Management of adverse events

Review Report | NHS Shetland

June 2013
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Contents

Executive summary 4
1 Introduction 8
2 NHS Shetland’s adverse event management policies and procedures 10
3 Detailed review findings 13
Appendix 1 – Details of review team 29
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 Shetland’s governance arrangements and processes for managing adverse events involved:

- an analysis of evidence provided by the NHS board, and
- a visit to NHS Shetland on Thursday 18 to Friday 19 April 2013.

NHS Shetland has plans to improve how it manages adverse events. This includes changes to systems and documentation, improved reporting, training for staff and improved engagement with patients, family and carers.

We acknowledge that NHS Shetland is a small NHS board. Staff reported that there is a challenge to maintain a consistent approach within a small NHS board, where systems can be person dependent and staff have multiple roles.

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

- strong engagement of nursing staff in reporting adverse events
- a comprehensive approach to adverse incident management in the obstetrics unit
- examples of established mechanisms to share learning, and
- regular discussion of adverse events within mortality and morbidity meetings, team meetings and risk management meetings.

We found that there are particular areas within NHS Shetland with good adverse incident management practice. However, we identified that adverse events are not managed in a consistent manner across the organisation. Our review identified weaknesses in the management of significant adverse events. The shortfalls include patient and family engagement, investigation, information management, timeliness and the sharing of wider learning. NHS Shetland needs to introduce a standardised and formal process for managing adverse incidents which can demonstrate staff consistently applying the policy guidance. Our review identified areas that the NHS board should improve to help ensure staff follow a consistent process, and to assure NHS
Shetland that adverse events are managed appropriately. The recommendations below aim to support this.

**Recommendations**

We expect NHS Shetland 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 Shetland’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, capture their feedback to support the investigation and outcomes, and ensure their involvement is consistently documented
2. introduce a process to track and respond to issues raised by patients, families and carers, and
3. develop a formal process to consistently engage and support relevant staff, with evidence to demonstrate their involvement in communications, investigations and action plans.

**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 Shetland should:

4. demonstrate evidence of formal training on Datix, risk management and investigations, for all relevant staff, and
5. ensure staff involved in managing significant adverse incidents have a clear understanding of investigation methods and apply them to adverse event reviews and action planning.
Roles and responsibilities

**Recommendation 20 from the NHS Ayrshire & Arran report**

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

To ensure clear functions and roles, NHS Shetland should:

6 document evidence of adverse incident information being fully reported and discussed at governance meetings to support clear oversight of how adverse incidents are managed across the 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 Shetland should:

7 introduce a standard operating procedure to help staff manage information, including appropriate document control and storage, and ensure staff make full use of Datix

8 ensure that staff include dates, version number and authors on all relevant documents to allow the NHS board to track progress of adverse incidents, and

9 introduce a system for capturing and sharing thematic learning from adverse incidents across the organisation, including learning from action plans and complaints.

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 Shetland should:

10 ensure all adverse incidents are systematically recorded on Datix at the time of the event and capture evidence of them being appropriately escalated

11 consistently record decision-making on Datix, to support a transparent and open process, and

12 introduce a standard approach for investigations, including use of report templates and checklists to support staff and ensure consistency across the NHS board.
Timely management, learning, dissemination and implementation

Recommendation 23 from the NHS Ayrshire & Arran report

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

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

13 implement the revised policy deadlines and monitor timelines for staff recording and investigating incidents to ensure they are in line with the policy

14 introduce a monitoring system to provide assurance that action plans are completed and actions are being implemented, and

15 embed a culture of capturing and sharing lessons learned across the organisation, supported by a system that provides evidence of discussions at meetings and thorough consistent feedback mechanisms to relevant staff.

We identified a further overall recommendation relating to the implementation of the NHS Shetland revised policy (2012) and supporting documentation.

NHS Shetland should:

16 incorporate recommendations from this report into the revised incident management policy and supporting documentation, and implement the guidance consistently across the organisation.

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

We would like to thank NHS Shetland and in particular all staff at Gilbert Bain Hospital, Lerwick, 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 Shetland in advance of the visit. This included:

- policies and procedures for adverse event management
- governance and reporting arrangements
- an assessment of the NHS board’s current and future planned approach following the recommendations of the NHS Ayrshire & Arran report
- a list of 15 significant adverse events recorded between 1 February 2011 and 31 July 2012, and
- details of four specific significant adverse event reviews.
1.1.8 Of the 15 recorded significant adverse events, we selected four cases for detailed review. We did this by reviewing the high level summary of each case, taking into account the location and specialty of the event and the level of investigation.

**Review visit**

1.1.9 The review visit took place on Thursday 18 to Friday 19 April 2013. The review team was made up of a number of individuals with relevant specialist knowledge from across Scotland (see Appendix 1 for membership of the review team).

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

1.1.11 We discussed the initial findings of our report with NHS Shetland’s chief executive on 8 May 2013.

**Improvement plan**

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

2.1.1 NHS Shetland is responsible for providing health services for the population of the Shetland islands (around 23,000 people). The NHS board has a rural district general hospital, the Gilbert Bain Hospital, in Lerwick. This provides local hospital and community services, supported by locally-based consultants in general medicine, general surgery, anaesthetics and psychiatry.

2.1.2 The NHS board has shared patient pathways and access to specialist services through NHS Grampian. Visiting consultants from NHS Grampian also provide outpatient clinics, inpatient and day case surgery to support NHS Shetland’s local service. The NHS board also has 10 GP practices, three of which receive a salary from NHS Grampian.

Adverse event definitions

2.1.3 NHS Shetland uses the electronic reporting system, Datix, to record and categorise adverse events. Staff use a risk matrix to grade an adverse event by assessing the likelihood and consequence of the event happening again. The risk matrix has four possible gradings for adverse events - low, medium, high or very high. If the event is graded high or very high at the time it happened, then it is considered a potential significant adverse incident.

2.1.4 The NHS board defines a significant adverse incident 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. Such events are likely to generate legal, media and/or other interest and may result in loss of the Board’s assets and/or reputation.”

2.1.5 NHS Shetland identified 15 significant adverse incidents between 1 February 2011 and 31 July 2012.

2.1.6 The top four themes for significant adverse events are:

- slips, trips and falls
- abuse of staff by patients
- appointments, and
- laboratory investigations.

Policy for managing adverse events

2.1.7 NHS Shetland has had an incident management policy since 2007–2008. Our review included analysis of four specific adverse incidents. At the time these four incidents took place, the NHS board was using the incident reporting, investigation and management policy (2010–2011) issued to staff in 2010. This document is hereafter referred to as the ‘policy (2010)’. It includes guidance on reporting, investigation, definitions and actions to be taken in the event of a significant adverse incident.
2.1.8 In November 2012, the NHS board approved an update to the policy (2010). The update reflected recommendations from the NHS Ayrshire & Arran report, and included revisions, such as improved guidance for staff. The revised document includes a flow chart which outlines the process for reporting, investigating and managing significant adverse events. The revised document is hereafter referred to as the ‘revised policy (2012)’. It was ratified by the strategy and redesign committee in January 2013. NHS Shetland reported that some aspects of the policy relating to significant incident management are subject to an ongoing implementation plan. However, other aspects of the policy are fully operational.

2.1.9 The revised policy (2012) includes more reference to the culture for reporting incidents:

“The Board has sought to develop and embed an open, just and non-punitive culture where all staff feel able to report adverse incidents, near misses and hazards in the knowledge that incidents are not normally investigated through the disciplinary procedure (see 8.5 below). As a consequence, staff feel empowered to be open and honest when reporting an incident and participating in an investigation.”

2.1.10 NHS Shetland has identified the following areas for improvement in how it manages significant adverse incidents:

- complete a gap analysis of significant incident management in response to the findings from the NHS Ayrshire & Arran report
- ensure that the operational guidance around reporting, managing and investigating significant adverse incidents is robust and works in practice
- ensure the clinical governance committee reviews clinical significant incident investigation reports, and
- work with NHS Grampian, as part of the partnership clinical governance arrangements, to ensure that the significant incident management process is robust and effective.

2.1.11 At the time of the visit, NHS Shetland had developed a draft flow chart to guide staff on how to manage a potential significant incident from the time it happens through to action planning and follow-up.

2.1.12 The NHS board has also developed an action plan to implement the revised policy (2012). This includes requirements for staff training and changes to procedures and documentation.

**Governance arrangements**

2.1.13 NHS Shetland reported that the strategy and redesign committee has overall responsibility for risk management governance, including risk registers and the risk management processes. Adverse incidents are discussed at the risk management group and summary reports are provided to the clinical governance committee. The clinical governance co-ordinating group undertakes clinical governance work at an operational level and reports to the clinical governance committee.

2.1.14 Figure 1 on page 12 outlines the current governance arrangements in place for the management of adverse events.
Figure 1: NHS Shetland’s governance structure

Solid lines denote the committees accountability and assurance structure  
Dotted lines denote functional links between committees with shared accountability and assurance roles
3 Detailed review findings

3.1 Engaging with stakeholders

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

Patient, family and carers involvement

3.1.1 The policy (2010) states that:

“Line managers should recognise the importance of communicating feedback to patients and carers in relation to patient safety incidents.” The document includes a footnote to this statement referencing the National Patient Safety Agency guidance: Being Open: Communicating Patient Safety Incidents with Patients and their Carers (2009).

3.1.2 Appendix B of the same policy states:

“If a patient has been directly involved in an incident, the senior clinician with responsibility for that patient should explain the incident to the patient at the earliest opportunity. The patient should be advised by that senior clinician of the process of incident investigation, and asked if they want to give a statement. The senior clinician should also ensure that the patient is also made aware of the final outcome of the investigation”.

3.1.3 This guidance remains largely unchanged in the revised policy (2012), although the wording is now included within the main body of the document.

3.1.4 We analysed documentation provided for the four cases selected for detailed review. In all four cases, there was no evidence of communication with the family or carers in the adverse event management process. On the visit, our discussions with staff revealed that there had been some contact with the family in three out of four cases, but this had not been formally recorded.

3.1.5 Neither version of the policy includes reference to family or carer involvement in the action plan development process.

3.1.6 NHS Shetland does not have a current system to reliably track and respond to issues raised by patients, families and carers in relation to adverse events.

3.1.7 The NHS board reported that it recently introduced a box on the summary checklist for significant adverse incidents to record patient or family involvement and reasons for not involving them.

3.1.8 We identified a challenge for NHS Shetland to ensure that patients and families are consistently involved where appropriate, and to record reasons for not engaging with them.
Staff involvement

3.1.9 The policy (2010) states that:

“Investigations should be objective and supportive to the staff involved. Line managers should consider whether staff may need additional support during the course of an investigation and should take appropriate action on this, if necessary, with advice from their line manager or a member of the senior management team. The Board aims for an open and honest culture, it is important that staff feel they can be open and honest when participating in an investigation. Patients and staff appreciate an apology for distress caused if appropriate, and expressions of sympathy and concern. Apologising does not necessarily mean acceptance of guilt. Matters of performance or failures in the system should be established from the investigation, and the appropriate feedback included in the reporting and actions arising from the investigation.”

3.1.10 The revised policy (2012) includes similar wording to the above. Both versions of the policy state that:

“A draft of the report should be agreed with relevant staff, specifically the person(s) directly involved in the incident before being finalised. Staff should be offered help in preparing their statements, which may come from their line manager, an experienced colleague, or an independent source such as a Trade Union or professional body.”

3.1.11 The revised policy (2012) provides more detail on support available to staff. This includes support from their line manager, human resources department, occupational health service or a member of the senior management team. The safety and risk manager is also able to provide advice and support on incident investigation.

3.1.12 NHS Shetland reported that local staff debriefs are consistently used in the maternity unit, although this is not standard practice across the NHS board. Our discussion with maternity staff confirmed that they were involved in debriefs and informed of adverse incident outcomes. However, there was a lack of documented evidence to demonstrate this.

3.1.13 Our discussions with staff on the visit revealed that staff had been engaged in the process. However, in all four cases we reviewed, there was a lack of documentation to demonstrate how staff were involved in the process or how outcomes were communicated to them.

3.1.14 NHS Shetland did not have a structured process for debriefing staff and undertaking investigations. In three of the cases, a single meeting, chaired by the medical director, was used to both debrief staff and undertake the investigation. We noted that organising an investigation meeting convenient for relevant multidisciplinary or external staff, could result in delays to staff receiving a debrief. We encourage the NHS board to introduce a formal process for debriefing staff that is separate from the investigation.

3.1.15 We noted good practice within one of the cases where positive feedback was given to staff to confirm that they had acted appropriately in response to the incident.

3.1.16 The majority of staff, who had been involved in an adverse incident, gave positive feedback on support available to them throughout the process. This included support
from line managers, colleagues and the former chaplain. Staff reported being involved at various stages including action planning, receiving a copy of the review report and taking actions forward.

3.1.17 We noted that staff engagement needs to be captured on Datix or within case documentation to provide assurance that it is taking place.

**Recommendations**

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

1. always consider involving patients and family in the review process, capture their feedback to support the investigation and outcomes, and ensure their involvement is consistently documented

2. introduce a process to track and respond to issues raised by patients, families and carers, and

3. develop a formal process to consistently engage and support relevant staff, with evidence to demonstrate their involvement in communications, investigations and action plans.

### 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 Shetland reported that risk management training is part of a compulsory training programme which all staff are required to complete. The safety and risk management team delivers a total of 24 induction and refresher training sessions each year. The training includes guidance on how to grade incidents using a risk matrix. The NHS board reported that feedback from participants is positive and presentations are regularly refreshed and updated in response to global, national and local events.

3.2.2 Individual Datix update and refresher training sessions are also provided to heads of department and senior managers. NHS Shetland reported that all heads of department attended recent training on recording, investigating and reporting incidents on Datix.

3.2.3 Our discussions with staff on the visit revealed that nursing staff had received training on Datix. However, not all medical staff had received training on Datix, although some reported being offered the training.

3.2.4 We observed good practice in the maternity team where a nominated midwife provides Datix support training to others in the team, where required. This is in addition to training support from the safety and risk management team.

3.2.5 We also noted good practice where NHS Shetland had undertaken a survey of staff to obtain feedback on the use of Datix and the adverse incident management process. The survey results indicated that most staff found Datix easy to use. However, a significant
number identified possible improvements, including the removal of the time limit in which to complete data entry into the incident record on Datix.

3.2.6 In 2009–2010, NHS Shetland offered training in root cause analysis to heads of department to support the investigation process.

3.2.7 Some staff informed us they had received training on how to undertake an investigation, including root cause analysis. However, the level of training was not consistent. Some staff were tasked with leading investigations without having received appropriate training.

3.2.8 The NHS board acknowledged that while it has provided basic training for staff, more training is needed to support staff, particularly for complex, multi-agency cases.

3.2.9 NHS Shetland has identified risk management and incident investigation training and introducing Datix user guides for staff as a priority for 2013–2014. NHS Shetland reported plans to review the training learning outcomes for adverse event management to ensure the training reflects the new revised policy process and meets staff learning needs. At the time of the visit, the NHS board was planning specific training on risk management for staff likely to be involved in adverse incident investigations.

### Recommendations

To support staff knowledge and training, NHS Shetland should:

4. **demonstrate evidence of formal training on Datix, risk management and investigations, for all relevant staff, and**

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

### 3.3 Roles and responsibilities

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

3.3.1 The revised policy (2012) states that:

“Incident reporting and risk management are the responsibility of all staff, and it is the responsibility of all staff to learn from incidents and risks identified, for the benefit of patients and the service... The handler of the incident is responsible for making sure that actions are completed and that this is recorded on the Datix system. Progress should be monitored via the line management structure. Line managers have additional responsibilities for ensuring the frameworks and processes highlighted in this policy and the principles highlighted in the Clinical Governance and Risk Management Strategies are adhered to... In particular line managers (usually the investigating manager) have responsibilities for communicating with staff about incidents they are involved...
in, and about the outcome of incidents, and for delivering the actions arising from them in a timely manner.”

3.3.2 NHS Shetland reported that adverse events are discussed through the board-wide governance structure. For example, clinical incidents are discussed at the clinical governance committee, and finance incidents discussed at the audit committee. Incidents are also discussed at departmental level. The surgical team within NHS Shetland holds a monthly multidisciplinary session to discuss surgical activity. The medical team has a multidisciplinary meeting every 2 weeks. At both team meetings, discussion is focused on individual cases and outcomes as well as encouraging suggestions for service improvement. Working action plans from both teams are tabled at the clinical governance co-ordinating group every 3 months for information and monitoring purposes. The maternity unit also reports outcomes from their practice review meetings in a similar manner.

3.3.3 The NHS board reported that it does not have a similar system for non-clinical incidents to be routinely reviewed by support services. However, non-clinical adverse events are investigated and actions fed back to teams and the respective standing committees.

3.3.4 NHS Shetland has a small risk support team, with some input from NHS Grampian through a shared service partnership arrangement. The team monitors the approval process for adverse incidents, the completeness of Datix records, and helps make sure that feedback is provided to whoever reported the incident. The team includes a safety and risk manager, a part-time Datix and systems support officer and a part-time safety and risk support assistant. The team provides reports to the risk management group, the clinical governance co-ordinating group and health and safety. Staff reported that Datix support can be person-dependent given the challenge of being a small team with multiple roles.

3.3.5 The NHS Shetland risk management group discusses adverse incidents every 6 weeks and provides a report to the clinical governance committee every 3 months. Historically, the 3-monthly report featured numerical data on adverse incidents. This included the number of incidents reported by category, severity, department and status of approval or review.

3.3.6 In three of the four cases selected for review, there was no evidence of the cases being discussed at governance meetings.

3.3.7 NHS Shetland has identified monitoring significant adverse incidents at different stages in the investigation process, as an area for improvement.

3.3.8 The NHS board acknowledged that the clinical governance committee has not always reviewed clinical significant incidents investigation reports. In autumn 2012, NHS Shetland implemented a new process to consistently present information on these investigations to the clinical governance committee. As part of the process, the risk management group now discusses full reports and the progress of significant adverse incidents. Summary reports of clinical significant adverse incidents are then compiled for the clinical governance co-ordinating group and the clinical governance committee. Summary reports for non-clinical incidents, such as estates or IT issues, are provided to relevant standing committees. The risk management group provides updates to the NHS Shetland Board meetings, although sometimes the updates are verbal.
3.3.9 The summary report includes detail of the incident and the actions taken. We saw evidence of the report produced in November 2012 and discussed at the clinical governance committee in January 2013. We noted it lacked detail on the learning from adverse incidents and how learning could be shared across the organisation.

**Recommendation**

To ensure clear functions and roles, NHS Shetland should:

6 document evidence of adverse incident information being fully reported and discussed at governance meetings to support clear oversight of how adverse incidents are managed across the 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 NHS Shetland began rolling out Datix from July 2008. Before this, a paper-based process was used to report adverse incidents. During 2009, Datix was rolled out across all secondary care sites, dental service and salaried GP practices. All staff have access to Datix, including GP practices. Some, but not all, independent GP practices use Datix. A paper-based reporting form is available as an alternative. The risk module of Datix was introduced at the beginning of 2011.

3.4.2 Staff can access Datix through the NHS Shetland intranet homepage. The homepage also includes a link to the incident or near miss reporting form. Any member of staff can report an adverse incident or risk on Datix. Once staff report the incident on Datix, they are unable to edit the record unless they have Datix manager level access. NHS Shetland uses security settings on Datix so that only specified staff can access significant incident records and see documents attached to the record.

3.4.3 Datix provides an audit trail of changes to an incident record. Only identified administrators have access to viewing the audit trail and removing documents from the system.

3.4.4 NHS Shetland reported that for non-clinical incidents, the complete incident record should be held on Datix, and there is the facility to upload documents, for example, emails, photographs, letters, file notes and reports. The policy (2010) allows for evidence for clinical incidents to be either uploaded onto Datix or be kept in a separate file, provided the location and holder of that file is clearly recorded on the Datix record with a summary of the investigation.

3.4.5 NHS Shetland reported that it encourages staff to use Datix as a sole repository for information on incidents and investigations. However, the remote and rural location can sometimes impact on information held electronically, particularly for privacy and sensitivity issues.
3.4.6 In three out of four cases selected for review, there was no evidence of documents uploaded to Datix, or information on where relevant documentation was stored. Staff on the visit confirmed that clinical investigation reports are generally not uploaded to Datix.

3.4.7 The revised policy (2012) provides more detailed guidance for staff on how to manage information:

“For non-clinical incidents the evidence gathered should be uploaded to the Datix incident record in the form of documents, photographs, emails, letters, faxes etc., in order to maintain a complete record of the investigation. For clinical incidents evidence may either be uploaded onto Datix or be retained in a separate file, provided the location and holder of that file is clearly recorded on the Datix record and a summary of the investigation is provided. For significant incident investigations a final report may also be produced and added.”

3.4.8 In all four cases we selected, there was no evidence of document control, such as version number and date, on reports or action plans. The NHS board is aware that documents uploaded to Datix do not always include versions numbers and dates, which makes it difficult to determine when they were updated. We also noted a lack of document control or audit to confirm changes made to items not held on Datix, such as review reports. NHS Shetland does not currently have a central repository for source documents attached to Datix or a board-wide document control system.

3.4.9 The NHS board reported plans to produce a standard operating procedure to help staff manage significant adverse incidents on Datix. This will include document control requirements and a single repository for documents stored on Datix.

3.4.10 NHS Shetland reported that the risk management group, clinical governance co-ordinating groups and clinical teams can identify themes from adverse incidents. However, the NHS board acknowledged that themes are not consistently identified.

3.4.11 The Datix system is set up to support learning within single departments, as incidents can be reviewed in one place. Designated members of staff have responsibility for certain areas of thematic learning, such as infection control, and health and safety. However, there is less support for other theme areas and for learning across the organisation. NHS Shetland is working on how to identify thematic learning for other areas, such as patient falls and medication. The NHS board is also reviewing its directorate level risk management to make sure it has a robust overview of incidents across the organisation for all themes, not just those with designated staff resource.

3.4.12 It was not clear from the evidence provided how action plans are reviewed across the organisation to inform thematic learning. The NHS board reported plans to reconfigure Datix to support themed learning through investigation of outcomes and tracking completed actions.

3.4.13 The incident and risk management report to the November 2012 clinical governance committee included, for the first time, details of reported and completed significant incidents. However, there was no evidence of learning points or themes identified from these updates.
3.4.14 NHS Shetland has a separate process for managing complaints, although the process is similar to that for adverse incidents. Information on complaints is provided to the risk management group. However, the NHS board acknowledged that it does not have an established system for integrating information from complaints with adverse incidents. The integration is sometimes limited by ability to cross reference patient details.

3.4.15 The revised policy (2012) outlines the responsibility of the manager to link adverse incidents and complaints for the purposes of identifying trends:

“The line manager (usually the investigating manager) also has a responsibility to ensure that incident reporting and investigation is linked where appropriate to the local complaints procedure (especially in terms of recognising patterns in incident trends and feedback through formal and informal complaints) and to team, directorate and corporate risk registers.”

3.4.16 NHS Shetland has identified a need for structured documentation, consistent use of Datix and capturing organisational learning from significant adverse incidents.

3.4.17 On the visit, nursing staff confirmed they view Datix as a useful tool and they have seen improvements brought about in response to them recording incidents.

3.4.18 We encourage NHS Shetland to document reasons for introducing changes in response to adverse incidents. This will help demonstrate how it is taking forward improvements and should improve engagement with all levels of staff.

**Recommendations**

To support its information management processes, NHS Shetland should:

7 introduce a standard operating procedure to help staff manage information, including appropriate document control and storage, and ensure staff make full use of Datix

8 ensure that staff include dates, version number and authors on all relevant documents to allow the NHS board to track progress of adverse incidents, and

9 introduce a system for capturing and sharing thematic learning from adverse incidents across the organisation, including learning from action plans and complaints.

### 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 Both versions of the policy state that when an adverse incident happens, staff should record it on Datix.

3.5.2 NHS Shetland reported that, historically, not all adverse events were recorded on Datix. A number of incidents, such as internal department reviews, were held as manual records within the organisation. NHS Shetland recently reviewed all significant adverse
incidents and retrospectively added incidents on Datix where required. The NHS board further reported that while it has been successful in recording non-clinical adverse incidents, it has been less successful in capturing clinical incidents on Datix.

3.5.3 On the visit, staff reported that the use of Datix had improved significantly since 18 months ago, with more people recording adverse incidents on the system.

3.5.4 Our discussions with staff revealed good engagement from nursing, allied health professionals and obstetrics staff in recording adverse incidents. However, medical staff were less engaged or positive about using Datix. NHS Shetland reported the active engagement of medical staff in policy development and implementation as an area for improvement.

3.5.5 Both versions of the policy set out a risk-based approach for the identification of adverse events:

“The ‘Investigation’ section of the Datix incident report form includes a risk matrix which allows the investigator(s) to grade the incident by assessing the likelihood and consequence of the incident taking place again. Assessing the grade also helps the investigator(s) to determine the significance of the incident and the required management actions, i.e. low, medium, high and very high level incidents will have differing levels of urgency and investigation requirements.”

3.5.6 Both versions of the policy also include an ‘incident reporting actions’ table, which signposts the investigator to select the correct pathway for adverse event investigation and management, based on the incident grading.

3.5.7 Obstetrics staff informed us they actively use Datix and refer to a defined list of ‘trigger’ events to help determine an adverse incident. Staff also record incidents which are outside of normal midwifery practice, including emergency caesarean sections. We identified this as good practice. The maternity team also reported that they discuss adverse incidents at their monthly risk management meeting. A monthly list of actions arising from adverse incidents is provided to the clinical governance co-ordinating group. Staff further reported that they have access to the North of Scotland Local Supervision Authorities resources for midwifery supervision support. The maternity team also has access to external investigators if required.

**Escalation of events**

3.5.8 If the incident rating is high or very high or falls into one of the categories of potential significant incident, then the member of staff is asked to contact an appropriate member of the senior management team. The NHS board informed us there is always a senior manager on call if the usual communication channels to directors are not available. The member of staff and the senior manager will discuss the incident risk grading and will agree a course of action, including any requirement for an investigation.

3.5.9 The revised policy (2012) includes detailed guidance on which director staff should contact depending on the type of significant incident. For example, clinical incidents, child protection, health and safety, financial or estates and facilities.

3.5.10 When incidents graded as high or very high are reported on Datix, an automatic email is sent to appropriate senior managers.
3.5.11 Three of the four cases selected for review revealed a lack of evidence on the Datix record to demonstrate how the incident was escalated. There was also significant delay in the incident being reported on Datix in three of the cases. On the visit, our discussions with staff revealed that the incidents had been appropriately escalated for three of the four cases. However, the NHS board needs to make sure that incidents are systematically recorded on Datix at the time they happen, and to capture evidence of them being appropriately escalated.

3.5.12 NHS Shetland reported different levels of review for investigating adverse incidents:

- table top review – generally a team level discussion with brief notes or actions to take forward
- local team debrief – team level discussion, often multidisciplinary, with detailed notes and actions, and
- full root cause analysis – facilitated discussion, often multidisciplinary, including analysis tools, detailed notes, timeline of events, actions and lessons learned.

3.5.13 Both versions of the policy refer to use of root cause analysis to support adverse incident investigation:

“Root cause analysis (RCA) is a class of problem solving methods aimed at identifying the root causes of problems or events. Staff are encouraged to use structured, systematic investigation analysis tools such as RCA and the procedure for investigation of incidents below is aligned to the investigation toolkit sponsored by the National Patient Safety Agency (NPSA).”

3.5.14 On the visit, staff reported that different tools are used in investigations depending on the case circumstances. This could include root cause analysis, significant event analysis or multidisciplinary discussions. However, we did not see evidence of root cause analysis or equivalent investigation tools being used in any of the four cases we reviewed.

3.5.15 We identified a variable approach to carrying out investigations. The medical director usually facilitates clinical significant incident reviews. We identified that further resources are needed to support the clinical significant adverse incident process including co-ordination of review meetings. NHS Shetland needs to introduce a standardised and formal approach for investigations and to make sure that all staff consistently follow the policy guidance.

3.5.16 NHS Shetland intends to work more closely with NHS Grampian to make sure that the significant incident management process is robust and effective. This is particularly important for incidents that involve a patient transfer to NHS Grampian. We encourage NHS Shetland to develop closer links with NHS Grampian to ensure significant adverse incidents affecting both NHS boards are managed effectively.

3.5.17 Through our discussions with staff, we noted they would benefit from guidance to help them manage adverse incidents which are referred to the Procurator Fiscal.

3.5.18 Maternity staff reported a recent improvement in how they compile investigations by using a report template based on the NHS Ayrshire & Arran maternity template.
3.5.19 NHS Shetland plans to implement a checklist for staff to capture decision-making and timelines for investigation. The NHS board also plans to develop a standard template to help staff record consistent information on investigation reports. The revised policy (2012) includes reference to this template.

3.5.20 NHS Shetland reported that since November 2012, the assistant director of clinical services, and the safety and risk manager, meet every 2 weeks to review all incidents reported on Datix. This includes a review of the severity of the incident, the correct allocation of handler, appropriate action taken and evidence that other key issues have been identified.

3.5.21 NHS Shetland recently introduced a new process to provide progress of incident investigations to the risk management group every 3 months (for incidents initially or eventually rated as high or very high). This provides a summary of progress, variations from the plan, risks and issues, and actions planned. At the time of the visit, one meeting had taken place where this discussion was captured.

3.5.22 We saw evidence of the corporate risk register and departmental risk register being discussed at the risk management group meetings. NHS Shetland reported that it has a risk assessment procedure and risk register guidance in place for staff (version 2 was approved in January 2013). This is to provide practical guidance for all staff on risk assessment techniques and how to compile risk registers. The procedure is based on the existing NHS Shetland risk management strategy (2012–2015).

**Recommendations**

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

10 ensure all adverse incidents are systematically recorded on Datix at the time of the event and capture evidence of them being appropriately escalated

11 consistently record decision-making on Datix, to support a transparent and open process, and

12 introduce a standard approach for investigations, including use of report templates and checklists to support staff and ensure consistency across the NHS board.

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

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

**Investigation and reporting timelines**

3.6.1 NHS Shetland has a process for reporting and reviewing significant incidents within set timescales. However, we noted some inconsistencies in the policy (2010).

3.6.2 The quick reference guide on page 1 of policy (2010) stated:
“Aim to complete the investigation within 20 working days’ and for management actions to ‘send the completed form to the Risk and Incident Coordinator, ideally within 25 working days of the incident taking place.”

3.6.3  Page 7 of policy (2010) indicated that:

“Investigation timescales are aligned with the complaints procedure and are set at 20 working days for the completion of initial management actions and feedback to staff initiating the completion of the incident form and the line manager of the designated manager.”

3.6.4  While, page 18 of policy (2010) had the wording “The usual timescale for completion of an initial investigation is 20 working days.”

3.6.5  The 20 working day deadline was applied to the completion of an “initial investigation”; completion of “initial management actions” and completion of the “investigation”. The use of the words “aim to complete” and “usual timescale for completion” would not have been helpful, particularly where the NHS board required assurance that it was meeting deadlines.

3.6.6  Three of the four cases selected for review revealed significant delays in recording the incident on Datix. On the visit, staff confirmed that, occasionally, adverse incidents were not recorded on Datix until the time of the investigation.

3.6.7  We found it difficult to determine whether the four selected cases met the 20 working day deadline due to inconsistent guidance within the policy (2010). None of the four cases showed sufficient evidence of investigations being completed within 20 working days of the incident happening.

3.6.8  The revised policy (2012) includes more defined guidance on timescales for investigation based on the following risk grading:

<table>
<thead>
<tr>
<th>Incident grade</th>
<th>Timescale in days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>10 working days for completion of investigation and initial management actions and feedback to reporter</td>
</tr>
<tr>
<td>Medium</td>
<td>20 working days for completion of investigation and initial management actions and feedback to reporter</td>
</tr>
<tr>
<td>High</td>
<td>20 working days for initial investigation and feedback to reporter 40 working days for completion of investigation and initial management actions</td>
</tr>
<tr>
<td>Very high</td>
<td>20 working days for initial investigation and feedback to reporter 50 working days for completion of investigation and initial management actions</td>
</tr>
</tbody>
</table>

3.6.9  NHS Shetland has identified timely review meetings as an area for improvement.

3.6.10 The NHS board reported that the risk management group has recently established a short-life working group to review how best to manage incidents on Datix which are overdue.
Action planning

3.6.11 The quick reference guide on page 1 of policy (2010) guides staff to “Record action plan on the Datix IR2 (DIF2) form.” However, the policy lacked guidance on what staff needed to include in the action plan and how it should be reviewed.

3.6.12 The revised policy (2012) includes more comprehensive guidance on action planning:

“Once an investigation has been carried out, it is the responsibility of the investigator to analyse the outcomes and use this information to identify the risk control measures that were missing, inadequate and/or unused and create an action plan to deal effectively with these shortcomings. The ‘Investigation’ section of the Datix incident report form includes free text boxes which allow the investigator to record details of the investigation (tasks carried out in respect of investigating the incident) and action taken as a consequence of the incident. This form is likely to be adequate for concise investigations of the type most commonly conducted by a single investigator that resulted in no, low or moderate harm. The Datix Incidents Module also has a separate ‘Actions’ section that allows investigators to record in much greater detail actions arising as a consequence of incidents as well as allocating action owners and setting completion dates. This section should be used for multi-stranded investigations and those requiring longer term actions. The handler of the incident is responsible for making sure that actions are completed and that this is recorded on the Datix system. Progress should be monitored via the line management structure.”

3.6.13 The revised policy (2012) also includes a principle that:

“There is a systematic approach to creating and implementing action plans as a consequence of investigations and progress is monitored via the line management structure.”

3.6.14 Only one of the four cases we reviewed had evidence of a formal action plan. In one of the case discussions, staff indicated that development of an action plan would have been helpful to capture all the agreed actions at the time of the review.

3.6.15 NHS Shetland accepts that not all significant incidents had a clear action plan in place as part of the final report. In future, it intends that action plans are recorded on Datix for all significant adverse incidents.

3.6.16 NHS Shetland has also identified clear ownership and delivery on agreed actions as an area for improvement.

3.6.17 Since November 2012, the risk management group has been monitoring significant adverse incidents and action taken in response to the incidents. The assistant director of clinical services and the safety and risk manager also meet every 2 weeks to review all incidents reported on Datix. NHS Shetland further reported that the senior management team receives outstanding actions from adverse incidents through the mortality and morbidity meetings.
Sharing of learning

3.6.18 Page 7 of policy (2010) states “It is the responsibility of all staff to learn from incidents and risk identified, for the benefit of patients and the service.”

3.6.19 Appendix B of policy (2010) says:

“It is the responsibility of the investigating manager to give the opportunity to discuss and feedback with person(s) directly involved in the incident, and key witnesses/other relevant staff, to deal with any unresolved issues and follow up actions arising from the incident, either directly themselves or via a designated manager. Also to consider wider dissemination of learning for the organisation e.g. via follow up actions reported at a departmental meeting, presentation at Clinical Governance meeting, topics for clinical audit.”

3.6.20 NHS Shetland reported that it is good at sharing learning from adverse incidents involving health and safety and equipment issues. While learning is shared in response to clinical significant incidents, it is done on a case by case basis with less evidence to demonstrate it happens.

3.6.21 The revised policy (2012) contains more guidance on how learning can be shared:

“One of the basic principles of incident reporting, investigation and management is that learning happens as a consequence of investigations into adverse incidents and is disseminated appropriately to enable the organisation to facilitate any wider local change and improvement. In particular, a thematic approach to learning from significant adverse events must support staff to change and adapt clinical practice accordingly. A variety of mechanisms are used to disseminate learning from incidents such as: Team meetings, case reviews, mortality and morbidity meetings, Team Brief and Message of the Day.”

3.6.22 On the visit, staff confirmed that adverse incidents and resulting action taken is discussed within mortality and morbidity meetings, multidisciplinary team meetings and departmental team meetings.

3.6.23 NHS Shetland reported a number of additional routes where learning is shared:

- clinical governance co-ordinating group
- health and safety committee
- risk management group
- clinical governance committee, and
- global email.

3.6.24 NHS Shetland has a programme of monthly ‘clinical governance afternoons’ which include specialty-specific presentations from the medical, surgical and anaesthetic teams. It reported that actions arising out of these meetings are shared with the wider organisation through the clinical governance co-ordinating group.
3.6.25 The Scottish Public Services Ombudsman monthly commentary report is a standing item on the clinical governance co-ordinating group’s agenda. This features a report on cases where complaints about public services across Scotland have been reviewed by the ombudsman.

3.6.26 All heads of department have access to Datix for their area of work and include learning from incidents within the departmental governance structure. The NHS board reported that mental health significant incidents are reviewed through the sudden death audit group and that learning is distributed both within the team and outside the team if required. Health and safety incidents are also reviewed through the health and safety committee. The health and safety team uses the intranet ‘message of the day’ to disseminate learning to the organisation.

3.6.27 None of the four cases we reviewed had evidence of learning being shared with wider staff, for example staff not involved in the incident. Our discussions with staff on the visit, revealed inconsistencies in how learning is communicated. Learning is often shared verbally rather than through formal documentation. Obstetric staff reported attending monthly risk management meetings where adverse incidents are discussed. This includes presentations from staff showing how particular incidents were dealt with and what lessons were learned.

3.6.28 At the time of the visit, NHS Shetland had developed a draft action plan, which identifies the need to “agree a set of process and outcome measures which give assurance that the process of investigation, reporting and learning from incidents is working effectively.”

3.6.29 NHS Shetland reported that summary incident reports are now shared through the 3-monthly reports to the clinical governance committee, including learning points from complaints. Going forward, the risk management group will monitor progress of all significant incidents and decide whether dissemination of learning has been adequate once the incident report is complete.

3.6.30 We saw evidence of updates on incidents from the surgical governance meetings being provided to the January 2013 clinical governance meeting. However, we note that the updates did not include detailed learning points.

**Recommendations**

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

13 implement the revised policy deadlines and monitor timelines for staff recording and investigating incidents to ensure they are in line with the policy

14 introduce a monitoring system to provide assurance that action plans are completed and actions are being implemented, and

15 embed a culture of capturing and sharing lessons learned across the organisation, supported by a system that provides evidence of discussions at meetings and thorough consistent feedback mechanisms to relevant staff.
3.6.31 We identified a further overall recommendation relating to the implementation of the NHS Shetland revised policy (2012) and supporting documentation.

**Recommendation**

To support a consistent and formal approach to adverse incident management, NHS Shetland should:

16 incorporate recommendations from this report into the revised incident management policy and supporting documentation, and implement the guidance consistently across the organisation.
Appendix 1 – Details of review team

The review of NHS Shetland was conducted on Thursday 18 and Friday 19 April 2013.

Review team members

Mark Aggleton
Senior Business Manager, Healthcare Improvement Scotland

Nanisa Feilden
Programme Manager, Healthcare Improvement Scotland

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Clinical Advisor

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Project Officer, Healthcare Improvement Scotland
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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.