2 Following initial recording, the person in charge of the ward, department or team grades the incident using the IHI global trigger tool categories. This assessment determines the actions taken to manage the adverse incident.

- Levels A–D (incidents where no harm occurs) are closed without investigation in most cases. There will be an option to investigate and escalate, if needed.
- Levels E–F (incidents where low or moderate harm occurs) require investigation. This may include a timeline review and interviews or statements from staff. This should be carried out by the relevant team leader or escalated if appropriate.
- Levels G–I (serious incidents) may require full root cause analysis. A member of the risk management team co-ordinates the investigation with senior medical, senior nursing, senior allied health professional and general manager input. These incidents may also require director or associate director input.

3.5.3 The grading process is outlined in the management of significant adverse events procedure, with examples of events that fall into each category.

3.5.4 The acute directorate risk triage group meets every week to review all Datix forms for the previous week, looking specifically at the level of harm and grading. A monthly acute directorate risk group meeting is then held to follow-up actions of each incident to ensure that the appropriate action is initiated. The chief operating officer has instructed the other directorates to put similar arrangements in place.
Escalation of events

3.5.5 The significant adverse event review process, which forms part of the management of significant adverse events procedure, states that the associate nurse director or associate medical director conducts an initial review for all G–I incidents. They then provide the executive medical and nurse directors with the original Datix form and their assessment of the event and recommendation whether or not to progress to a full significant adverse event review. The executive medical and nursing directors then decide whether to progress to a full review and the general manager is informed of the result.

3.5.6 While the categorisation of incident was recorded in Datix for each of the four cases selected for detailed review, the decision to escalate incidents to a full significant adverse events review was not detailed in the case documentation for any case. The status of one of the cases changed mid-review this decision was not documented on the Datix record.

3.5.7 The NHS board has identified this as an area for improvement and has redesigned adverse events review paperwork to ensure consistent processes and documentation are used across the NHS board. The procedure contains a checklist for decision-making in commissioning a significant adverse event review which documents the process and the rationale for or against progression. This checklist is part of a suite of documentation that will be completed during a review.

3.5.8 The significant adverse event review process also states that when the decision has been made to progress to a significant adverse events review, the quality and patient safety leadership group reviews these incidents. This is done on a weekly basis as part of the new arrangements.

Recommendations
To support a risk-based, informed and transparent approach, NHS Dumfries & Galloway should:

9 implement its suite of documentation to ensure consistency of the adverse events review process across the NHS board, in particular, documenting the decision-making to escalate or re-grade incidents.

3.6 Timely management, learning, dissemination and implementation

NHS boards should ensure that the management of significant adverse events is completed in a timely manner and that the thematic learning is appropriately disseminated and acted upon throughout the organisation.

Investigation and reporting timelines

3.6.1 The policy details that an online adverse incident reporting form must be completed within 12 hours of the incident being identified. It states that:

“A significant incident should be reported as a priority once the immediate safety of the situation has been achieved.”
3.6.2 Of the four cases selected for detailed review, two were reported on Datix within 1 day of the incident occurring, one was reported within 2 days and another was reported within 4 days.

3.6.3 The policy also provides timescales for completion of investigations for incidents. It outlines that the investigations of incidents rated as high and very high risk should be completed within 40 working days.

3.6.4 Of the four cases selected for detailed review, the average time taken to complete the investigation was 51 days, with a variance in timescales ranging from 15 days to 85 days. Documentation provided from the NHS board showed inconsistent reporting dates. These calculations were made based on the latest investigation closed dates provided.

**Action planning**

3.6.5 The management of significant event procedure contains a section entitled: ‘checklist for significant adverse event review action plan development’, which describes the action planning process. The checklist includes:

- checks that the service has received the significant adverse event review report and recommendations and have had a chance to comment
- action plan development, including responsibilities and timeframes for their development
- the process for designing action plans
- how to write action plans, including the use of templates, wording, measurement, responsibilities and timescales for completion, and
- checks for follow-up and monitoring of actions and ensuring that these are taken to the relevant committees and groups.

3.6.6 The NHS board is currently implementing this checklist across the organisation. It intends that this will form part of a suite of documentation that is used during a review. This will ensure there is a consistent process for developing action plans.

3.6.7 Of the four cases selected for detailed review, two contained action plans. However, only one of these provided evidence of follow-up and completion of specific actions.

3.6.8 At the time of the review, staff reported that the investigation team developed action plans. These should be made in consultation with staff involved in the incident and those involved in undertaking the actions. This ensures ownership and support in action completion. However, we noted that this was not applied consistently across all cases.

3.6.9 The senior management team told us that the acute risk triage group meets weekly and looks at all adverse events from across the directorate from the previous week. A meeting of the monthly acute directorate risk group monitors actions. All significant adverse events are escalated for discussion at the quality and patient safety leadership group. The risk management team monitors all actions and updates which are reported back and reviewed after 3 and 6 months to ensure progress. The NHS board told us that there are issues with the timely completion of the 3 and 6 month reviews. However, we were assured that systems were being put in place to address this.
Sharing of learning
3.6.10 The policy states that feedback is a vital part of ensuring the transparency of the incident reporting process. It states that this will be achieved in several ways:

- individual feedback must be offered to the person reporting the incident by the person leading the investigation and this must be recorded on Datix
- learning events, and
- newsletters and news items.

3.6.11 During the review, staff told us that feedback was provided to them following completion of the investigation. Staff were also aware that documents related to open cases were attached to Datix, and were comfortable contacting the risk management team for information relating to closed cases.

3.6.12 Of the four cases selected for detailed review, two cases demonstrated that learning was shared within the organisation. This was through the risk and feedback newsletter. Staff confirmed this during the visit. Staff also noted that learning was shared through ward safety briefs. In one case, information was sent by email to all staff. However, this was not sent with information in connection to the context of the incident.

3.6.13 During the review, staff told us that verbal communication was largely used to share learning across the organisation. We were told that this was done at team meetings where managers would cascade information from monthly management meetings to staff. Safety action notices have also been used to put actions in place and disseminate learning.

3.6.14 The pre-visit evidence submitted states that NHS Dumfries & Galloway is planning to improve the organisational learning following incidents, including strengthening organisational learning when local teams instigate learning and improvements from incidents in their areas. The NHS board also reported that the quality and patient safety leadership group is currently considering ways to build on and improve these learning systems. A variety of mechanisms is required to ensure learning is shared across the organisation. It reported that one example of this is a current project to improve the medical incident reporting culture. This was confirmed by staff during the review.

3.6.15 Although staff told us, and the NHS board submitted evidence to show, that learning was shared across the organisation, there was no consistent mechanism to assure that learning is effectively disseminated or acted upon by staff.

3.6.16 The NHS board told us that the risk management team or risk triage groups would feed incident trends into NHS Dumfries & Galloway improvement programmes. This ensures that thematic learning is applied throughout the NHS board. During the visit, staff reported that in one of the cases selected for detailed review, the NHS board is developing a tool as a result of the incident.

3.6.17 The NHS board also told us about work to identify common issues happening in GP practices. It circulates this information to all GPs to ensure learning is disseminated throughout primary care.
Recommendations
To improve timely management, learning and dissemination following adverse events, NHS Dumfries & Galloway should:

10. demonstrate that the timescales for various stages of the adverse incident management process are met in line with the policy

11. ensure there is a consistent process for developing and monitoring action plans and outcomes, and

12. ensure lessons learned are captured and shared across the organisation, and develop a system to quality assure that learning has been shared with a focus on making improvements.
Appendix 1 – Details of review team

The review of NHS Dumfries & Galloway was conducted on Friday 22 February 2013.

Review team members

**Mark Aggleton**  
Senior Business Manager, Healthcare Improvement Scotland

**Ken Barker**  
Public Partner

**Nanisa Feilden**  
Programme Manager, Healthcare Improvement Scotland

**Susan Lowes**  
Project Officer, Healthcare Improvement Scotland

**Jamie Malcolm**  
Clinical Advisor

**Kevin Rooney**  
Consultant in Anaesthesia & Intensive Care Medicine, NHS Greater Glasgow and Clyde

**Claire Scrim**  
Project Officer, Healthcare Improvement Scotland

**Lesley Anne Smith**  
Quality Improvement Programme Director, NHS Education for Scotland
We can also provide this information:

- by email
- in large print
- on audio tape or CD
- in Braille (English only), and
- in community languages.

Edinburgh Office
Gyle Square
1 South Gyle Crescent
Edinburgh
EH12 9EB
Phone: 0131 623 4300

Glasgow Office
Delta House
50 West Nile Street
Glasgow G1 2NP
Phone: 0141 225 6999

www.healthcareimprovementscotland.org

The Healthcare Environment Inspectorate, the Scottish Health Council, the Scottish Health Technologies Group, and the Scottish Intercollegiate Guidelines Network (SIGN) are part of our organisation.