Management of adverse events

Review Report | NHS Fife
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 Fife’s governance arrangements and processes for managing adverse events involved:

- an analysis of evidence provided by the NHS board, and
- a visit to NHS Fife on Thursday 6 December 2012.

Through our review of documentation and interviews with staff, we noted that NHS Fife has been working to improve how it manages adverse events. This included changes to systems and documentation, improved reporting, increased support for staff and a focus on using improvement methodologies to drive forward improvement.

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

- a clear, responsive and accountable governance structure
- an ‘open door’ culture where senior staff are available to support staff in the adverse event management process
- evidence of positive engagement by frontline staff in reporting adverse events, and
- an overarching ‘reducing harm’ action plan that identifies and brings together themes and actions, including those identified through adverse events, from across the organisation.

The NHS Fife incident management policy states that:

“NHS Fife endorses the view, within its incident management policy, that organisations with effective systems for reporting, reviewing and learning from adverse events, are more able to respond to improve quality of care and patient and staff safety. This can best be achieved if the culture of the organisation is open, supportive, non-threatening and just.”

At the time of the visit, NHS Fife had drafted a revised incident management policy. The document was written to reflect the recommendations from the NHS Ayrshire & Arran report.
and the Institute for Healthcare Improvement (IHI) paper: *Respectful Management of Adverse Incidents.*

Our review identified areas that NHS Fife should improve to ensure arrangements in practice match the revised incident management policy and procedures. This will help ensure that the policy is consistently applied across the NHS board.

**Recommendations**

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

1. always consider notifying patients, family and carers of adverse events that affect them and informing them of the outcomes, and demonstrate this occurs and is documented consistently

2. always consider involving patients and family in the review process and capture their feedback to support investigation reporting and outcomes of adverse events, and demonstrate this occurs and is documented consistently

3. include a process to track and respond to issues raised by patients, families and carers, and

4. develop a process to consistently involve and support relevant staff and provide them with appropriate documentation and feedback to meet their needs.

**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 Fife should:

5. implement the revised policy and develop a process to monitor the effectiveness of training. This should include support for staff to take forward actions, and include specific targets for improving over time.
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 Fife should:

6 embed the role of the new quality, safety and governance group in line with the group’s remit.

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 Fife should:

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

8 ensure that staff include dates and version control on all relevant documents to allow the NHS board to track progress 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 Fife should:

9 include more detailed guidance within the revised policy and Datix to help staff determine the severity of the adverse event, and

10 implement a system to ensure staff use consistent templates for recording incident investigations.
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 Fife should:

11 implement the revised policy and monitor investigations to ensure they are being carried out in line with the policy deadlines

12 introduce a system to monitor action plans and progress updates on Datix to ensure that actions are implemented, and

13 embed 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 relevant staff.

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

We would like to thank NHS Fife and in particular all staff at the Victoria Hospital, Kirkcaldy, 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 Fife 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 81 recorded significant adverse events over the past 18 months, and
• details of four specific significant adverse event reviews.

1.1.8 Of the 81 recorded significant adverse events, we selected four cases for detailed review.
We did this by reviewing the high level summary of each case, taking into the location and specialty of the event and the level of investigation.

**Review visit**

1.1.9 The review visit took place on Thursday 6 December 2012. 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. The chief executive of NHS Fife was interviewed on 13 December 2012, as he was unable to attend on the day of the visit.

1.1.11 We discussed the initial findings of our report with NHS Fife’s chief executive on 10 January 2013.

**Improvement plan**

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

2.1.1 NHS Fife provides healthcare to a population of around 364,000 people, accounting for 7% of the Scottish population. The NHS board currently has two main acute hospitals, the Victoria Hospital, Kirkcaldy, and Queen Margaret Hospital, Dunfermline. Following the opening of a new wing in January 2012, the Victoria Hospital now provides all acute services for NHS Fife. At the time of the visit, work was under way to transform the Queen Margaret Hospital into a diagnostic and treatment centre. NHS Fife also has a network of eight community hospitals and eight day hospitals located across Fife. Three community health partnerships (CHPs) are responsible for delivering local, community-based healthcare:

- Dunfermline & West Fife CHP (population covered 139,407)
- Kirkcaldy & Levenmouth CHP (population covered 96,894), and
- Glenrothes & North East Fife CHP (population covered 127,284).

Adverse event definitions

2.1.2 The policy describes an adverse event as follows:

“The term ‘incident’ includes personal accident, clinical incident, violence / abuse / harassment, ill health, near miss, medication or blood transfusion incident. An incident is defined as any event or circumstance arising during NHS Scotland care or service provision that could have or did lead to unintended or unexpected harm, loss or damage.”

2.1.3 NHS Fife defines significant adverse events as extreme or ‘red’ events as graded against the categories in the risk matrix. The policy defines a red event as:

“A situation or event which may produce significant public, legal, media or other interest, that has resulted in loss of life or loss of the organisation’s reputation or assets or which if not managed effectively may do so.”

2.1.4 As of September 2012, NHS Fife had recorded 15,255 adverse events over a period of 18 months. The NHS board reported that 81 of these (0.5%) were categorised as significant adverse events and had either been investigated or were in the process of being reviewed.

2.1.5 NHS Fife has identified the top five themes for significant adverse events as:

- patient falls
- clinical incidents
- neonatal incidents
- personal accident, and
- violence and aggression.
**Policy for managing adverse events**

2.1.6 NHS Fife has an incident management policy (implemented in July 2008, with a review date of June 2010). This document is hereafter referred to as ‘the policy’. It provides guidance on the incident reporting and investigation process, roles and responsibilities of those involved and expected timescales.

2.1.7 We reviewed the policy and analysed the information and evidence provided by NHS Fife. This helped us to identify areas of improvement needed to meet the recommendations set out in the NHS Ayrshire & Arran report.

2.1.8 The policy states that:

“NHS Fife endorses the view that organisations with effective systems for reporting, reviewing and learning from adverse events, are more able to respond to improve quality of care and patient and staff safety. This can best be achieved if the culture of the organisation is open, supportive, non-threatening and just. This policy provides a framework for incident management across NHS Fife. It is designed to encourage staff to report incidents and near misses with the assurance that these will be reviewed, analysed and the knowledge gained disseminated in the interests of improving safety.”

2.1.9 The policy guides staff to complete a reporting form for all adverse incidents or near misses. Staff are required to grade all incidents using the NHS Fife risk assessment matrix. The severity of the immediate impact of the event and the level of identified future risk informs what level of action, incident review and analysis should be undertaken. Staff we spoke with on the visit were aware of the policy and knew where to find it.

2.1.10 The policy contains guidance on how to use the risk assessment matrix to determine future risk. However, we noted that the policy does not include guidance on how to determine the severity of the incident. NHS Fife reported that it plans to clarify definitions and terminology used in the policy to provide clearer guidance to staff.

2.1.11 NHS Fife has been using the electronic reporting system, Datix, since 2006 to capture information on adverse events. At the time of the visit, NHS Fife was using both a web-based Datix system and a paper-based form to report incidents. Incidents reported on paper would subsequently be added to Datix. The Datix system is used across acute and community services in the NHS board area. Staff reported that they used Datix and were aware of the value of recording adverse events and near misses.

2.1.12 At the time of the visit, NHS Fife had drafted a revised incident management policy. The document was written to reflect the recommendations from the NHS Ayrshire & Arran Report and the Institute for Healthcare Improvement paper: *Respectful Management of Adverse Incidents*. NHS Fife reported that it hopes to agree the revised policy by the end of March 2013 and to implement it across the NHS board area by June 2013. The NHS board intends to promote the revised policy through the intranet and staff communications supported by staff engagement sessions.

2.1.13 The revised policy aims to ensure that all adverse events and near misses in NHS Fife are:

- identified and reported in a timely manner
• managed in partnership with patients, families, carers, staff, staff side and partnership representatives investigated appropriately, and
• learned from in a way that supports safety and improvement in line with recognised standards of good practice, and reduces risk and harm.

2.1.14 The revised policy was discussed at the quality, safety and governance group meeting on 18 October 2012. NHS Fife reported that the quality, safety and governance group will be responsible for ensuring the delivery of the revised policy.

Governance arrangements

2.1.15 Figure 1 on page 12 outlines the current governance arrangements in place for the management of adverse events. Each department within NHS Fife reviews reported incidents, monitors actions taken and participates in regular discussion of incidents at the appropriate clinical governance and risk management group meetings. The core risk management group provides annual and 6-monthly anonymised incident reports to the clinical governance committees and other NHS Fife groups where appropriate, including the Board.
Figure 1: NHS Fife 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 current policy outlines the involvement of patients, carers or relatives affected by the adverse incident:

“For incidents/near misses involving patients, the patient should be informed that they have been involved in an incident and supportive explanation and advice offered as necessary. Incidents will normally only be disclosed to patients next of kin/carers with the patient’s explicit consent. In the case of particular patient groups e.g. children, ventilated patients or vulnerable adults, this may not be possible. At all times patients and relatives must be notified before the media and the media should never be notified about an incident without the patient’s explicit consent.”

3.1.2 NHS Fife provided evidence of a detailed guidance document for staff entitled ‘Being open when things go wrong’. This document is based on the National Patient Safety Agency guidance: *Being Open: Communicating Patient Safety Incidents with Patients and their Carers* (2009). The guidance aims to ensure that when things go wrong, staff communicate effectively with patients, carers and other service users in a clear, timely and honest manner. The document states:

“This policy aims to ensure that staff communicate effectively with service users and carers when things go wrong. Promoting a culture of being open is a pre-requisite to improving service user safety and the quality of healthcare systems. The over-riding principle is that NHS Fife will be open with service users and carers unless there is a valid reason not to. This would include a situation where, after full discussion and consideration, it is considered that it would be more harmful to be open. When deciding whether or not to share all the information, staff must discuss the issues with their line manager.”

3.1.3 We noted that the document did not include a creation date or version control, although it had a review date of December 2012. Also the document was not attached to the existing incident management policy or listed as a linked document. However, the document is now referenced and linked within the revised incident management policy.

3.1.4 The ‘Being open when things go wrong’ document includes a commitment from NHS Fife to learn from events following feedback from service users and carers:

“NHS Fife is an organisation that seeks to learn from events and to continuously improve its practice. Therefore, it is vital that the organisation learns from the information and feedback given by service users and their carers and from staff when things go wrong. Through its participation in the Scottish Service User
Safety Programme and its commitment to service user focus and public involvement, NHS Fife seeks to minimise and manage the risks associated with the delivery of healthcare and to learn from things that go wrong. In this way, we can develop safer services and improve the quality of the care we deliver.”

3.1.5 We were unable to identify from the policy how NHS Fife actually involves patients, family or carers in investigations of adverse events. We analysed the documents provided for the four cases selected for detailed review. In two of the four cases, there was no evidence of communication with the family or carers in the adverse event management process. Overall, we identified a lack of consistency in how NHS Fife engages with patients, family, or carers.

3.1.6 NHS Fife does not have a current system to reliably track and respond to issues raised by patients, families and carers. This is listed as one of NHS Fife’s planned improvements. The NHS board acknowledges that it needs to improve how it involves family, relatives and carers in the adverse event process. Staff reported that they are increasingly trying to engage family, relatives or carers early in the process. This includes asking them if they have particular issues and offering to share investigations reports with them. The family would be provided with an anonymised version of the report and offered a copy of the original version if required. The NHS board reported that there are occasions where it may not be appropriate to engage stakeholders at certain stages in the process, such as a grieving family.

3.1.7 NHS Fife reported that it is working to embed the ‘Being open when things go wrong’ document to make it systematic throughout the organisation.

**Staff involvement**

3.1.8 In the event of a serious incident, the policy states that the line manager can seek support for staff through the occupational health and safety advisory service or psychology services. The ‘Being open when things go wrong’ guidance also confirms support available for staff as:

“Staff who find themselves involved in a situation where things have gone wrong can access help through Occupational Health and Safety Advisory Services (OHSAS), peer support or other appropriate means.”

On the visit, staff we spoke with confirmed that this support was available to them.

3.1.9 The policy indicates that in the event of an incident where serious harm has occurred, a debrief session should be arranged for all staff affected by the incident. Our review of case documentation revealed inconsistencies in the way staff are engaged in the adverse event review process. The evidence provided for the four selected cases revealed varying levels of staff involvement in the investigation. Only one of the cases demonstrated active involvement of staff in debrief sessions and interviews as part of the investigation. Some staff reported that the de-brief process was not used by all specialties within NHS Fife.

3.1.10 NHS Fife reported that it has been working to improve how it involves staff in the adverse incident process. The revised policy includes more reference to supporting staff:
"Adverse events may cause staff distress and emotional trauma regardless of the severity or the consequence of an event. When there is a significant adverse event, it is likely that some staff may require support to cope with the emotional stress arising from the event and any subsequent investigatory process."

3.1.11 On the visit, staff we spoke with reported that communication has improved since last year and that they feel better supported by managers. We saw some excellent examples of managerial and frontline staff engagement. However, the level of support provided to staff was sometimes variable. We identified a need for consistency in the way staff receive support following an adverse incident. Also certain staff may prefer face to face meetings rather than email communication.

3.1.12 All staff we spoke with had received feedback following a relevant adverse event.

3.1.13 The majority of staff we spoke with had been involved in reviews and some had input to the action plans. Those involved in investigations or action plans reported good communication and support from their peers, managers and clinical governance team. We also heard that there is a good ‘open door’ culture where senior staff are available to support staff in the adverse event management process.

3.1.14 NHS Fife aims to provide relevant staff with a copy of the investigation report. However, staff reported that this is not always done. Staff reported that they would welcome progress updates for those investigations which take a long time to complete. For example, those investigations requiring external advice.

3.1.15 Staff reported that the daily safety briefings in clinical areas were very useful for communicating issues and incidents to staff.

3.1.16 NHS Fife acknowledges the need to explore what staff understand about the scope to share information on significant adverse event reviews and their interpretation of the policy. NHS Fife is considering developing a ‘staff support crisis intervention care bundle’ to include:

- a standard template for personal statements
- supporting guidance for staff on making personal statements, and
- investigation interview guidance for interviewers and staff based on the National Patient Safety Agency approach.

**Recommendations**

NHS Fife’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 notifying patients, family and carers of adverse events that affect them and informing them of the outcomes, and demonstrate this occurs and is documented consistently

2. always consider involving patients and family in the review process and capture their feedback to support investigation reporting and outcomes of adverse events, and demonstrate this occurs and is documented consistently

3. include a process to track and respond to issues raised by patients, families and carers, and
develop a process to consistently involve and support relevant staff and provide them with appropriate documentation and feedback to meet their needs.

3.2 Staff knowledge and training

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

3.2.1 The policy contains little reference to staff training on adverse event management. The ‘Being open when things go wrong’ document states that:

“Managers will establish local training sessions to complement the Board approach for local learning.”

3.2.2 NHS Fife informed the team that it offers a range of risk-related education and training. This includes:

- in-house core training
- induction training for trainee doctors, registered nurses and nursing assistants
- mandatory consultant training
- incident reporting including the use of Datix
- root cause analysis training
- risk assessment training, and
- customised training for departments and teams.

3.2.3 NHS Fife reported that each area has a local training register. Training events are used to provide feedback to staff and lessons learned.

3.2.4 On the visit, all staff we spoke with had received training on Datix. Staff reported that they had a good understanding of the system. Ongoing coaching is available from senior charge nurses or specifically trained support staff for those who are less familiar with the system, such as new or bank staff. Nursing staff reported that medical staff are aware of Datix, although they sometimes needed to be encouraged to use it. Some staff suggested that medical staff may require more education to increase their awareness and use of Datix.

3.2.5 The NHS board reported that incident reporting is included within the trainee doctors’ corporate induction programme. Information services provide DatixWeb training to staff in accordance with the requirements of their role. Staff we spoke with informed us that they felt supported to undertake training. Staff also reported a positive open culture within NHS Fife for reporting adverse incidents.

3.2.6 NHS Fife is considering various actions to improve staff knowledge and training. These include:
• training and development for key staff who have specific roles and responsibilities in significant adverse event reviews
• running briefing sessions for staff on how to undertake reviews and to learn from adverse events
• exploring opportunities to develop tailored training for teams, and
• supporting reporting skills for frontline staff and the wider organisation to allow the service to present clear data to various groups including the clinical governance committees.

3.2.7 Historically, NHS Fife has provided training on root cause analysis to a wide range of staff. In the last 2 years, it has moved towards a more targeted approach of training lead investigators to allow the NHS board to have a cohort of appropriately skilled staff to undertake investigations. On the visit, staff involved in investigations confirmed that they had received root cause analysis training. Staff also informed us that they were clear about their role in the investigation.

3.2.8 Midwifery nursing staff reported receiving training in completing statements as part of their training. They also confirmed they receive good support from managers when completing statements. However, some staff reported that there are different processes across NHS Fife and that certain staff may require guidance or education in completing statements.

3.2.9 NHS Fife reported that over the past 2 years, some 400 staff had accessed training on quality improvement. NHS Fife is currently developing a quality improvement hub, bringing together staff from risk management, patient safety, practice development, information services and senior clinicians. Improvement advisors are also being identified to support key improvement projects. The hub will help to drive improvement in services, including how adverse events are managed.

3.2.10 The revised policy includes more detail on the training opportunities available:

“Line Managers must ensure that staff receive training commensurate with their role and responsibilities. This might include:

• In house Core Training, Trainee Doctors’ Core Induction
• Mandatory Consultant Training
• Incident reporting including the use of Datix
• Root Cause Analysis Training for staff who play a role in the review and investigation of adverse events
• Risk Assessment training.”

3.2.11 The revised policy also refers to the availability of customised training if necessary:

“Customised training tailored to the needs of Departments and Teams developed on request or as part of a targeted approach to improvement e.g. concerns about the level of reporting.”

3.2.12 NHS Fife has focused on training and educational needs for staff and acknowledges the need for customised training in the revised policy. We observed positive engagement by frontline staff in reporting adverse events and also a recognition of the need to improve
engagement from medical staff in the process. The introduction of the quality improvement hub and improvement advisor roles should further support staff to implement actions and share learning following adverse events.

**Recommendation**

To support staff knowledge and training, NHS Fife should:

5 implement the revised policy and develop a process to monitor the effectiveness of training. This should include support for staff to take forward actions, and include specific targets for improving over time.

### 3.3 Roles and responsibilities

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

3.3.1 The policy states that:

“Staff must demonstrate awareness of this policy and an appreciation of the importance of incident/near miss reporting. All staff have a responsibility to use the NHS Fife Incident/Near Miss Reporting Form to report any incidents and near misses involving a patient, member of staff, visitor/other.”

3.3.2 The policy states that each line manager is responsible for ensuring that:

- “Staff are aware of and have access to this policy
- An Incident / Near Miss Reporting Form is completed accurately
- Any other reporting requirements are met e.g. Racial Incident Monitoring Form, Scottish HealthCare Supplies Adverse Incident Report Form, RIDDOR report
- Appropriate action/escalation and follow up is taken depending on the grade of the incident e.g. Root Cause Analysis.
- Consistent feedback is given to local staff to maintain the momentum of incident reporting and its benefits to patients and staff safety.”

3.3.3 Appendix 2 of the policy includes an incident management flow chart. The flow chart shows reporting arrangements and associated roles and responsibilities for each category of incident (very low, low, moderate, major and extreme). Appendix 6 of the policy provides a checklist for the internal reporting requirements.

3.3.4 Appendix 5 of the policy demonstrates a clear escalation process for red events. In three of the four cases we reviewed, the evidence demonstrated that incidents were reported and escalated. The remaining case was not escalated in line with the usual process and timeline. The case was not originally identified as an incident, but emerged following an inquiry from an external source.

3.3.5 The policy states that:

“The Directorates/Departments/Services will review the incidents reported, monitor actions taken and participate in regular discussion of incidents at the appropriate Clinical Governance/Risk Management Group meetings. Annual and 6-monthly anonymised incident reports for NHS Fife will be produced by the Core Risk Management Group and provided to Clinical Governance Groups/Committees and other NHS Fife groups as appropriate.”

3.3.6 We reviewed minutes of the NHS Fife Board clinical governance committee, the operational division clinical governance committee, and the operational division executive team meetings. The Board clinical governance committee receives reports from the following groups:

- Kirkcaldy & Levenmouth CHP clinical governance group
- Dunfermline & West Fife CHP clinical governance group
- Glenrothes and North East Fife CHP clinical governance group
- operational division clinical governance committee
- public health governance group
- patient safety implementation group
- infection control committee
- information governance group, and
- the e-health strategy board.

3.3.7 The clinical governance committees receive an overview of risks reported in each sector at each meeting. The overviews include the most commonly reported clinical incidents, incidents graded major and extreme, and a confidential summary of extreme incidents including action taken.

3.3.8 NHS Fife reported that all staff who work in primary care, but are managed by the CHP, are required to work to the guidance in NHS Fife policy. The policy and associated procedures are also applicable to contractors working across NHS Fife. This includes independent GPs, dental, pharmacy and orthoptic contractors. The NHS board acknowledged that the accountability arrangements of independent contractors differ from those of NHS Fife employees. NHS Fife reported that the policy may be viewed as good practice guidance in these instances, to be used alongside requirements set by the contractors’ professional body.

3.3.9 The policy includes a defined role for the NHS Fife chief executive to ensure effective arrangements are in place to manage all health and safety matters. The policy does not explicitly mention the role of the Board or non-executive directors in the management of adverse events. NHS Fife reported that non-executive directors sit on the divisional and CHP clinical governance committees and on the Board clinical governance committee. A non-executive director, who has a clinical background, also chairs the Board clinical governance committee. NHS Fife reported that serious incidents are reported and discussed at the various clinical governance committees and the Board.

3.3.10 NHS Fife recently reformed its clinical governance steering group as the NHS Fife quality, safety and governance group. The aim of the group is to:
“Bring together several complementary strands of work which have traditionally been dealt with separately – Clinical Governance, Patient Safety, and Patient Focus Public Involvement/Person Centred Care as outlined in the Quality Strategy. The key functions of the group are to co-ordinate and facilitate the implementation of the Quality Delivery Plan and the Reducing Harm Action Plan, connecting Clinical Governance, Risk Management, Patient Safety and Person Centeredness agendas. The group will set the key performance and assurance measures for quality and clinical governance and monitor progress of implementation of the Quality Delivery Plan and the Reducing Harm Action Plan.”

3.3.11 The first meeting took place on 18 October 2012. NHS Fife expects that the group will meet every 2 months. The group reports to the clinical governance committee.

3.3.12 During 2011, NHS Fife developed and tested reports which combined incidents, complaints, claims and other risk data. The directorate management teams (acute hospitals) and the Board medical and nurse directors discuss the reports during meetings about quality, safety and improvement. Currently, reports on incidents and complaints are reported separately to the clinical governance committee. NHS Fife believes that combining this kind of information could provide more meaningful reports. Significant event analysis updates and combined reports will become standing agenda items for the NHS Fife quality, safety and governance group.

3.3.13 NHS Fife previously used key performance indicator reports, but stopped using them one year ago as they were not informing them of outcomes or driving forward improvements. Reports are now provided every 3 months to the clinical governance committee and Board concerning specific issues, for example patient falls or complaints. NHS Fife reported that it is currently looking at measures for improvement, particularly around the reducing harm action plan and links to safety, effectiveness and wider improvement.

3.3.14 We noted that NHS Fife has a clear, responsive and accountable governance structure.

Recommendation
To support its information management processes, NHS Fife should:

6 embed the role of the new quality, safety and governance group in line with the group’s remit.

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 Fife has been using the Datix risk management system in the acute hospitals since 2002, and in the CHPs since 2006. The system is used across acute and community services in the NHS board area to capture information on adverse events. Staff use the complaints, incidents, claims and risks modules within Datix.
3.4.2 In 2009, NHS Fife started to implement electronic incident reporting using Datix. This allows staff to report adverse incidents directly onto the system, rather than complete a paper-based reporting form. This helps to speed up the escalation process and the completion of actions.

3.4.3 At the time of the visit, NHS Fife was using both the DatixWeb system and the paper-based form to report incidents. For incidents reported on paper, nominated data input staff transfer the incident information into Datix so that all adverse incident information is captured on a single system. NHS Fife reported that approximately one third of incidents were being reported through DatixWeb at the time of the visit. A project is under way to roll out DatixWeb across the NHS board area. Training to support implementation is a key element of the project. NHS Fife aims to complete the roll-out of DatixWeb by April 2013.

3.4.4 The policy states that staff should complete a reporting form for all adverse incidents or near misses. Staff are then required to grade all incidents using the NHS Fife risk assessment matrix. The severity of the immediate impact of the event and the level of identified future risk, informs what level of action, incident review and analysis should be undertaken.

3.4.5 The Datix system allows staff to save documents such as action plans and incident reports in the system. The Datix reference number is considered to be a key feature of document control. Staff are expected to log all material and actions relevant to adverse events in the Datix record.

3.4.6 In two of the four cases we reviewed, the Datix record noted that related documentation was attached to the record. A third case had a rapid events investigation carried out in early October 2012. However, the Datix record had not been updated to reflect that a review had been undertaken.

3.4.7 NHS Fife intends to review the use of Datix to ensure that staff are clear on what process to follow. NHS Fife also intends to more fully exploit Datix as a central repository for significant adverse events and associated documentation. The NHS board reported that it is also considering the most appropriate system and location for publishing significant adverse event reviews.

3.4.8 We noted that staff use version control on adverse event-related documents. However, many of the documents we reviewed, including action plans, did not include a creation or review date. This makes it difficult to track progress and to identify what stage each review is at.

3.4.9 An action planning module is available on Datix. However, staff do not use it consistently. NHS Fife reported plans to focus on this module once DatixWeb is fully rolled out. NHS Fife acknowledges that it needs to strengthen its document management system, particularly for documents attached to Datix.

3.4.10 Nursing staff confirmed that they use Datix to identify trends, such as the incidence of patient falls following the introduction of new equipment to prevent patient falls. NHS Fife recently brought together thematic learning from data held on Datix concerning patient falls. NHS Fife is considering a similar approach to that used for falls for other key areas identified on Datix.
3.4.11 Nursing staff in accident and emergency informed us that they use an additional book to record minor issues to help identify trends. The book is used to anonymously capture minor incidents or near misses and is there to complement rather than replace Datix. NHS Fife reported that discussions are taking place around testing this out in other areas.

**Recommendations**

To support its information management processes, NHS Fife should:

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

8 ensure that staff include dates and version control on all relevant documents to allow the NHS board to track progress 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 The flow chart in Appendix 2 of the policy states that the individual member of staff must complete an incident or near miss reporting form and grade the incident using the NHS Fife risk assessment matrix. The severity of the incident determines the level of investigation and reporting to be followed.

3.5.2 The policy defines what should be reported:

“Any incident/near miss, event or circumstance arising during NHS service provision that could have or did lead to unexpected harm, loss or damage.”

3.5.3 Appendix 5 of the policy also gives example of what should be reported as red incidents and the reporting timescales for these incidents.

3.5.4 NHS Fife has a two-step process to grading incidents. Firstly, the immediate impact (severity) is determined. Then staff use the risk matrix to grade and quantify the potential future risk. Significant adverse events are defined as extreme or red events, graded against the categories in the risk matrix.

3.5.5 The policy contains guidance on how to use the matrix to assign the likelihood and consequence in order to determine future risk. However, the policy contains only minimal guidance on determining the severity of an incident. We noted that Datix does not include guidance on determining severity.

3.5.6 NHS Fife reported that it is planning to develop and clarify definitions and terminology associated with significant adverse events. NHS Fife also intends to review how to support and train staff in the use of the grading matrix to ensure greater reliability, consistency and interpretation.

3.5.7 In June 2012, NHS Fife began an exercise to examine all major and extreme incidents.
added to Datix between January 2009 and May 2012. This involved assessing the appropriateness of the grading and documentation, the level of review, lessons learned, and whether any additional actions were considered necessary. NHS Fife also examined all incidents involving or referring to a patient death, regardless of grading, and incidents with an ‘unknown’ severity grading. This was to determine the ultimate appropriate grading and any need for review. The review highlighted some areas for action, including to:

- “Improve the consistency and reliability of processes at operational level around timeliness and rigour of incident management and review
- Strengthen organisational systems for escalation of significant adverse events and subsequent tracking of progress on action plans and changes implemented
- Rationalise templates used for recording of adverse event reviews and rapid event investigations
- Clarify processes governing patient, family & staff involvement following a significant adverse event and publication of reports
- Develop mechanisms for identifying thematic learning to enable change & improvement in practice.”

3.5.8 The October 2012 minutes of the quality, safety and governance group outlined some positive outcomes from the Datix exercise. These include the following:

- “Many incidents re-graded on Datix to lower severity ratings. Almost all incidents relating to patient deaths had also been updated.
- The system of daily checks on Datix has resulted in quicker initial reviews of major or extreme incidents.
- Fewer incidents are also being graded as ‘unknown’ on Datix.
- Where incidents are still graded as unknown, more timely, definitive incident grading is applied. Many of these incidents have been reclassified and addressed.”

3.5.9 The meeting minutes also documented the following areas for improvement:

- “timeliness of adding documentary evidence to Datix to reflect that incidents have been thoroughly investigated, and recommendations and actions followed through to completion
- inconsistencies in the severity grading applied to patient deaths, in particular still births and unexpected neonatal deaths
- inconsistencies in the severity gradings applied to pressure ulcers, and
- inconsistencies in the use of standardised templates for the recording of incident reviews.”

3.5.10 On the visit, line managers reported that they encourage staff to report incidents, particularly if staff are unsure that it is an adverse event. Staff sometimes over-grade adverse events. However, Datix is checked daily to identify any inconsistencies in the risk grading for major and extreme incidents. NHS Fife reported that it would aim to discuss
inaccurate gradings or escalation with staff at the time of the event, to allow staff to be coached directly.

**Escalation of events**

3.5.11 The policy states that the line manager must review the content of the incident or near miss reporting form, check the grading, indicate if an incident review is required, then sign and date the form. It also states that if an incident review is required, the line manager must initiate this as soon as possible after the event. Appendix 5 of the policy includes the escalation process for red events.

3.5.12 The incident grading identifies the required level of investigation, for example root cause analysis. For low grade and moderate events, the line manager analyses the incident and prioritises the incidents that require investigation. The policy does not contain any further guidance on how this prioritisation should be determined.

3.5.13 NHS Fife reported that sometimes a significant adverse event review arises from outside the normal reporting procedure, such as the investigation of a complaint. NHS Fife is considering identifying wider triggers which may require a significant adverse event review.

3.5.14 On the visit, NHS Fife reported that a medical director, CHP manager, clinical director or nurse director can instigate or lead an investigation. The NHS board also reported that reviews can be undertaken very quickly if necessary. However, occasionally investigations can take longer if external advice is required. The obstetrics team reported that sensitive adverse events would be managed quickly as routine.

3.5.15 NHS Fife reported that ownership of actions is determined by the investigation outcomes. The person tasked with leading the incident review will allocate responsibility for specific actions to the appropriate individuals.

**Recommendations**

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

9 include more detailed guidance within the revised policy and Datix to help staff determine the severity of the adverse event, and

10 implement a system to ensure staff use consistent templates for recording incident investigations.

**3.6 Timely management, learning, dissemination and implementation**

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

**Investigation and reporting timelines**

3.6.1 The policy highlights the importance of staff reporting all incidents or near misses as soon as possible after the event. A significant or red event must be reported immediately. Appendix 5 of the policy provides explicit guidance on the reporting procedures for a red
event. The policy states that the line manager must submit an executive summary for red events to the appropriate senior manager or executive director within 24 hours of the event occurring.

3.6.2 Of the four cases we reviewed, three were reported within 24 hours. One incident occurred in early February 2011, but was only identified following an inquiry from an external source several months later. A significant event analysis was carried out in March 2012. The incident was retrospectively added to Datix in October 2012.

3.6.3 The policy does not provide clear guidance on the timescales for investigation. The policy states that:

“If an incident review is required, the Line Manager must initiate this as soon as possible after the event.... The Line Manager must ensure that all outcomes, action plans and RCA/SEA reports are timeously recorded in DATIX. He /she must submit a report to the Directorate/Departmental/CHP Manager within 4 weeks (or agreed timescale).”

3.6.4 It is not clear in the policy whether the above 4-week deadline relates to the incident date or the date of the investigation. NHS Fife informed us that it relates to within 4 weeks of the incident occurring.

3.6.5 Appendix 2 of the policy also only refers to an ‘appropriate and realistic timeframe’ for undertaking reviews of major and extreme incidents using root cause analysis or significant event analysis.

3.6.6 In three of the cases we reviewed, the investigations were not completed until 7-8 months after the incidents were reported.

3.6.7 NHS Fife reported that it keeps incident records open on Datix until all related actions are completed. Action plans developed following major or extreme incidents are included on the agenda of the divisional or CHP management team meetings and remain so until actions are completed.

3.6.8 The revised policy includes recommended timescales for undertaking an investigation based on the identified consequence of the adverse event. For example, the revised policy states that incidents categorised as ‘no harm or minor harm’ require an investigation to be undertaken within 10 working days. An incident graded as having major or extreme consequence should have an investigation carried out and completed within 40 working days.

**Action planning**

3.6.9 The existing policy contains little reference to action plans, ownership and the sharing of wider learning. We saw evidence of action plans for three of the four cases we reviewed. The fourth case had no information on Datix to confirm what action had been taken.

3.6.10 Staff we spoke with reported that they are clear on how to take forward actions to reduce the risk of an adverse event happening again. Staff gave us examples of where the adverse event process had led to improved processes. This included improved communication between management and staff around capacity planning issues, and improved notification of a patient’s condition before arrival at hospital.
3.6.11 However, from the evidence provided, it was not clear how action plans are implemented and monitored. It was evident that some action plans are presented to clinical governance groups or committees. However, this does not appear to be consistent for all significant adverse events.

3.6.12 NHS Fife reported that it is reviewing its processes for undertaking a significant event analysis such as commissioning a significant adverse event review, ownership of actions and learning, and implementing actions and tracking progress. The revised policy includes a flow chart showing the procedure for reporting and management of non-clinical adverse events and near misses. The flow chart includes the requirement for an action plan and evaluation of progress for adverse events.

3.6.13 In 2011, NHS Fife introduced a reducing harm action plan. The action plan focuses on addressing patient safety and quality improvement issues. Actions from significant adverse event reviews are included in the reducing harm action plan and are reported through the NHS Fife clinical governance committees. We noted the benefit of NHS Fife having an overarching action plan to identify themes and actions from adverse incidents across the organisation.

Sharing of learning

3.6.14 The policy has limited reference to the sharing of learning and systems to support this. In Appendix 2, the incident flow chart includes a ‘good practice point’ that managers must feedback to staff the practical improvements and information about incidents. This appendix also notes that very low grade incidents should be discussed at departmental meetings and all reports reviewed to identify trends.

3.6.15 Appendix 2 of the policy also states that the core risk management group will produce anonymous reports for feedback to the various parts of the organisation and committees. However, the policy does not describe how this feedback would be circulated throughout the organisation.

3.6.16 The ‘Being open when things go wrong’ guidance states that:

“Events should be discussed at local clinical governance fora and consideration given to how the lessons learned form the incident and the ‘being open’ process can be shared widely across the organisation. This may include the SHARE/SEA Learning newsletters, presentation at meeting or discussion with colleagues.”

3.6.17 The minutes of the clinical governance committee and operational division clinical governance committee demonstrate that discussions do take place concerning adverse events.

3.6.18 NHS Fife reported that a number of routes are used to share reports of significant adverse events at operational and strategic level. Summary significant adverse event reports, outcomes of reviews and key learning points are reported through various risk management and clinical governance groups and committees. Staff attending must share information with their own staff. Reports are also shared at senior nurse meetings, multidisciplinary team debriefs and safety briefs. The risk management team produces the ‘SHARE’ newsletter which may include learning points from adverse events.

3.6.19 Staff reported that they receive feedback on learning from incidents which occur within their area. However, we noted inconsistencies in the level of feedback that staff receive.
Some staff reported that they hear about incidents or near misses which happen on other wards. Other staff reported that they only get feedback about incidents which have happened in their own area.

3.6.20 Staff reported areas of good practice where teams share learning from adverse events. This included the maternity team debriefing to a large number of staff and a planned workshop in January 2013 to feedback learning to other specialties. Learning from significant adverse events and review outcomes are also shared at maternity clinical risk manager forum meetings held every 3 months. Staff reported that the obstetrics team holds monthly, multidisciplinary medical midwifery and perinatal meetings. Cases and incidents are discussed at these meetings and educational requirements for staff identified.

3.6.21 NHS Fife reported that senior managers meet weekly at a strategic level and will discuss relevant incidents and the progress of investigations. At an operational level, various opportunities are used to discuss issues and share learning from incidents including:

- weekly senior nurse meetings with directorate nurse managers (operational division in acute hospitals)
- monthly CHP service manager team meetings
- clinical governance groups and committees, and
- the NHS Fife risk reference group.

Other groups in NHS Fife also discuss adverse events including:

- information governance
- medication safety
- managing violence and aggression group, and
- health and safety divisional CHP (Fife-wide) group.

3.6.22 Senior management walkrounds on wards are also used to share information on adverse events. Staff informed us that they are comfortable reporting near misses to senior managers.

3.6.23 NHS Fife has recently brought together thematic learning from data on patient falls which has resulted in improvement measures. The NHS board has also reviewed rapid event investigations for *Staphylococcus aureus* bacteraemia. This resulted in the NHS board inviting external experts to help staff review their routine and systematic processes and to help them understand underlying issues. NHS Fife is considering a similar approach to that used for falls for key areas identified on Datix, or areas of concern arising from other methods such as complaints. The NHS board’s reducing harm action plan also pulls together thematic learning. NHS Fife reported that it is currently working on how to develop measurable objectives and improvements for those actions identified.

3.6.24 The NHS board is considering mechanisms for formally publishing significant adverse event review reports and action plans.

3.6.25 The revised policy provides more guidance to staff on the need to capture and share
learning from adverse events. All incidents, including those categorised as no harm or moderate “should be reviewed to identify learning or improvement actions.” The revised policy also outlines the responsibility of the line manager to ensure wider learning is captured and shared with staff:

“The Line Manager is responsible for ensuring:

- findings from investigations are entered into Datix to enable an audit trail and wider organisational learning
- local staff are given feedback, lessons learned are shared, evaluated.”

3.6.26 The flow chart in the revised policy indicates that action plans and progress updates would feed into an annual trend analysis report.

### Recommendations

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

11 implement the revised policy and monitor investigations to ensure they are being carried out in line with the policy deadlines

12 introduce a system to monitor action plans and progress updates on Datix to ensure that actions are implemented, and

13 embed 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 relevant staff.
Appendix 1 – Details of review team

The review of NHS Fife was conducted on Thursday 6 December 2012.

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.