Management of adverse events

Review Report | NHS Grampian

March 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 Grampian’s governance arrangements and processes for managing adverse events involved:

- an analysis of evidence provided by the NHS board, and
- a visit to NHS Grampian on Wednesday 30 January 2013.

We found that NHS Grampian is committed to continuously improving and developing its management processes and saw evidence of the many developments that have been implemented over the past 10 years. The NHS board had also developed an improvement plan to address the recommendations from *The Management of Significant Adverse Events in NHS Ayrshire & Arran* report and we noted this was due to be updated following further discussion in February 2013.

Our review identified the following areas of good practice within NHS Grampian:

- exemplary use of the information management system (Datix) which provides one integrated system for incidents, complaints risks and safety alerts
- an innovative project with the surgical team to improve the recording of adverse events and allow lessons to be identified and shared
- a well-developed formal education and training programme for adverse event management, and
- staff are generally engaged and positive about reporting adverse events.

We found that there are areas within NHS Grampian where the adverse incident management guidance is implemented. However, we were less assured that adverse events were managed consistently across the NHS board. We found further improvements could be made in relation to engagement with patients and families, open and transparent decision-making and system-wide learning following adverse event review. NHS Grampian has already identified these areas as challenges and is undertaking improvement work. The recommendations below aim to support this.
Recommendations

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

1. always consider involving patients and family in the review process to support investigation reporting and outcomes of adverse events, and demonstrate this occurs and is documented consistently
2. revise guidance documents to include more detail on notifying and engaging with patients and family, including explicit statements about the importance and benefits of stakeholder engagement, and
3. demonstrate that staff receive appropriate documentation and feedback following reporting or involvement in an adverse event.

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 Grampian should:

4. systematically monitor and record staff training, and assess the impact of training, to ensure staff have appropriate skills and knowledge.
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 Grampian should:

5 demonstrate that the clinical governance structure allows clear oversight and ownership of how adverse events are managed across the whole organisation.

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 Grampian should:

6 continue to develop and encourage staff to use Datix as a tool to support effective and consistent management of adverse events.

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 Grampian should:

7 consistently escalate events to appropriate governance groups across the organisation
8 demonstrate that the problem assessment group supports consistency across the organisation, and
9 improve the recording of decisions on Datix to support transparent and open decision-making.
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 Grampian should:

10 introduce a process to ensure that action plans are consistently created, monitored and completed across all areas in line with the guidance

11 implement a culture of capturing and sharing lessons learned across the organisation, supported by a system that provides evidence of discussions at meetings and through consistent feedback mechanisms to all relevant staff

12 monitor the number of cases meeting guidance timescales and ensure that all staff across the organisation use the same guidance and deadlines, and

13 strengthen their organisation-wide adverse event management policy, ensuring this provides appropriate guidance for staff for all aspects of the process, from reporting through to sharing learning, and demonstrate this policy is consistently implemented across all services within the NHS board.

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

We would like to thank NHS Grampian and in particular staff at Aberdeen Royal Infirmary for their assistance during the review.
1 Introduction

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.

1.2 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 NHS Scotland as a whole.

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

1.4 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.

1.5 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.

1.6 The review process has two key phases:
   • pre-visit analysis, and
   • the review visit.

Pre-visit analysis

1.7 We reviewed information provided by NHS Grampian 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 181 recorded significant adverse events over the past 18 months (of which 54 had undergone formal review), and
   • details of four specific significant adverse event reviews.

1.8 Of the 181 recorded significant adverse events, we selected four cases for detailed review. We did this by reviewing the high level summary of each of the 54 events which had
undergone a formal review, taking into account the location and specialty the event occurred within, and the level of investigation.

**Review visit**

1.9 The review visit took place on Wednesday 30 January 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).

1.10 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 discussed the initial findings of our report with NHS Grampian’s chief executive on 12 February 2013.

**Improvement plan**

1.11 We expect NHS Grampian 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.

1.12 We have asked NHS Grampian 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 Grampian’s adverse event management policies and procedures

2.1 NHS Grampian provides healthcare services to the north east of the country, covering the local government areas administered by Aberdeen City, Aberdeenshire and Moray councils. It has an annual budget of around £860 million and provides services to half a million people spread across urban and rural communities. Aberdeen Royal Infirmary is the largest hospital in NHS Grampian, while Dr Gray’s Hospital in Elgin is the main general hospital serving the Moray area. There are 17 community hospitals located in each of the main towns across the region. NHS Grampian includes three community health partnerships (CHPs) - Aberdeen City, Aberdeenshire and Moray.

2.2 NHS Grampian has processes and systems in place for the management of adverse events. Complaints and adverse events, whether clinical or non-clinical, require the same manner of investigation. Guidance documents state that appropriate investigation and follow-up of adverse events, near-misses and complaints increases an organisation’s knowledge of why these events happen and improves its capacity to prevent them happening again by sharing the outcomes of investigations. NHS Grampian also has a voicing concern policy which sets out its commitment to a ‘no blame’ culture.

Adverse event definitions

2.3 NHS Grampian uses the electronic reporting system, Datix, to record and categorise adverse events. The person reporting the event estimates the severity by selecting one of four gradings on Datix – low, medium, high and catastrophic.

2.4 NHS Grampian defines a significant adverse event as one graded high or above, or if it meets any of the following criteria:
   - a death, serious injury/illness, criminal act, major incident
   - a significant potential of death, serious injury/illness, major incident
   - likely media interest as a result of the incident, or
   - any incident that has to be reported under national legislation, such as to the Health and Safety Executive.

2.5 There are additional specific criteria in place which are used to define significant adverse events in maternity, mental health and child protection cases. For example, severe maternal morbidity, suicide or concerns about practice, communication or service delivery in children’s services. We noted that maternity, mental health and child protection services had their own specific procedures for handling adverse events.

2.6 Between February 2011 and end of July 2012, NHS Grampian recorded a total of 31,326 adverse events. The NHS board reported that 181 (0.58%) of these were categorised as significant adverse events. This included 23 child protection events, 112 events from within maternity services and 46 events from across the rest of the organisation.

2.7 The NHS board has identified the top six themes for significant adverse events as:
   - abusive, violent, disruptive or self-harming behaviour
   - delayed or failed diagnosis
   - accidents (including slips, trips, falls and exposure to blood)
   - implementation of care or ongoing monitoring (including infection control issues, inadequate pain management, delay in monitoring)
2.8 Data are also collated on specific key themes for significant adverse events within maternity, mental health, and child protection.

Policy for managing adverse events

2.9 NHS Grampian has the following policies, procedures and guidance in place for the management of adverse events:

- guidance on the investigation of complaints or incidents (June 2011) (hereafter referred to as the guidance)
- mental health services procedure for response to critical incidents (February 2011), and
- policy for risk management investigation in Aberdeen Maternity Hospital (no document date).

The NHS board also follows the North East of Scotland Child Protection Committee’s Initial and Significant Case Review Protocol (2008).

2.10 The guidance states that:

“NHS Grampian requires that all incidents resulting in actual harm or with the significant potential to have done so or is regarded as a near miss is recorded in the Risk Management Information System (Datix), including property damage or loss. This allows local management of the incident by managers who are also responsible for initiating an investigation and escalating or fast-tracking incidents to managers or to topic specialists, as appropriate.”

2.11 The guidance document was due to be formally reviewed in June 2012. NHS Grampian reported that it had begun revising the document in summer 2012. However, this was delayed to allow recommendations from the NHS Ayrshire & Arran review to be included.

2.12 At the time of the visit, NHS Grampian had developed a revised significant incident investigation flow chart (version 3, dated November 2012, pending final approval) which provides concise guidance on the roles, responsibilities, required actions and timescales for incident investigation. The revised flow chart strengthens management involvement in the adverse event process and includes timescales for each stage of the incident investigation.

2.13 The NHS board had also drafted an improvement plan in response to the recommendations set out in the NHS Ayrshire & Arran report. NHS Grampian reported that this was due to be discussed and agreed by the operational management team in February 2013.
Governance arrangements

2.14 An overview of the clinical governance arrangements within NHS Grampian is shown in Figure 1. This includes eight sector/service groups, which have their own clinical governance lead responsible for co-ordinating an integrated approach to clinical governance and quality improvement.

Figure 1: NHS Grampian clinical governance committee relationship to the Board and other committees
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 guidance provides information on involving key stakeholders in the investigation process. It states:

“It is expected that investigations are carried out with a high degree of confidentiality, however staff and patients involved in the incident should be kept well informed of any investigation and action. Guidance on ‘Being Open’ should be utilised in order to ensure that there is a consistent approach to engaging with patients.”

3.1.2 NHS Grampian reported that the lead investigator will agree with the investigation team who the key stakeholders will be. This will include staff involved in the incident, experts, patients and the family. The lead investigator and investigation team are responsible for providing feedback to patients and carers and involving them in the development of the action plan, where appropriate.

3.1.3 The incident investigation flow chart (version 2.1, dated June 2011) contained within the guidance document states:

“Patients and carers involved receive feedback and, where appropriate, input to the development of the action plan.”

3.1.4 However, we noted that the draft flow chart (version 3, dated November 2012) does not include any reference to patients, carers or family.

3.1.5 The mental health services procedure states:

“A difficult question will be whether and to what extent to involve family members. In some cases, Panel members may feel that relatives are a source of important information.... The decision about involvement of relatives and feedback on outcome will be very much influenced by the circumstances of the case. Panel members should exercise discretion on this issue and should seek the advice of clinicians who were responsible for the patient. If there is concern about the medico-legal implications of relatives’ involvement then advice should be sought from the Chair of the Mental health Clinical Governance Group and, if appropriate, the Scottish Health Service Central Legal Office. Provision should be made to offer feedback to families or carers following the review.”

3.1.6 Through discussions with staff, we identified that positive engagement with patients and families is taking place in certain areas. However, the guidance provides limited advice for staff on when and how to notify patients, family and carers of significant adverse incidents that affect them, or how to involve them in analysis of the event.
3.1.7 We did not see evidence of a process in place to reliably track and respond to issues raised by patients, families and carers as part of the adverse event management process, or a consistent mechanism for involving stakeholders in the incident investigation. Of the four cases we reviewed, only two documented some level of engagement with the family or relatives.

3.1.8 During the visit, mental health staff reported that they consistently involve the family, particularly in suicide reviews. The family would be invited to a meeting to discuss the incident and invited to take part in any investigation.

3.1.9 Within the maternity service, staff reported that the level of patient or family involvement varies depending on the nature of the incident. In serious instances, a letter is sent to the family offering to provide feedback. Otherwise, staff discuss issues with the patient and follow-up is provided by the community midwife or health visitor. Neonatal clinics are also in place where staff can engage with patients.

3.1.10 NHS Grampian recognises the need to strengthen its guidance and education for staff on engaging with patients and family. While there are pockets of good practice within NHS Grampian, a challenge remains for the NHS board to ensure all sectors consistently engage patients and families in the management of adverse events.

**Staff involvement**

3.1.11 NHS Grampian has been working to embed its vision statement of ‘caring, listening, improving’ across the organisation. This reflects the NHS board’s commitment to an open culture and is being supported through face to face meetings, patient safety walkrounds, regular meetings between executives and staff, and an ‘open door’ culture.

3.1.12 Any member of staff can enter information onto the electronic reporting system (Datix). The NHS board has tried to ensure the incident reporting form is easy to find by including a shortcut link to the form on its computers.

3.1.13 Staff we spoke with during the visit were knowledgeable about the adverse event management process and confident with reporting. We found that nursing staff were particularly committed to a reporting culture. Although we found medical staff were less engaged, we noted that development work is under way which has encouraged medical staff to report incidents.

3.1.14 The guidance states that:

“Support for undertaking investigations should be sought from management and Clinical Leads. Additional advice and support can be gained from Specialists e.g. Infection Control, Fire Safety. In addition Clinical Governance and Risk Management Unit staff can offer support if required, to areas during an investigation. This can be discussed by contacting the Clinical Governance and Risk Management Unit.”

3.1.15 On the visit, staff confirmed that they felt supported throughout the incident management process. Staff are aware of support available, including the services of the spiritual care team or occupational health counselling.
3.1.16 The maternity services procedure states:

“Individual feedback is sent to members of staff who have been involved in cases either to highlight good standards of care or areas where improvements could be made. For major incidents, or as requested by staff, informal debriefing sessions are arranged within a short time of an incident occurring as a supportive mechanism for those involved.”

3.1.17 The mental health services procedure provides guidance to staff on how incidents may affect them:

“Critical incidents, such as the death of a patient by suicide, are distressing to staff and may impair therapeutic effectiveness. At present, we have no formal system for providing support to members of staff who experience such events. It is important that we try to learn from such events in order to improve our therapeutic effectiveness... There appear to be three distinct phases which clinicians pass through in coming to terms with suicides.... Suicide is obviously a traumatic event for bereaved relatives and friends, and how the news is broken to them and the support they receive is of great importance in helping them cope with their bereavement. The management of such events should take account of the reactions of staff and relatives and is most likely to be effective if it addresses the specific needs of each phase.”

3.1.18 Of the four cases reviewed, one case had no documentation to demonstrate how staff were engaged in the adverse event management process. The other three cases showed limited involvement of staff, primarily around inviting them to interview, as part of the investigation. Only one of the cases documented support being offered to staff.

3.1.19 During the visit, staff confirmed that they received feedback following adverse incidents either through staff debriefs, the daily safety briefing or in team meetings. Staff reported that a feedback form is available to support team leaders and medical staff to communicate with staff.

3.1.20 We identified good practice where the performance reference group openly reviews the performance of medical staff to help share information and learning. Issues, including adverse events, are discussed in an anonymised format.

3.1.21 NHS Grampian recognises the need to consistently engage and inform staff within the incident management process and told us of the following planned actions:

- enhance the incident guidance around engaging with patients, families and carers
- use resources such as the National Patient Safety Agency guidance ‘Being Open: Communicating Patient Safety Incidents with Patients and their Carers’ (2009), and the Institute for Healthcare Improvement ‘Respectful management of adverse incidents’ paper to help inform training
- develop resources for patients and families
- develop a method for recording communication with patients and families within Datix
- incorporate learning from patients and families into education, and
- consider use of patient stories.
**Recommendations**

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

1. always consider involving patients and family in the review process to support investigation reporting and outcomes of adverse events, and demonstrate this occurs and is documented consistently
2. revise guidance documents to include more detail on notifying and engaging with patients and family, including explicit statements about the importance and benefits of stakeholder engagement, and
3. demonstrate that staff receive appropriate documentation and feedback following reporting or involvement in an adverse event.

**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 NHS Grampian has developed a range of training programmes relating to the management of adverse events. The NHS board reported that it has provided a 1-day incident investigation course for staff since 2003. This was supplemented with a 1-day root cause analysis course in 2006, after a number of staff received training from the National Patient Safety Agency. This is delivered to clinical leads, unit and service managers, and senior nurses.

3.2.2 The NHS board works with Aberdeen City Council’s Department of Social Care to deliver training programmes for child protection staff. NHS Grampian staff also work with the University of Aberdeen to deliver a risk module to medical students, featuring clinical scenarios, Datix reporting, the investigation process and learning from incidents.

3.2.3 NHS Grampian reported that it currently provides the following training for staff on incident reporting and investigation:

- core and clinical induction programmes
- managing safely course
- 1-day incident investigation course
- 1-day root cause analysis course
- multi-agency root cause analysis training
- undergraduate medical students patient safety module
- final year medical students 1-day programme
- quality, governance and risk unit support, and
- an annual GP trainee session on clinical governance.
3.2.4 The NHS board informed us that it also provides training on:

- complaints handling
- person-centred care
- Datix reporting
- acute sector investigation workshops, and
- suicide reporting.

3.2.5 All staff spoken with during the visit confirmed they had received training on the use of the electronic reporting system, Datix. The NHS Grampian ‘AT learning’ system captures staff attendance on training courses. This system is linked with staff performance and development plans. It is not mandatory for staff to attend training on how to use AT learning. However, the system is being rolled out to managers to allow them to monitor the status of staff training.

3.2.6 NHS Grampian provides a range of information and tools on the intranet to support staff following an incident. This includes:

- guidance, handbooks and flow charts to support the use of Datix
- guidance on completing statements about the event
- investigation roles and responsibilities, and
- investigation tools and templates.

3.2.7 During the visit, staff reported that adverse incident investigations involved at least some members of staff trained in root cause analysis. They also reported good support from clinical governance staff who are trained in root cause analysis. NHS Grampian informed us that it is currently reviewing the number of staff trained in incident investigation to ensure there is a good spread of skills across all sectors. NHS Grampian has also introduced mandatory child protection training courses. Staff are required to attend this training every 3 years. NHS Grampian reported that it is also collating a training directory to encourage training in significant adverse incidents for health visitors and GPs.

3.2.8 We noted that NHS Grampian has a well-developed formal education and training programme in place. However, to further enhance staff knowledge and training, the NHS board told us of its future plans to:

- undertake a review of all staff trained in root cause analysis and maintain a comprehensive list of personnel who can carry out investigations
- enhance the use of structured debriefs for staff and include a structured process within the incident guidance
- further support staff to carry out structured debriefs, and
- work with stress management, human resources and occupational health and safety colleagues to enhance support available for staff.
Recommendation
To support staff knowledge and training, NHS Grampian should:

4 systematically monitor and record staff training, and assess the impact of training, to ensure staff have appropriate skills and knowledge.

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 incident investigation flow chart contained in the guidance details roles and responsibilities of staff. The flow chart outlines the responsibility of the senior manager or lead clinician to inform the general manager and clinical governance lead of the incident and action being taken.

3.3.2 The information management system provides automatic email alerts to executives, general managers, senior managers and clinicians as significant incidents are reported. General managers are responsible for reviewing significant incidents within their area and ensuring incidents are being managed appropriately and recorded on the system. A monthly meeting takes place to review all significant incidents, including clinical and non-clinical, from across the organisation. This is attended by the chief operating officer, director of nursing and quality, director of workforce, and head of quality, governance and risk.

3.3.3 Feedback is provided to general managers after this meeting and general managers are responsible for seeking assurance that lessons are being learned and action is taken. We were told incidents continue to be reviewed at the monthly meeting until there is evidence of appropriate management and learning.

3.3.4 One of the cases we reviewed concerned child protection. Since the incident occurred, and in response to a trend of similar issues, NHS Grampian introduced several improvements to roles and responsibilities within child protection. For example, any concerns or issues involving child protection are now discussed with a paediatric consultant in Aberdeen.

3.3.5 NHS Grampian provided evidence of a clinical governance statement of intent (2008) which clearly describes that the chief executive, supported by the medical and nursing directors, is responsible for implementing effective clinical governance arrangements through the existing management structure.

3.3.6 The director of nursing and quality is responsible for clinical governance, supported by the head of quality, governance and risk, and the professional lead for governance. The eight clinical governance leads are supported by the clinical governance co-ordinators and are professionally accountable to their sector leads.
3.3.7 During the visit, we spoke with the chair of the clinical governance committee, a non-executive director of the Board. He told us that the clinical governance committee has a responsibility to assure the Board of the effectiveness of clinical governance and clinical service arrangements across NHS Grampian. This includes assurance of action taken to address areas of significant clinical risk. The committee also has a role to ensure that processes support the systematic reporting of incidents and near misses to help identify trends and learning, and minimise the risk of them happening again.

3.3.8 A number of sector/service groups and committees report to the clinical governance committee as shown in Figure 1 on page 12.

3.3.9 NHS Grampian reported that in addition to the clinical governance committee, the staff governance committee also regularly reviews incident data, focusing on trends and improvements. The staff governance committee has oversight of relevant risks on the organisation’s risk register and advises the Board on policy, targets and organisational effectiveness.

3.3.10 Each year, NHS Grampian reviews its sector clinical governance arrangements to examine the effectiveness of governance processes. The 2011-2012 review identified that:

“The majority of groups perform very well, know their remit and have a good level of awareness of how they connect into other parts of the framework.”

3.3.11 However, the review identified a number of ongoing challenges for clinical groups, including consistent escalation and discussion of high and catastrophic incidents, and staff engagement.

3.3.12 NHS Grampian acknowledges that it would be useful to clarify the role of the existing governance groups in the management of adverse events. We noted that the NHS board needs to be able to demonstrate that the Board clinical governance committee has oversight of how adverse events are managed across the whole organisation. NHS Grampian reported that the clinical governance committee held a development session in 2012 and that this work is ongoing.

**Recommendation**

To ensure clear functions and roles, NHS Grampian should:

5 demonstrate that the clinical governance structure allows clear oversight and ownership of how adverse events are managed across the whole organisation.
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 In 2005, NHS Grampian introduced the electronic system Datix to replace a paper-based system for reporting adverse incidents. The NHS board was an early pioneer of Datix and is considered to be an ‘exemplar user’ by the Datix provider. NHS Grampian uses a variety of modules on Datix including incidents, complaints, risks, safety alerts, claims and requests for information.

3.4.2 At the time of the visit, a project was under way to extend the use of Datix to independent GPs within Grampian. Six GP practices were identified to take part, two in each CHP area. Two practices have already been trained and are using the system. A further two practices were due to implement the system in February 2013. NHS Grampian reported plans to evaluate the pilot and an intention to ultimately engage all GP practices in the use of Datix. This will allow themes and learning to be identified across primary and secondary care.

3.4.3 NHS Grampian hopes to extend the availability of Datix to independent dentists and community pharmacy contractors in the future. The NHS board reported that any adverse event involving a community pharmacy is currently entered onto Datix within the relevant CHP or acute sector, and investigated as necessary.

3.4.4 Any member of staff can access Datix through the NHS Grampian website. Maternity staff informed us that a paper-based reporting form is also available for staff who would rather report anonymously. All incidents are ultimately recorded on Datix which provides an audit trail of emails sent through the system, who uploaded documentation and who made changes to records. All communication in and out of the system is time and date stamped. Datix also allows for staff to input actions on the system and work is under way to expand this function.

3.4.5 Through discussions with staff, we observed a positive attitude towards reporting adverse events on Datix, particularly among nursing staff. The NHS board provided evidence that incident reporting had steadily increased since the introduction of Datix. In 2012, 22,500 incidents were reported compared to 15,000 incidents in 2007. NHS Grampian reported that it also monitors the number of incidents resulting in patient harm and that the percentage of incidents involving harm had not been increasing.

3.4.6 Staff informed us that medical staff are less likely to record adverse events on Datix and relied on nursing staff to record the event. We met with members of the surgical team who have recently developed an anonymous reporting system to encourage medical staff to use Datix. This involved adapting the Datix incident form to make it more relevant for medical staff and to reduce the time required to report incidents.

3.4.7 This project was undertaken in collaboration with the quality informatics team, general surgery and the Scottish Patient Safety Programme (SPSP) manager. Staff reported that this approach has helped to remove barriers to medical staff reporting incidents, has resulted in a significant rise in the number of incidents recorded and allowed lessons to
be identified and shared. Although surgical staff use the Datix management system, we noted that these events are processed separately to the majority of incidents. Care needs to be taken that all information systems are integrated and that a consistent adverse event management process is adhered to across the organisation.

3.4.8 The guidance includes references to storing documentation relating to adverse incidents on Datix:

“All relevant information relating to the investigation process should be stored in Datix, enabling secure and confidential storage. A summary of the lessons learned and actions taken should be added directly to the investigation section. Individual actions should be added to the action plan section, where they can be monitored. Other relevant documents such as reports can also be uploaded. Assistance with uploading of relevant documents can be provided by the Quality Informatics (Datix) Team. It is not necessary to upload statements onto Datix as the report should capture information from these that is relevant to the investigation. However it is good practice to record on the system where these statements can be obtained from.”

3.4.9 NHS Grampian reported that it has been encouraging staff over the last 6 months to use Datix as a sole repository for incident and investigation documentation. Staff we spoke with reported that they usually upload relevant documents onto Datix, including investigation reports. We saw evidence of dates and version control used on adverse incident documentation. Staff reported that the use of templates and version control on relevant documents has been improving over time. Staff also reported an open culture of sharing information held on Datix with other staff, where appropriate.

3.4.10 In three of the four cases we reviewed, we saw evidence of information uploaded onto Datix and automatic email alerts sent to staff on the progress of the review. However, we did not see a consistent process for sharing progress updates with staff.

3.4.11 Staff can access reports from Datix which show the number of incidents reported by the type of event such as patient falls, medication or security. Staff can also use Datix to view ‘live’ charts showing relevant adverse incidents, referred to as a ‘dashboard’, to help identify trends in local areas.

3.4.12 The quality informatics team can use Datix to analyse all incidents across the organisation. This allows system-wide trends to be identified, for example highlighting issues affecting particular groups of patients. Reports are provided on a regular basis to the clinical governance committee.

3.4.13 We commend NHS Grampian for its innovative use of Datix to provide one integrated system for complaints, incidents and risks. However, we identified a need to ensure information is consistently stored within Datix across the organisation.

3.4.14 NHS Grampian informed us their future plans include:

- enhancing the use of the action planning and task generating functions of Datix
- recording the involvement of patients and family on Datix, and
- ensuring all leads and managers are aware of the guidance and use Datix as an information system.
Recommendation
To support its information management processes, NHS Grampian should:

6 continue to develop and encourage staff to use Datix as a tool to support effective and consistent management of adverse events.

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 NHS Grampian reported that it does not distinguish between clinical and non-clinical incidents and that the guidance supports staff to assess the severity of the incident.

3.5.2 The guidance states that:
“The severity grading is recorded by the incident reporter at the time of reporting the incident on Datix given the knowledge they have at that time, and is then reviewed by the manager. If the severity grading remains high or above when reviewed by the manager, a formal investigation must be carried out.”

3.5.3 NHS Grampian reported that the risk advisor for patient safety reviews the grading of significant adverse events. The advisor reports changes in grading to the chief operating officer, director of nursing and quality, and head of quality governance and risk, as part of the monthly significant adverse events review meeting.

3.5.4 The guidance advises that events meeting the NHS Grampian significant adverse event criteria, such as accidental death or those reportable under national legislation, should be formally investigated. NHS Grampian reported that managers can also decide to initiate investigations or further action for incidents graded low or medium.

3.5.5 However, following our review of evidence, we noted that only 54 significant adverse events were listed as being formally investigated, and 17 reviewed locally, out of the total 181 recorded over the 18-month period analysed.

Escalation of events
3.5.6 The guidance states that:
“Significant incidents or complaints that involve more than one sector or other agencies should be escalated to senior management (i.e. General Manager, Lead Nurse, Medical Director/Nursing Director, Chief Operating Officer or Head of Health and Safety) for the identification of a lead investigator.”

3.5.7 NHS Grampian reported that incidents graded as high or catastrophic on Datix or that require external reporting, trigger an email notification to the general manager of the area where the incident occurred. An email is also sent to the chief operating officer, the director of nursing and quality, and the head of the quality, governance and risk management unit, for information. NHS Grampian told us that incidents graded as high
or catastrophic remain ‘live’ on Datix until these senior managers are assured that the incidents have been fully investigated and actioned.

3.5.8 We saw evidence of a separate ‘management escalation policy’ flow chart for obstetrics, gynaecology and neonatology. This documents which individuals should be contacted for specified incidents such as patient death, major civil incident, baby abduction, severe injury, and staffing issues affecting patient safety.

3.5.9 The NHS board reported a systematic approach in place for escalating issues on medication safety. A medication safety officer analyses medication-related data on Datix and escalates issues to the medication safety committee and clinical governance committee where necessary. The process includes links to universities, primary care and the acute sector in order to share learning.

3.5.10 The NHS Grampian draft incident flow chart proposes that a problem assessment group will meet within 12 hours of a significant incident occurring. Group membership will include a general manager and either a lead clinician or senior manager. The group is tasked with reviewing significant incidents, determining whether an investigation is required, appointing a lead investigator and agreeing timescales for the final report. Staff reported that the problem assessment group could be used to check consistency of decision-making using comparable cases.

3.5.11 Staff informed us that they do not necessarily record decisions that have been made, but acknowledged that Datix would be a good place to do this. We noted that this would support an open and transparent decision-making process.

3.5.12 Evidence provided for the four cases demonstrated that each case was discussed at a risk management or clinical governance meeting. Our review of meeting minutes also revealed that incidents are escalated for discussion at clinical governance groups. We saw evidence of a robust and consistent process used by the Moray sector and acute sector clinical governance groups. This included escalating key concerns to the Board clinical governance group through standardised sector reports. We were told this process was used across the organisation.

3.5.13 The NHS board also reported that 6-monthly reports combining complaints, claims and incidents have been provided to the clinical governance committee since May 2011 in order to inform decision-making.

3.5.14 NHS Grampian told us of its plans to:

- record decision-making on Datix
- review the email notification process for high and catastrophic incidents in line with the escalation processes, and
- undertake development work with management and governance groups including the clinical governance committee and the staff governance committee.
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 guidance states:

“It is recommended that investigations should be initiated as soon as possible, within 5 working days from the reporting of the incident. In-depth investigations can take some time to complete and setting of appropriate deadlines is essential to ensure that all vital information is gathered. It is expected that the majority of investigations will be completed within 30 days. If it is not possible to complete an incident investigation within this timeframe, regular ‘progress reports’ should be provided to the Sector/CHP/Directorate Management Team and the Clinical Governance Lead.”

3.6.2 Additionally, the incident escalation and case review flow chart identifies timescales for incident reporting and investigation within maternity services. This outlines that notes should be reviewed by a multi-professional team within 72 hours, and a follow-up review with recommendations and actions should be produced within 3 weeks.

3.6.3 Of the four cases we reviewed, three met the timescales specified by the guidance for starting an investigation. The investigation of the fourth case appeared to start 2 months after the initial incident report. However, the evidence demonstrates that ongoing case discussions were taking place in advance of the formal investigation.

3.6.4 Of the three cases we reviewed that had a formal investigation, none of them met the timescale for completion of the investigation within 30 days.

3.6.5 In November 2012, NHS Grampian developed a revised significant incident investigation flow chart (version 3, dated November 2012, pending final approval). The revised flow chart includes timelines for each stage of the process. Staff are required to report a significant incident to a senior manager within 2 hours of the incident happening and to record it on Datix before the end of the shift. The problem assessment group is required to meet within 12 hours of the incident to review the incident risk grading and determine whether an investigation is required. Any investigation should commence within 48 hours of the incident happening.
Action planning and sharing of learning

3.6.6 The investigation flow chart states that the investigation team will ensure “staff are involved in identifying the learning points and developing the action plan.”

3.6.7 NHS Grampian reported that monitoring the progress of actions is primarily part of the management and approval process. General managers are responsible for monitoring the progress of actions.

3.6.8 Of the four cases we reviewed, we only saw evidence of a formal action plan in place for one of the cases. Another two cases had actions included on the Datix record, but it was not clear whether these were the only actions required. We noted there were plans to enhance the use of the action planning function in Datix.

3.6.9 The guidance states:

“The lead investigator must report findings back to the relevant management team, including the person who commissioned the investigation. This includes Service/Sector/Directorate Management Team. A report may also be required for submission to the relevant Sector Clinical Governance Groups and/or Health and Safety Committees to facilitate the sharing of transferable lessons.”

3.6.10 NHS Grampian provided evidence that learning points are shared across primary care. The ‘Significant Event Learning Points – Aberdeenshire July 2012’ report collates the learning points from the significant event analyses carried out in GPs across Aberdeenshire. This has been shared with all GP practices and is a comprehensive summary of the event and subsequent actions taken.

3.6.11 Within maternity, the risk management midwife reviews data input to Datix. Relevant data and required actions are included in the risk management report for discussion at the monthly multidisciplinary risk management group. Staff informed us that the report is cascaded to all medical staff, gynaecologists, obstetric staff, supervisor of midwives, and university teams and lecturers (for student training) to share learning.

3.6.12 On the visit, staff reported that the chairs of the sector clinical governance committees meet individually with sector management staff to share information and encourage learning from adverse incidents.

3.6.13 NHS Grampian acknowledges the lack of a co-ordinated organisational process for sharing learning from incidents or risk at a local level. However, the NHS board currently has the following mechanisms in place to support the sharing of learning:

- circulation of risk management reports across the service
- shared learning notices distributed through the safety alerts broadcast system (a function of Datix)
- ‘quality matters’ staff newsletter produced by the quality, governance and risk unit
- discussion of key points at clinical meetings
- learning in local or established training sessions, such as study days
- including recommendations in work plans, and
- adapting training and guidance.
3.6.14 However, we saw some evidence that thematic learning does happen. For example, NHS Grampian reviewed a number of incidents where blood samples had been incorrectly labeled. In each case, the error was detected before it could have resulted in an adverse event. Following analysis of the incidents, NHS Grampian issued a risk control notice across the organisation to raise awareness of the issue and remind staff of the correct procedure to follow.

3.6.15 For the four cases that we reviewed, we saw some evidence of learning being shared following the investigation. However, there is no consistent mechanism for system-wide action planning to take forward learning and improvements from adverse events across the whole organisation.

3.6.16 The NHS board told us of their future plans:

- to work with each sector general manager to implement systems for overseeing incident processes and reporting
- for senior managers to attend the delivery unit to reinforce guidance and timelines, and report on progress
- to extract thematic learning and incorporate this into reports and newsletters
- to continue to implement the use of sharing learning notices
- to continue developmental work using Datix for mortality and morbidity meetings
- to take the quality dashboard to the NHS Grampian Board, and
- for the acute sector to include learning from incidents within the quality portfolios.

**Recommendations**

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

10 introduce a process to ensure that action plans are consistently created, monitored and completed across all areas in line with the guidance

11 implement a culture of capturing and sharing lessons learned across the organisation, supported by a system that provides evidence of discussions at meetings and through consistent feedback mechanisms to all relevant staff

12 monitor the number of cases meeting guidance timescales and ensure that all staff across the organisation use the same guidance and deadlines, and

13 strengthen their organisation-wide adverse event management policy, ensuring this provides appropriate guidance for staff for all aspects of the process, from reporting through to sharing learning, and demonstrate this policy is consistently implemented across all services within the NHS board.
Appendix 1 – Details of review team

The review of NHS Grampian was conducted on Wednesday 30 January 2013.

Review team members

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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.