Management of adverse events

Review Report | NHS Highland

September 2013
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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 Highland’s governance arrangements and processes for managing adverse events involved:

- an analysis of evidence provided by the NHS board, and
- a visit to NHS Highland on Wednesday 7 August 2013.

NHS Highland has policies and procedures documentation in place to support and inform staff through the process of managing adverse events. In response to the NHS Ayrshire & Arran’s report and recommendations, the NHS board set up a short life working group in November 2012 to review these recommendations alongside a review of the current policies and procedures for the management of adverse events. Areas for improvement emerged from this work and will be incorporated into an updated policy and procedures document as well as updating working practices within NHS Highland.

We noted the following areas of good practice within NHS Highland:

- consistent approach to patient, family and carer involvement
- strong local governance structure with cohesive local teams, and
- openness and transparency in sharing learning across the organisation.

We identified a number of challenges in how adverse events are managed within NHS Highland. The review team found that further improvements could be made in terms of assurance of consistency in the practice of managing adverse events across the four operational units, consistency in approach to investigations and the use of IT systems to their full potential.
Recommendations

We expect NHS Highland 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 Highland's active and planned approach to engaging with key stakeholders affected by a significant adverse event should:

1. continue to implement a consistent process for involving patients, families and carers in the adverse event review process;
2. ensure a consistent process for recording the engagement with patients, families and carers, and;
3. consistently provide timely and meaningful feedback to staff to encourage a reporting culture.

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 Highland should:

4. implement the training and education improvement plans and demonstrate a systematic approach to staff training, ensuring staff are appropriately trained, and;
5. ensure staff involved in managing significant adverse incidents have a clear understanding of investigation methods and apply them to adverse event reviews and action planning.
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 Highland should:

6 clearly define roles and responsibilities for escalation and decision-making.

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 Highland should:

7 introduce a process to ensure that staff make full use of Datix for significant event reviews, including its additional features, and consistently capture all documentation relating to each stage of the significant adverse event process, and

8 ensure there is a single integrated approach to document management, monitoring, scrutiny and assurance across the NHS board.

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 Highland should:

9 implement a system to ensure consistency in decision-making for undertaking significant adverse event reviews across the NHS board.
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 Highland should:

10 ensure the timescales for various stages of the adverse event review process are met in line with the incident management policy and procedures

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

12 ensure lessons learned from individual adverse events as well as thematic learning are captured, shared and implemented across the NHS board.

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

We would like to thank NHS Highland and in particular all staff who attended the review visit at Raigmore Hospital, Inverness, 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 Highland 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 281 recorded significant adverse events over the past 18 months, and
- details of four specific significant adverse event reviews.
1.1.8 Of the 281 recorded significant adverse events, we selected four cases for detailed review. We did this by firstly randomly selecting 150 cases and then 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 Wednesday 7 August 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. We interviewed the chief executive of NHS Highland on Thursday 8 August 2013, as she was unable to attend on the day of the visit.

1.1.11 We discussed the initial findings of our report with NHS Highland’s chief executive on Monday 26 August 2013.

Improvement plan

1.1.12 We expect NHS Highland 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 Highland 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 Highland’s adverse event management policies and procedures

2.1.1 NHS Highland has the largest land area of all NHSScotland boards, covering around 40% of Scotland and serving a population of approximately 310,000.

2.1.2 There are two partnerships which manage NHS Highland’s four operational units: Highland Health and Social Care Service and Argyll and Bute Health Partnership. Highland Health and Social Care Service manages:

- North and west unit
  - Caithness
  - Sutherland
  - Lochaber and Skye
  - Lochalsh and Wester Ross

- South and mid unit
  - Easter Ross
  - Mid Ross
  - Inverness west
  - Inverness east
  - Nairn and Ardersier, and Badenoch and Strathspey

- Raigmore Hospital

The Argyll and Bute Health Partnership manages acute, primary, community health and mental health services across Argyll and Bute:

- Oban, Lorn and the Isles
- Mid Argyll, Kintyre and Islay, and
- Cowal, Bute, Helensburgh and Lomond.

2.1.3 Since April 2012, NHS Highland has worked towards the integration of health and social care services within its region. The NHS board is now responsible for the delivery of adult community care services following transfer from Highland Council.

2.1.4 NHS Highland has policies and processes in place to manage adverse events. These are outlined in the following three organisation-wide documents.

- Incident management policy and procedures (dated November 2009): outlines the NHS board’s requirements and responsibilities for the management of both clinical and non-clinical adverse events. This document also outlines incident management procedures for all staff.
• Policy for supporting staff involved in a serious incident, complaint or litigation claim (dated November 2011): provides guidance to support staff to ensure that staff are provided with adequate support.

• Critical incident report resource pack for managers (dated February 2010): assists managers to carry out investigations into adverse events.

2.1.5 Raigmore Hospital has developed a document: “Raigmore Hospital quality and patient safety division standard operating procedures”, which provides details for staff to understand the way in which quality and patient safety strategies are carried out. This includes Datix submissions as well as undertaking adverse event investigations.

Adverse event definitions

2.1.6 NHS Highland defines a significant adverse event, referred to as a serious untoward incident (SUI) in the incident management policy and procedures document, as “when an accident or incident involving a patient, member of staff, visitor on NHS property, contractor or other person to whom the organisation owes a duty of cares, occurs causing significant loss or damage, serious injury or unexpected death.”

2.1.7 From 2011, NHS Highland has used the term “significant event review” across all sites and departments other than in mental health services where the term “critical incident review” is used to define the incident investigation.

2.1.8 The electronic reporting system Datix is in place across NHS Highland to record and categorise adverse incidents. The NHS board introduced this system in 2009. The incident reporter estimates the severity of the incident by selecting one of four gradings on Datix:

• low
• medium
• high
• very high.

2.1.9 Between 1 March 2010 and 31 August 2012, NHS Highland recorded 281 incidents that were graded as high or very high which should have resulted in investigation. The level of investigation ranged from local investigation through to significant event review. Of these investigations, 52 were significant event reviews. The NHS board informed us that systems were in place to follow up those that had not yet been completed.

2.1.10 Following the above mentioned significant event reviews, NHS Highland has identified the themes for significant adverse events as:

• delay or failure to escalate care of deteriorating patients to senior consultant level
• complications in procedures
• suicide, and
• unexpected death.
Governance arrangements

2.1.11 The NHS Highland Board receives regular reports from the clinical governance committee on the operation of the clinical governance processes and any current issues. In turn, the clinical governance committee receives reports from:

- north and west clinical governance and risk management group
- south and mid clinical governance and risk management group
- Argyll and Bute CHP clinical governance and risk management group, and
- Raigmore quality and patient safety committee.

2.1.12 Until recently the risk management steering group also reported to the clinical governance committee. This group has since been adjourned following an internal audit of NHS Highland’s risk management process which resulted in a review of the group’s remit and reconsideration of its current model.

2.1.13 Figure 1 below outlines the current governance arrangements in place for the management of adverse events in NHS Highland.

Figure 1: NHS Highland’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 NHS Highland incident management policy and procedures promotes communication with patients, their family and carers:

“Communicating effectively with patients and/or their carers is a vital part of the process of dealing with errors or problems in their treatment. In doing so, NHS Highland can hopefully reduce the trauma suffered by patients and potentially reduce complaints.”

3.1.2 The document outlines the information that should be provided to patients in connection to any incidents that have affected them, such as:

- an acknowledgement and apology for any distress caused as result of the incident
- an explanation of the incident, and
- plans in place to address the harm caused.

It also outlines that a named person is to be identified as the key contact for the patient, family or carer.

3.1.3 For continued involvement in the investigation, the incident management policy and procedures outlines the way in which the patient, family and carers should be involved:

- “Being informed that a detailed review is taking place
- Being invited to discuss whether and if so, how the patient and or carers will be involved
- Being made aware of the process and the purpose and logic which underpins it
- Being kept up to date with the progress of the review
- Being informed of the outcome and the actions which NHS Highland will take following the outcome.”

3.1.4 During discussion with senior management, we were told that a meeting is held with the patient, family or carers before the significant event review meeting to outline the process and gather any questions or issues that they would like addressed to ensure their contribution to the investigation. They are not invited to the significant adverse event review meeting as this has been seen to affect the willingness of staff to openly discuss an incident. The staff member that meets with the patient, family or carer will act as an advocate on their behalf during the significant event review, and a follow-up meeting is held to relay the outcomes and recommendations as well as to respond to their earlier questions. The final review report is then shared. This process is also outlined within the
Raigmore Hospital quality and patient safety division standard operating procedures and all operational units follow the incident management policy and procedures for involving patients.

3.1.5 During a demonstration of the Datix risk management system, we were shown how the system records the involvement of the patient, family and carer. In those cases where they were not involved, a narrative to outline the reasons for this decision is required.

3.1.6 The National Patient Safety Agency (NPSA) guidance, Being Open: Communicating Patient Safety Incidents with Patients, their Families and Carers (2009), is also referenced within the NHS Highland incident management policy and procedures. This outlines how to communicate effectively with patients, their family and carers following harm to ensure that they are appropriately informed and involved throughout the investigation process.

3.1.7 Review of information submitted by the NHS board before to the review visit, and discussion with staff showed that there was a consistent approach to patient, family and carer involvement across the cases selected for review.

3.1.8 We noted that that NHS Highland intended to fully implement the NPSA Being Open guidance on principles of respecting dignity and promoting transparency. The NHS board is also developing a leaflet for patients to provide information to patients, families and carers on significant adverse event reviews.

Staff involvement

3.1.9 The NHS Highland incident management policy and procedures sets out that the NHS board is “committed to advocating an ‘Open and Fair Culture’.” It also states:

“Support for staff involved in incidents, complaints, claims or inquests is vital and support mechanisms will be reviewed and widely publicised for all groups of staff. NHS Highland recognises that whilst it is important to promote a culture of learning and closing the loop with regards to risk management, the effect on staff directly involved in an incident or enquiry should not be underestimated.”

3.1.10 All staff have access to the incident reporting system, Datix. To report an incident, log-in details are not required. To ensure ease of access, the NHS Highland intranet has a shortcut to the Datix system placed prominently on the home page.

3.1.11 Staff spoken with during the review visit reported that they were confident as to how to report an incident. They also appeared to be engaged with the principles of reporting and were aware of the benefits of reporting all incidents. However, some staff told us that they often did not receive feedback on incidents that they had reported which were graded as low or medium.

3.1.12 In three of the four cases, staff reported that they felt that they had been provided with sufficient feedback and information following the investigation. However, in one of the cases, some of the staff involved in the incident reported that feedback had not been provided to them following the review meeting.

3.1.13 The NHS board incident management policy and procedures outlines the specific support that is available to staff following an incident:

- any support required in the case of any legal proceedings
• debrief discussion with a manager
• encouragement to contact staff side representation if felt appropriate, and
• information on and access to occupational health services, chaplaincy, psychology services and any other appropriate counselling and therapy services.

3.1.14 As with patient, family and carer involvement, the NPSA Being Open guidance is applicable to the support and involvement of staff.

3.1.15 The policy for supporting staff involved in a serious incident, complaint or litigation claim outlines the professional advice and support available to staff following an incident. It also sets out the following processes to support staff:

• immediate and ongoing support
• debriefing (at various time points following an incident)
• throughout significant adverse reviews, and
• follow-up support.

3.1.16 During discussion with staff, they reported that they knew how to access support and received support when they felt that they required it. Much of the support reported was from their peers, from their operational units or other staff involved in the investigation.

3.1.17 Through discussion with senior management, they highlighted the open and honest reporting culture outlined within the incident management policy and procedures document. To ensure staff involvement in significant event reviews, the disciplinary procedure was stated to be independent to that of the review. In cases where negligence was highlighted, a disciplinary hearing may run parallel to the event review. However, the review would not be used as evidence against that member of staff during the hearing.

3.1.18 Information provided by the NHS board outlined a staff survey that was circulated to all staff who had been involved in a significant event review within NHS Highland. This was to get staff’s view on the significant event review process in terms of their involvement in the last investigation that they had taken part in. Although analysis of the survey had not yet been carried out, senior management informed us that improvements emerging from this would be implemented.

3.1.19 As with patient, family and carer involvement, NHS Highland stated that it planned to fully implement the NPSA Being Open guidance. The leaflet in development for patients involved in an adverse event is also being extended to include staff that will be involved in such investigations.
Recommendations

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

1. continue to implement a consistent process for involving patients, families and carers in the adverse review process
2. ensure a consistent process to recording the engagement with patients, families and carers, and
3. consistently provide timely and meaningful feedback to staff to encourage a reporting culture.

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 NHS Highland incident management policy and procedures states:

“In order to facilitate an open and transparent incident reporting culture and to support the implementation of this policy throughout NHS Highland, the Clinical Governance Support Team and the Health and Safety Team will provide training to staff across the organisation.”

3.2.2 Following the introduction of Datix in 2009, all staff were provided with training to guide them through the process of reporting incidents. For those joining the organisation after this time, training has been included within induction training sessions.

3.2.3 Ongoing training courses are held for staff responsible for reviewing incident reports on Datix and have been delivered since introduction of Datix in 2009. The clinical governance team also reported that it would provide ad hoc training to existing meetings, for example, at operational unit meetings and charge nurse meetings. Further ad hoc assistance is provided to those completing or reviewing Datix reports over the phone, guiding staff through the process with a working example of an incident. Staff also told us that they had learned how to complete the reviewer section by shadowing another colleague or through peer support.

3.2.4 Staff involved in significant adverse event reviews, either as part of the review team or as chair, reported mixed levels of investigation training. Some staff had attended national training, training organised by the NHS board, shadowed other colleagues or received peer support, whereas others had “learned on the job.”

3.2.5 To support staff training, investigation tools are outlined in the resource pack for managers. The clinical governance support team developed this to guide managers through the investigation process. This resource consists of:

- incident management guidance flow chart
templates
- critical incident report template
- critical incident review action plan and monitoring template
- example of critical incident report and action plan

procedures and quick guides
- incident management procedures
- serious untoward incident procedures

tools for investigations
- key questions
- fishbone template
- root cause analysis
- five why’s.

3.2.6 Most staff spoken with during the review visit were aware of the support available to them from the clinical governance team. All were aware of the documentation and guidance located on the NHS Highland intranet.

3.2.7 The NHS board also provided a training schedule for all operational units which includes regular training throughout 2013 and early 2014:

- reporter training
- reviewer training, and action plan and monitoring
- reports and dashboards
- significant event reviews and critical incident reviews in Datix, and action plan and monitoring, and
- searching and building reports.

3.2.8 In evidence submitted before the review visit and during discussions with senior management, NHS Highland stated that the following plans were in place to improve current adverse events training and education within the organisation:

- continue with Institute of Leadership Management training for staff in managerial or supervisory positions
- link with national work on suicide reporting systems
- develop current training on chairing significant adverse event reviews and root cause analysis
- develop further guidance on SMART (Specific, Measurable, Achievable, Result-oriented and Time-bound) improvement and action plans
- introduce National Patient Safety Agency training
- hold further Scottish Public Services Ombudsman workshops in September 2013 similar to the three held in 2011 and 2012, and
• incorporate quality and quality improvement objectives into staff annual performance appraisals.

3.2.9 Following the integration of health and social care services within NHS Highland, the NHS board, and in particular the clinical governance support team, are working towards ensuring all staff are using the same incident management system and are appropriately trained.

Recommendations
To support staff knowledge and training, NHS Highland should:

4 implement the training and education improvement plans and demonstrate a systematic approach to staff training, ensuring staff are appropriately trained, and

5 ensure staff involved in managing significant adverse incidents have a clear understanding of investigation methods and apply them to adverse event reviews and action planning.

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 organisation’s governance structure.

3.3.1 The NHS Highland incident management policy and procedures states:

“It is the responsibility of everyone working for NHS Highland to report all occasions where something has happened that has or could have caused harm to a patient, member of the public, staff member or contractor, or affected the ‘day to day running’ of the organisation.”

3.3.2 This document also sets out the detailed roles and responsibilities of staff, managers and senior managers for reporting and managing incidents. However, the policy does not outline the role of the medical director, nurse director and chief executive.

3.3.3 The incident management policy and procedures includes the objectives of the significant event review team. Staff spoken with during the review visit showed a clear understanding about their responsibilities in terms of reporting incidents as well as their roles in the review team and subsequent action plans.

3.3.4 Staff involved in incident investigations in Raigmore Hospital are supported through the process by a quality and patient safety facilitator who co-ordinates the review and carries out background information searches before the review meeting. For the other operational units, this role is carried out by investigating managers or review team members.

3.3.5 The clinical governance support team plays a key role in the management of adverse events:
• inputs and monitors all significant event reviews on Datix
• inputs action plans on Datix
• monitors and follows up actions
• shares lessons learned through NHS Highland, and
• provides training and ongoing support to all staff.

3.3.6 All incident investigation reports are monitored and reviewed at the clinical governance and risk management group specific to each of the operational units. These groups provide assurance that all systems, processes and procedures are in place to support the clinical governance and risk management strategy. The operational groups report four times a year to the clinical governance committee meeting, which the clinical directors from each of the operational units attend.

3.3.7 The nurse and medical director oversee all reports submitted to this committee and decide on whether the reports are tabled for discussion at the NHS Highland Board as part of the committee’s reporting structure.

3.3.8 Senior management, and the non-executive chair of the clinical governance committee, reported that the non-executive directors are kept fully up to date on the high level information of the significant adverse events within the NHS board.

3.3.9 During discussions with senior management, they told us that they had previously set up, and later disbanded, a clinical governance forum. This looked at all final incident reports and action plans in detail and existed as a forum so that clinical leads could discuss incidents across all areas within NHS Highland. The forum fed into the clinical governance committee with an overview report of all incidents and any specific details that required to be escalated to the committee. The NHS board is currently considering whether there is a need to re-establish the clinical governance forum to ensure a detailed overarching process to oversee significant event reviews across the NHS board.

3.3.10 All four cases selected for review had evidence of the event being discussed at the relevant governance committee. Minutes reviewed from NHS Highland’s governance committees demonstrated an assured oversight of the incident investigation process for significant events.

**Recommendation**

To ensure clear functions and roles, NHS Highland should:

6 clearly define roles and responsibilities for escalation and decision-making.
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 Highland uses Datix to report and record all incidents across all operational units. All incidents are reviewed by managers. However this system is not used consistently across all units to report and record significant adverse event reviews and to monitor associated investigations and action plans.

3.4.2 During discussion with staff, we were told that not all significant adverse events arise from incident reports. These may be identified from other sources such as complaints, Procurator Fiscal enquiries and mortality reviews.

3.4.3 The local systems for reporting and recording investigation and actions of significant adverse event reviews, across the four operational units were outlined:

- Argyll and Bute: most recorded on Datix
- North and West: recorded on an Excel spreadsheet saved on local drives
- South and Mid: recorded on a local database saved on a shared drive
- Raigmore: recorded on excel spreadsheets on a shared drive.

3.4.4 NHS Highland is moving towards all operational units reporting and recording investigations and actions plans related to significant adverse event reviews on Datix. The short life working group will lead on this piece of work supported by the clinical governance support team to ensure that all significant adverse events, however identified, are recorded on Datix.

3.4.5 Datix is easily accessible to staff on the NHS board’s intranet home page. For those who do not have readily available access, the incident management policy and procedures document outlines:

“NHS Highland recognises that not all staff will have easy access to a computer, accordingly it is the responsibility of each department which envisages a problem with access to ensure that they nominate an administrative person who can assist staff to report incidents via the DIF1, or who can input the information from a paper-based version.”

3.4.6 Datix is also used to record and monitor claims and complaints made to the NHS board. These sections of the system can be linked together if required.

3.4.7 Staff spoken with during the review visit reported that they saw the benefits of using the incident reporting system and subsequently learning from incidents. Discussions with senior management also echoed this positive attitude towards a learning and reporting culture.
3.4.8 The incident management policy and procedures document outlines “a summary of the actions taken following an incident review will be provided to the individual who reported the incident.” However, staff spoken with reported that feedback was not always provided to them in terms of how the incident was to be addressed and investigated following their initial report.

3.4.9 Members of the clinical governance support team demonstrated Datix to us. We were shown the reporting form which is open to all members of staff. This form features a variety of mandatory and non-mandatory fields, drop-down menus and prompts for each section to act as a guide for staff completing the form. We were also shown the reviewing form, access to which is restricted to ward, department and senior managers, where the grading and investigation of the incident occurs. The following have recently been added to the managers review form.

- decision-making: to record the rationale as to whether a significant event review is required. If the decision is taken not to progress to the review is taken, this must be recorded. If it has progressed, such information must be recorded:
  - chair
  - date of meeting review
  - date the draft report was circulated, and
  - date the draft report was approved.

- patient and family involvement: to record whether the patient or family have been informed about the incident and involved within the investigation as part of a mandatory field. Reasons for not involving the patient or family must be completed. When patients or families are involved, various details must be recorded:
  - how the patient or family member would like to be involved
  - date of the initial meeting
  - any issues raised to be addressed at the review meeting
  - method of feedback, and
  - date of feedback.

3.4.10 The clinical governance support team also described sections in Datix that have been developed, and are currently being refined, to address NHS Highland’s specific needs:

- action planning module: used to track actions created as part of an incident review
- safety alerts broadcasts: used to circulate internal alerts relating to incidents
- reports: allows managers to track progress of incidents and investigations in specific areas
- dashboards: creates visual overview of selected categories in relation to incidents, and
- coding of significant adverse events: to allow the tracking of actions and to identify themes and trends.
3.4.11 We were also shown the section restricted to those who are responsible for reviewing incident reports. This allows reviewers to “sense-check” all reports and can amend details or grading if necessary. However the original information will still be available to create an audit trail. This access-restricted section also allows the reviewers to use the data recorded to create reports and dashboards to monitor all incidents and investigations that they are responsible for or to report to various groups and committees.

3.4.12 Senior management reported that comments provided by the investigation team are considered and incorporated in the report if appropriate. We noted in one case that comments had been received following wider circulation to those involved in the incident. However, these agreed amendments did not appear to be included within the final report. Version control also did not appear to be consistent across case evidence reviewed.

3.4.13 Actions that are developed as part of the investigation reviews are monitored by way of a locally stored Excel spreadsheet or local database. As part of the planned Datix roll-out of the action planning module across NHS Highland, the clinical governance support team is working to upload all action plans to Datix to track the progress of all actions across the NHS board.

3.4.14 During discussions with both senior management and clinical governance staff, we were informed that all reports produced following an investigation within Raigmore Hospital are anonymised and uploaded to the NHS Highland intranet. This is done in the spirit of openness and transparency and to facilitate sharing learning. Staff reported that searching for reports on this page was difficult and time-consuming; however the short life working group is working to develop a more user-friendly system. They further reported that the NHS board plans to include the other operational units’ investigation reports on the intranet.

3.4.15 During the demonstration of Datix, we were informed that the clinical governance support team plans to save investigation documents on the system following consistent implementation across all operational units:

- staff statements
- timelines
- root cause analysis
- report, and
- action plan.

Recommendations
To support its information management processes, NHS Highland should:

7 introduce a process to ensure that staff make full use of Datix for significant event reviews, including its additional features, and consistently capture all documentation relating to each stage of the significant adverse event process, and

8 ensure that there is a single integrated approach to documentation management, monitoring, scrutiny and assurance across the NHS board.
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 incident management policy and procedures document states that all incidents, including near misses, must be reported on Datix. Examples of potential incidents are listed in the incident management policy and procedures document. The report should be completed by the person who was involved in the incident as soon as possible and no later than 24 hours after the incident.

3.5.2 Automatic notifications are then sent out to the appropriate managers. These managers are then responsible for reviewing the report and applying a grading to each incident which helps determine the level of investigation required. This is separate to the initial severity grading applied by the reporter.

Escalation of events

3.5.3 The critical incident report resource pack for managers includes an incident management flow chart which shows the steps to be followed immediately after an incident depending on the assigned grading:

- low: monitor for reoccurrence within ward department
- medium: review undertaken with ward department
- high: directorate/locality general manager or head of department considers escalation, directorate/locality manager is then responsible for ensuring a critical incident review is undertaken, this is then reported to the clinical governance group
- very high: directorate/locality general manager or head of department considers escalation, the directorate/locality general manager will inform the general manager/clinical head of clinical governance and risk management to ensure a serious untoward incident review is undertaken which is then reported to the clinical governance group.

3.5.4 The NHS Highland incident management policy and procedures document outlines the process of alerting key individuals during working-hours and out-of-hours. However, it does not outline how the nurse and medical directors are notified of an incident.

3.5.5 Following review of case information provided before the review visit, there did not appear to be a clear and consistent process across all four operational units to establish what type of review should be undertaken following an incident. However, the Raigmore Hospital quality and patient safety division standard operating procedure outlines four criteria for defining a significant adverse event as:

- an incident graded as high or very high
- an event that did or had the potential to cause serious harm to an individual or group of individuals (patients or staff)
- an unusual or extraordinary clinical event with or without an adverse outcome, or
• an event that may have reputational harm to the organisation.

Further information provided by the NHS board confirmed a lack of consistency when defining a significant adverse event. The NHS board stated that it is aware of the need to clarify which incidents constitute a significant event review to be held. The short life working group has been tasked with taking this forward.

3.5.6 During discussions with senior management, they told us that there are key people within the operational units who can request that a significant event review is carried out in light of an incident, these individuals are:

• associate medical director
• clinical directors, or
• lead nurse.

3.5.7 Staff reported that the decisions made to escalate to a full significant event review were reported on the appropriate database or spreadsheet used within the operational unit. Likewise, if the incident was not escalated, this is also recorded. This option is also available on the Datix system, but it was not clear how widely this was recorded in this way.

3.5.8 Our review of the minutes of the operational unit clinical governance and risk management meetings showed specific discussion of each of the four cases. Review of the clinical governance committee minutes also evidenced discussion and operational awareness of the incident management processes in general as well as discussion of significant event reviews.

3.5.9 During discussions with staff involved in the significant adverse reviews, they told us of the awareness of the local clinical governance and risk management group of the reports and associated action plans. Once submitted following approval of the review team, the group will often request amendments made to the documentation.

**Recommendation**

To support a risk-based, informed and transparent approach, NHS Highland should:

9 implement a system to ensure consistency in decision-making for undertaking significant adverse event reviews across the NHS board.
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 NHS Highland incident management policy and procedures states that incidents are to be reported as soon as possible after the event and no later than 24 hours after the incident. It also includes the timescales in which investigations and action plans are to be completed in relation to the incidents’ grading (see Figure 2):

**Figure 2: NHS Highland’s timescales for incident management**

<table>
<thead>
<tr>
<th>Incident grading</th>
<th>DIF1 completed</th>
<th>DIF2 review</th>
<th>DIF2 completion and approval/investigation</th>
<th>Action plan</th>
<th>Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>DIF1 to be completed within 24 hours of incident</td>
<td>DIF2 review and grading within 3 working days of incident being submitted</td>
<td>Manager to undertake review and approve within 10 working days of incident</td>
<td>Any learning points/improvement measures communicated and monitored at ward/department meetings</td>
<td>Monitored at ward/department level. Quarterly trend report to CG&amp;RM groups</td>
</tr>
<tr>
<td>Medium</td>
<td>DIF1 to be completed within 24 hours of incident</td>
<td>DIF2 review and grading within 3 working days of incident being submitted</td>
<td>Manager to undertake review and approve within 20 working days.</td>
<td>Any learning points/improvement measures communicated and monitored at ward/department meetings and where relevant shared with other areas</td>
<td>Directorate/locality general manager responsible for monitoring and ensuring action is taken. Quarterly trend report to CG&amp;RM groups. Outstanding actions to be followed up by final approvers within 1 month</td>
</tr>
<tr>
<td>High</td>
<td>DIF1 to be completed within 24 hours of incident</td>
<td>DIF2 review and grading within 30 working days of incident being submitted. This incident will include a root cause analysis</td>
<td>DGM/AGM or team to carry out a critical incident review. Manager to undertake review and approve within 30 working days.</td>
<td>Action plan to be prepared following critical incident review. Any learning points/improvement measures should be shared across the operational unit and other units where applicable.</td>
<td>Actions monitored through the CG&amp;RM groups and completed within 3 months.</td>
</tr>
<tr>
<td>Very high</td>
<td>DIF1 to be completed within 24 hours of incident</td>
<td>DIF2 review and grading within 40 working days of incident being submitted. This incident will include a root cause analysis</td>
<td>SUI review team convened within 3 working days. Interim report within 14 days. If SUI investigation team set up full report within 40 working days. Manager to undertake review and attach investigation and action plan within 40 working days.</td>
<td>Action plan to be prepared following SUI incident review. Any learning points/improvement measures should be shared across the operational unit and other units where applicable.</td>
<td>Actions monitored through the CG&amp;RM groups and completed within 6 months.</td>
</tr>
</tbody>
</table>
3.6.2 During our review of the four cases, it appeared that two were reported within the timescale set out in the policy and procedures as they were reported immediately following awareness of the incident. One case was linked to a complaint as a result of a previous incident which was reported within the 24-hour timescale. The final incident was recorded on Datix retrospectively.

3.6.3 Figure 2 shows that investigations graded as medium are to be completed within 20 working days, and those graded high are to be completed within 30 working days. Of the four cases reviewed, none of these met the assigned timescales set out in the incident management policy and procedures document.

3.6.4 Information provided before the review visit outlined that performance indicators are currently being developed to monitor the timeliness of review, investigation and closure of incidents.

**Action planning**

3.6.5 The NHS Highland incident management policy and procedures document states:

> “An action plan must be developed to address the concerns identified following the root cause analysis. The action plan must detail a timetable for action, responsible individuals and/or teams, and a schedule for review.

> “A summary of the actions taken following an incident review will be provided by the Local Manager to the individual who reported the incident and to those who were involved in the incident analysis. The summary will be prepared taking full account of duties with regard to confidentiality.”

3.6.6 Case evidence provided by the NHS board showed that action plans had been developed for each of the four cases. These featured:

- assigned action owner
- target date for completion
- status of action, and
- comments and updates.

3.6.7 Figure 2 shows that action plans developed during an incident review are to be completed within 3 months for incidents graded as medium and 6 months for the incidents graded as high.

3.6.8 Of the four cases reviewed, we were assured that all actions had been completed and implemented. However, this assurance was provided by the staff spoken with during the review visit. Action plans provided by the NHS board often stated that the actions were complete, but no dates were provided to confirm adherence to the timescales set out in the incident management policy and procedures document. Clinical governance staff told us that they have been developing the action planning module for significant event reviews in Datix as not all operational units are currently using this and are continuing to use their local systems for significant events reviews as they find these easier to use and navigate.
3.6.9 Individual actions are monitored by clinical leads who will contact the assigned action owners before the completion date to request updates or information on completion.

3.6.10 The clinical lead shares action plans with the appropriate operational unit clinical governance and risk management group. The clinical governance support team will then pull together a report of the incidents and action plans for the clinical governance committee.

Sharing of learning
3.6.11 The incident management policy and procedures states that the NHS board aims to ensure that:

“The knowledge thus gained is regularly disseminated to improve the performance of the organisation. This will encourage and strengthen a learning culture in which the quality of care for patients and working lives for staff will continuously be improved.”

It also states:

“The reporting of incidents and near misses will enable trends to be identified and reported throughout the organisation in order that appropriate action may be taken, learning disseminated and better quality services delivered.”

3.6.12 During discussions with staff and following review of evidence provided before the review visit, learning was reported to be shared across NHS Highland in various ways:

- safety alert briefings
- case studies shared on the clinical governance support team intranet page, and
- articles in team update
- publication of Raigmore incident reports on the NHS Highland intranet page
- distribution of guidance for using equipment
- discussion at various groups and meetings so that information can be shared verbally with staff
- dashboards, and
- reports.

3.6.13 We were also informed of future plans to develop sharing learning:

- distribute quality and improvement newsletter to staff six times a year which will:
  - highlight incident complaints and reviews
  - lessons learned, and
  - actions taken to address these findings.
- hold learning events involving all operational units to share learning from cases twice a year, and
- hold an annual all staff event to share lessons learned from adverse events.
3.6.14 Staff spoken with during the review reported that they were aware of occasions where learning points had been shared across wards, departments and the wider organisation. However, they were not confident that this was done consistently after each significant event.

3.6.15 The NHS Highland incident management policy and procedures document states:

“The comprehensive system of reporting and analysing incidents and near misses will result in the collection of considerable quantities of useful data. This information can be used to show trends, acting as an early warning system for both potential and realised problems. It can also provide timely information on possible future liabilities.”

These trends are monitored at local level by managers using Datix. Managers are encouraged to regularly share this information with their staff. Trends are reported to and discussed at the various clinical governance committees with corrective actions discussed as necessary.

3.6.16 Senior management and the clinical governance support team told about dashboards which are used as a method of depicting themes. These dashboards have been developed to show various strands of information useful for managing and raising awareness of adverse events.

3.6.17 During discussions with staff, it appeared that they were not aware of the availability of the thematic dashboards as staff mentioned that it would be useful to have an overview of incidents in graph or pictorial form.

3.6.18 NHS Highland recognised that this is an area to be developed and will be addressed within the remit of the short life working group.

**Recommendations**

To improve timely management, learning and dissemination following adverse events, NHS Highland should:

10 ensure the timescales for various stages of the adverse event review process are met in line with the incident management policy and procedures

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

12 ensure lessons learned from individual adverse events as well as thematic learning are captured, shared and implemented across the NHS board.
Appendix 1 – Details of review team

The review of NHS Highland was conducted on Wednesday 7 August 2013.

Review team members

Mark Aggleton
Senior Programme Manager, Healthcare Improvement Scotland

Nanisa Feilden
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Jamie Malcolm
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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.