Management of adverse events

Review Report | NHS Western Isles
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 Western Isles’ governance arrangements and processes for managing adverse events involved:

- an analysis of evidence provided by the NHS board, and
- a visit to NHS Western Isles on Thursday 8 November 2012.

We noted that NHS Western Isles is a small NHS board delivering healthcare services to 26,000 people across 11 islands. 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.

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

We noted the following areas of good practice within NHS Western Isles:

- a wide range of staff recording adverse events on the electronic reporting system (Datix), including GPs and practice staff
- examples of mental health staff involving carers in investigations, which has resulted in service improvement
- an example of maternity staff involving the family in the adverse event management process and informing them of outcomes, and
- senior managers committed to improving the adverse event management process across the organisation.
NHS Western Isles states that it is:

“committed to ensuring the system is in place to facilitate reporting, investigation, learning and action to continually drive the standards of care upwards and to improve the patients experience and outcome.”

However, our review identified weaknesses in the management of significant adverse events. Many of the shortfalls relate to patient, family and staff engagement, risk-based decision-making and the sharing of wider learning.

Our review identified areas that the NHS board should improve to ensure arrangements in practice match the NHS board's existing adverse event management policies and procedures.

In summary, the NHS Western Isles’ adverse incident management and learning policy is not reliably or consistently applied across the NHS board.

**Recommendations**

We expect NHS Western Isles 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**

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<th>Recommendation 18 from the NHS Ayrshire &amp; Arran report</th>
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<td><strong>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.</strong></td>
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NHS Western Isles’ 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
2. demonstrate the involvement of patients/family in the review process and capture their feedback to support the investigation reporting and outcomes of adverse events
3. monitor compliance with the planned approach to engaging patients, family and carers to provide appropriate assurance, and
4. ensure relevant staff are involved or have an input into investigations and action plans, and receive relevant documentation and communications.
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 Western Isles should:

5 demonstrate evidence of formal training for staff on the use of Datix
6 ensure staff involved in managing serious untoward events have a clear understanding of root cause analysis methodologies and apply them to investigations and action planning, and
7 ensure staff identified to take forward actions as a result of serious untoward events are appropriately trained or supported by staff experienced in improvement methods.

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 Western Isles should:

8 clearly define roles and responsibilities for escalation and decision-making, including responsibilities for identification, investigation, action planning and learning
9 demonstrate evidence of incident information being fully reported and discussed at governance meetings to allow the committee to fulfil its role as defined in the policy, and
10 ensure that the clinical governance structure does not limit timely review and progression of investigation and actions arising from adverse events.

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 Western Isles should:

11 ensure that staff make full use of the Datix system and consistently capture all documentation for each stage of the adverse event management process, including how a decision is made to carry out a particular level of investigation and who made the decision
12 ensure that staff include version number, date and author on all relevant documents to allow the NHS board to track progress of adverse events, and
13 introduce a system for capturing and sharing thematic learning from adverse events across the organisation.

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 Western Isles should:

14 introduce a more systematic approach to risk grading supported by staff training and a quality mechanism to ensure risks are graded and responded to consistently, and

15 develop an integrated approach that includes linking the complaints, adverse event and risk management processes. This should include a shared assurance framework throughout the entire process.

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 Western Isles should:

16 ensure that the timescales for various stages of the adverse event management process are met in line with the policy. This should include support for staff to allow them to complete actions in a timely manner, and

17 embed a culture of capturing and sharing lessons learned across the organisation, supported by evidence of discussions at meetings and through feedback to staff.

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

We would like to thank NHS Western Isles and in particular staff at Western Isles Hospital, Uist & Barra Hospital and St Brendan's Hospital 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 Following our review, 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 Western Isles 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 25 recorded significant adverse events over the past 18 months, and
- details of four specific significant adverse event reviews.
1.1.8 Of the 25 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 8 November 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. We interviewed the chief executive on 16 November 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 Western Isles’ chief executive on 3 December 2012.

Improvement plan

1.1.12 We expect NHS Western Isles 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 Western Isles 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 Western Isles’ adverse event management policies and procedures

2.1.1 NHS Western Isles provides healthcare to a population of over 26,000 residents across 11 islands off the north west coast of Scotland. The Western Isles cover 130 miles in length from the Butt of Lewis in the north to the Isle of Barra in the south. The NHS board has three hospitals. The largest is the Western Isles Hospital, a rural general hospital located in Stornoway on the Isle of Lewis. The Uist & Barra Hospital in Benbecula provides a local service for the population of the Southern Western Isles, with medical support provided by a GP practice. St Brendan’s Hospital, on the Isle of Barra, is supported by the local GP practice to provide care of the elderly and other services.

2.1.2 Where required, NHS Western Isles can access healthcare for Western Isles residents through external agreements with other NHS boards, primarily NHS Highland and NHS Greater Glasgow and Clyde. NHS Western Isles also has support from the NHS-wide managed clinical networks, and the Emergency Medical Response Service for patients who need to be urgently transferred to another hospital. NHS Western Isles also works with NHS 24, the Scottish Ambulance Service and voluntary sector services to deliver healthcare services to the residents of the Western Isles.

Adverse event definitions

2.1.3 NHS Western Isles categorises adverse events as (i) adverse incidents, (ii) near miss incidents, and (iii) serious untoward incidents.

2.1.4 The NHS board describes an adverse event as:

“An event that causes, or has the potential to cause, unwanted effects involving the safety of patients, users, staff or other persons – or which results in loss or damage. Such incidents would include (amongst other examples) loss, harm or injury arising from a clinical procedure, treatment or episode of care, or loss, harm or injury arising from unexpected hazards, or actual or threat of physical/verbal abuse.”

2.1.5 A serious untoward incident is described as:

“Something out of the ordinary or unexpected, with the potential to cause harm and/or likely to attract public and media interest that occurs on NHS premises or in the provision of an NHS or a commissioned service. This may be because it involves patients, there is a question of poor clinical or management judgment, a service has failed, a patient has died under unusual circumstances, or there is the perception that any of these has occurred.”

2.1.6 Between January 2011 and end of July 2012, NHS Western Isles recorded 1,338 adverse events. The NHS board reported that 25 (1.8%) of these were categorised as serious untoward incidents and had either been investigated or were in the process of being reviewed.

2.1.7 NHS Western Isles has identified the top five themes for significant adverse incidents as:

- failure to follow the correct clinical protocol for chest pain
- failure to complete medicine reconciliation
• failure to comply with clinical record-keeping standards
• delay in the transfer of patients, and
• incidence of Staphylococcus aureus bacteraemias.

Policy for managing adverse events

2.1.8 NHS Western Isles has an adverse incident management and learning policy (hereafter referred to as ‘the policy’). The policy, dated February 2012, outlines the process for managing adverse events within the NHS board. The document includes adverse incident reporting and management arrangements, accountabilities, responsibilities and compliance.

2.1.9 In August 2012, the NHS board introduced a resource pack for investigation and learning to support managers through the adverse incident management process. The pack includes guidelines, reporting templates and investigation tools. It provides guidance that is not available within the policy document.

2.1.10 NHS Western Isles uses the electronic reporting system, Datix, to capture information on adverse events. We noted that a wide range of staff record adverse events on the Datix, including GPs and practice staff.

2.1.11 NHS Western Isles states, within its policy, that it is:

“committed to ensuring the system is in place to facilitate reporting, investigation, learning and action to continually drive the standards of care upwards and to improve the patients experience and outcome.”

2.1.12 The policy states that the manager handling the adverse event has responsibility for producing the adverse incident report. The report should include:

• details of the incident, the initial investigation and the identified causes
• learning from events
• a plan of action, and
• a record of which actions have been completed and which remain outstanding.

2.1.13 The NHS board policy listed a number of committees which receive a report on adverse events every 3 months:

• quality improvement programme board
• clinical governance committee
• health and safety committee
• drug and therapeutics committee
• corporate management team, and
• single operating division management team.

2.1.14 The clinical governance annual public report also includes information on adverse events.
Governance arrangements

2.1.15 Figure 1 below outlines the current governance arrangements in place for the management of adverse events. The risk action team has responsibility to monitor progress with action plans and to report to the single operating division management team, the risk monitoring and audit committee and the clinical governance committee. NHS Western Isles reported that adverse events graded as high on the risk matrix, are presented to the risk action team in the form of a summary report and action plan.

Figure 1: NHS Western Isles governance structure
3 Detailed review findings

3.1 Engaging with stakeholders

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

**Patient, family and carers involvement**

3.1.1 The policy outlines the involvement of patients, carers or relatives affected by the adverse incident:

“In all cases, patients (and where appropriate, and with the patient’s consent, their relatives and carers) will be informed of all adverse incidents and near misses that have affected them or their care. They will also be given the opportunity to discuss the incident, remedy or action taken with appropriate staff members.”

3.1.2 We reviewed evidence provided by NHS Western Isles for four selected significant adverse incident cases. The evidence did not demonstrate when and how patients, carers or relatives are notified of an incident affecting them. In one of the four cases, the adverse incident was not recognised until after the patient had been discharged from hospital. Staff reported that the patient had not been made aware of the incident. There was no evidence that patients, family or carers were made aware of the investigation or action plan. Staff confirmed that none of the four cases reviewed involved family or carers in the investigation or action plan process. However, on the visit, staff demonstrated that other incident reviews, such as mental health and maternity incidents, involved the patient and family.

3.1.3 We spoke to mental health staff on the visit who said they had a positive experience of working with carers in investigations, which resulted in service improvement. We also viewed evidence of maternity staff involving the family and keeping them informed of adverse event outcomes. We saw examples of patient or family involvement in the adverse event management process. However, there is an inconsistency in the way NHS Western Isles considers involving family and patients on a routine basis.

3.1.4 In August 2012, NHS Western Isles introduced a resource pack to support staff. The pack includes more detail about involving patients or their relatives in a review:

“In the case of a serious untoward incident where a more detailed analysis of the incident is to be carried out patients and/or their carers should be involved as follows:

- Being informed that a detailed review is taking place
- Being invited to discuss whether and if so how the patient and or carers will be involved
- Being made aware of the process and the purpose and logic which underpins it
- Being kept up to date with the progress of the review
- Being informed of the outcome and the actions which NHS Western Isles will take following the outcome.”
We acknowledge that the resource pack will take time to become embedded across the organisation.

Staff involvement

3.1.5 Through discussions with staff on the visit, it was clear that staff are not formally supported in the incident management process. None of the four cases involved all the relevant staff in the investigation or the development and updating of the action plan. Relevant staff were not kept up to date on the progress of actions.

3.1.6 In one case, GPs were engaged in the initial complaints process. However, they were not involved in the subsequent management review of the event, or the drafting of the investigation report. They also did not receive a copy of the final report. Whilst an action plan was sent to the local team, it is unclear whether this was discussed in any detail. Staff we spoke with expressed a clear interest in receiving reports and feedback from reviews.

3.1.7 We did not see evidence of a formal procedure for supporting staff who are involved in a significant incident. The NHS board reported that occupational health staff are available to support staff involved in serious untoward incidents. Nominated confidential contacts are also made available if staff need to speak in confidence. Staff can be referred to a staff counselling service, if required. We were informed after the visit that additional support is available through the NHS Western Isles’ chaplaincy service and the stress policy which outlines the support offered to staff experiencing work-related stress. The chief executive also conducts open meetings to allow any member of staff to discuss topics of interest or concern to them.

3.1.8 The policy includes a clear statement that a named person is responsible to inform and support staff. Staff reported good support from their managers and their peers. If the incident happened out of hours, they would phone the on-call manager.

3.1.9 There is no defined procedure for what information should be provided to staff who were not involved in the incident. NHS Western Isles reported that it would decide what information to provide on a case by case basis.

3.1.10 NHS Western Isles reported it is currently refining its adverse incident management process to improve how it involves staff in follow-up investigations.

3.1.11 NHS Western Isles has a clear ambition to raise awareness of the need to involve relatives in the adverse incident process, by amending Datix and relevant documentation. The NHS board has recently introduced a new field on Datix and made it mandatory for staff to log whether the patient or relative has been informed of the incident. Staff select a yes or no answer. We suggest that NHS Western Isles introduces a quality check within the process to ensure there are good reasons for staff to select a ‘no’ answer.

3.1.12 Datix has been changed to make it mandatory for staff to record feedback given to relatives or carers on the outcome of the investigation. The NHS board will need to monitor this feedback.

3.1.13 The NHS board reported that it has also revised its record-keeping documentation to allow staff to record their discussions with relatives or carers for serious untoward incidents.

3.1.14 The risk action team plans to monitor any feedback provided to staff, patients and
relatives.

3.1.15 NHS Western Isles is currently developing an open disclosure policy to formalise the NHS board’s communication with patients, relatives and carers. This document will include guidance on when and how patients should be involved in the process. The NHS board aims to send this out for consultation in early 2013 through the patient focus and public involvement representative. The draft document includes guidance on the following areas:

- openness and timeliness of communication
- acknowledging the adverse event to the patient or carer
- expression of regret
- recognition of the reasonable expectations of patients and their support person
- staff support
- integrated risk management and systems improvement
- good governance, and
- confidentiality.

3.1.16 We encourage NHS Western Isles to amend the draft open disclosure policy to make it more specific to NHS Western Isles and to include measurable outcomes.

Recommendations
NHS Western Isles’ 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 outcomes in a timely manner
2. demonstrate the involvement of patients/family in the review process and capture their feedback to support the investigation reporting and outcomes of adverse events
3. monitor compliance with the planned approach to engaging patients, family and carers to provide appropriate assurance, and
4. ensure relevant staff are involved or have an input into investigations and action plans, and receive relevant documentation and communications.

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 Western Isles provided a comprehensive list of risk management policies and resources to support staff with incident reporting, investigation and learning:

- an adverse incident management reporting and learning policy
• risk register policy
• Datix risk management reporting system and ongoing training on its use
• ongoing risk management training
• a risk management section on the clinical governance website
• risk management, Datix and patient safety ‘learn pro’ modules
• a regular clinical governance newsletter, which includes a section on risk management and incident reporting, and
• 3-monthly Datix reports shared with senior management teams, health and safety and clinical governance committees. These reports include examples of lessons learned from incident reporting.

3.2.2 The policy states that:

“Where an Operational Serious Incident Review Team (OSIRT) is to be established in the event of a ‘High’ or ‘Very High’ incident, the appointing Director must appoint:

• the Chair, who is independent from the incident
• the membership of the Team, which will vary according to the characteristics of the incident
• a dedicated administrative support
• a named representative to inform and support staff
• someone trained in Root Cause Analysis.”

3.2.3 A definition of root cause analysis is included within the policy as follows:

“Root cause analysis is an investigative technique, which seeks to ‘drill down’ beneath the obvious actions and errors (usually perceived to be human) which have preceded an adverse event. This is achieved by identifying and analysing all latent conditions and active failures present, mapping a chain of events from its starting point, and inter-connecting cause and effect, through to the moment when all the factors present resulted in the adverse event or near miss situation.”

3.2.4 NHS Western Isles reported that 15 staff have undertaken training in root cause analysis. The chief executive and risk manager have attended root cause analysis training organised by the National Patient Safety Agency and the Institute for Healthcare Improvement. NHS Western Isles reported that training in root cause analysis is available if staff require it. However, there is no systematic approach to ensure that staff receive refresher training on root cause analysis.

3.2.5 Staff reported that in practice the adverse event investigation teams do not specifically involve a member of staff trained in root cause analysis. Staff undertaking root cause analysis rely on each other to informally learn how to carry out investigations.

3.2.6 We saw evidence of the NHS board’s risk management and training plan for April 2012 to end March 2013. The plan outlines the following training courses available to staff:
• mandatory training on risk management for all staff
• root cause analysis, and
• an introduction to risk management for non-executive directors.

3.2.7 The NHS board has mandatory staff training which includes a section on risk management. The training includes use of the risk matrix, definitions of serious untoward incidents, and the importance of being open with staff, patients, family and carers. The corporate induction programme for new staff includes an introduction to the Datix system.

3.2.8 We spoke with staff on the visit about training they had received. The majority of staff reported they had not received up-to-date training on the use of Datix. There was limited evidence of an ongoing systematic approach to continued training on Datix for all staff.

3.2.9 In the cases we reviewed, we did not see evidence that root cause analysis techniques were robustly applied. The team observed inconsistencies in how root cause analysis was undertaken, how analysis tools were used and how documentation was completed. Our discussion with staff involved in the four cases, revealed a lack of clear understanding of root cause analysis methodologies and how to apply them in investigations.

3.2.10 NHS Western Isles intends to review the use of coding on Datix to allow staff to make appropriate judgements on what is a serious untoward incident, and what level of investigation is required. The NHS board also reported it will be training more staff to become investigators.

3.2.11 The NHS board does not consistently provide formal support or training for staff to allow them to manage patients, family and carers affected by the adverse incident. The maternity team provided a positive example of how they involved relatives when developing their training and learning plan.

3.2.12 NHS Western Isles reported that staff are involved in taking forward actions arising from all adverse events including any follow-up investigations. However, in some action plans a number of actions were outstanding and there was a lack of evidence of actions informing change in the Western Isles.

3.2.13 NHS Western Isles does not formally capture and share staff knowledge and learning from adverse events to ensure that staff awareness is kept up to date and to help prevent adverse events happening again.

3.2.14 We asked staff if they had received information on learning from adverse events. Some, but not all, staff read the clinical governance newsletter which includes examples of lessons learned.

3.2.15 The NHS board reported plans to:
• roll out a half-day training session on root cause analysis to staff
• provide training sessions on investigation and learning from adverse events, and
• implement the National Patient Safety Agency guidance – *Seven Steps to Patient Safety* (2009), to promote incident reporting, investigation and learning.
## Recommendations

To support staff knowledge and training, NHS Western Isles should:

5. demonstrate evidence of formal training for staff on the use of Datix

6. ensure staff involved in the managing serious untoward incidents have a clear understanding of root cause analysis methodologies and apply them to investigations and action planning, and

7. ensure staff, identified to take forward actions as a result of serious untoward incidents, are appropriately trained or supported by staff experienced in improvement methods.

## 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 policy states that:

“All NHS Western Isles employees have an obligation to report and manage adverse incidents and near misses in line with this policy. Simply reporting an adverse incident or near miss does not fulfil the requirements of the policy and all staff members will be expected to manage the identification of an actual or potential incident, and the action required by this policy as a result, until explicitly relieved of that responsibility by their line management structure. Line Managers have the delegated responsibility for ensuring that these obligations are being undertaken within the organisation. The Risk Manager/Adverse Incident Manager has a supporting role in ensuring that appropriate incident investigations are occurring and has delegated responsibility for keeping and retaining incident and outcome records. The Risk Manager/Adverse Incident Manager will be involved in ensuring that the learning from adverse incidents is shared with all relevant people.”

3.3.2 On the visit, staff reported that they were aware of the policy and knew where to find it. Staff also reported that they used Datix and were aware of the value of recording adverse events and near misses.

3.3.3 The policy defines the role of the clinical governance committee as:

“The Clinical Governance Committee are responsible for assuring the Board that there are robust measures in place to record and manage adverse incidents, and that learning and improvement have taken place to reduce the risk of recurrence of an adverse incident.”

3.3.4 We looked at six sets of meeting minutes of the clinical governance committee covering February 2011 to May 2012. The team found a lack of evidence in the minutes to demonstrate that incident information was being appropriately reported and discussed at meetings. The committee receives reports on adverse events linked to key performance indicators. However, there was no detailed record of discussions and a lack of assurance
that incidents had been appropriately managed and reviewed, action plans developed and learning shared across the organisation, in line with policies and procedures.

3.3.5 There was also no evidence of the clinical governance committee taking action in response to key performance indicator reports which showed continuing poor performance. Staff reported that the clinical governance committee was not receiving sufficient details of adverse events, and the high level key performance indicator information was not enough to provide assurance that the process is appropriately applied.

3.3.6 NHS Western Isles should amend the reports being sent to the clinical governance committee to allow the committee to fulfil its role as defined in the policy. The reports should provide assurance that the review process is being consistently applied. They should also support learning and improvement and help reduce the risk of an adverse event happening again. The NHS board reported that an amended detailed report was going to the November 2012 meeting of the clinical governance committee.

3.3.7 NHS Western Isles recently introduced two new operational clinical governance committees for primary care and acute services, which will report to the central clinical governance committee.

3.3.8 The terms of reference of the new primary care committees states:

“The key role of the primary care clinical governance committee is to agree the clinical governance work schedule primary care, monitoring activity, reassuring the organisation on clinical governance and risk management and prioritising activity. The Committee will report to the CHaSCP Management Group and Quality Improvement Programme Board providing reassurance to the organisation on clinical governance and risk management issues within primary care acting on, escalating and cascading issues as appropriate.”

3.3.9 NHS Western Isles should ensure that this new layering of committees does not limit timely review and progression of actions arising from adverse events. It is important that the clinical governance committee maintains its accountability.

3.3.10 NHS Western Isles has a risk action team which has responsibility for monitoring progress of action plans. Managers handling adverse events graded as high on the matrix are required to provide a summary report and action plan. The risk action team receives a monthly incident report on all serious untoward incidents, a report of investigations, an update on root cause analysis and an update on key performance indicators. The risk action team reports to the single operating division management team and the clinical governance committee.

3.3.11 We looked at four sets of meeting minutes from the monthly risk action team from May 2012 to August 2012. We identified that although issues were being raised, there was a lack of actions being taken within required timescales, and lack of responsibility and accountability to take actions forward.

3.3.12 The NHS board reported that the risk action team and clinical governance committee review trend reports and key performance indicators for all adverse events every 3 months.
3.3.13 The operational management team meetings have risk management and patient safety as a standing agenda item. NHS Western Isles intends to provide a monthly incident report for each operational area for discussion and action at their meetings. The clinical governance and quality framework is currently being reviewed to include detailed governance arrangements. This will help ensure that standard reporting and lessons learned are addressed at local clinical governance forums for acute, primary care and mental health.

3.3.14 On the visit, NHS Western Isles reported that staff are good at reporting adverse events and reporting rates continue to increase year on year. However, the NHS board reported a challenge to engage staff in the adverse incident management process beyond the initial recording on Datix. Staff can find it logistically difficult to get together to discuss and investigate adverse events. NHS Western Isles reported it had recently changed its management structure to ensure better communication within acute and community teams.

3.3.15 We identified a lack of clarity in the escalation procedure for adverse events. There was limited evidence in the cases reviewed of senior managers having appropriate or effective ownership of adverse events management.

3.3.16 We also noted a lack of defined responsibility in practice for taking forward actions following the recording of adverse events.

3.3.17 We identified the need for senior management to support staff dealing with adverse events and to help them progress outstanding actions within required timescales. Staff reported a challenge within a small NHS board where systems are person dependent and staff have multiple roles. Staff also need to feel empowered to make decisions about adverse incident cases and need to know how to take forward improvement actions resulting from the incident.

**Recommendations**

To ensure clear functions and roles, NHS Western Isles should:

8 clearly define roles and responsibilities for escalation and decision-making, including responsibilities for identification, investigation, action planning and learning

9 demonstrate evidence of incident information being fully reported and discussed at governance meetings to allow the committee to fulfil its role as defined in the policy, and

10 ensure that the clinical governance structure does not limit timely review and progression of investigation and actions arising from adverse events.
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 The policy states that:

“Full and accurate records of adverse events and action taken must be entered in the patient case notes. Entries must be legible, timed, signed and dated.”

3.4.2 We noted that staff from all disciplines report adverse events on Datix, including GPs and practice staff. Most incidents are logged by nursing staff. The NHS board was not aware of any staff groups under-reporting adverse events.

3.4.3 The Datix system has the potential to capture all documentation relating to any adverse incident. In practice, this relies on staff uploading relevant documents to Datix from their computer.

3.4.4 Staff within NHS Western Isles do not consistently upload documentation onto Datix. As a result, the risk management team recently compiled a separate internal database to capture all documentation relating to significant adverse events. The investigating teams tend to use hard copy incident files rather than download information from Datix. We identified this as an unnecessary complication. All staff should make appropriate use of the Datix storage facility to allow the NHS board to have one central repository for all adverse incident documentation.

3.4.5 The Datix system times and date stamps all communication in and out of the system. In practice, staff tend to capture documentation at the start of the incident process with less communication captured as the investigation progresses.

3.4.6 NHS Western Isles reported it plans to highlight to staff the importance of using Datix as a central repository and communication hub during the investigation of any adverse incident.

3.4.7 Risk management staff reported problems with how staff use adverse incident codes on Datix. Identified incident handlers or managers do not always ensure that the coding is correct. This leads to problems finding adverse events on Datix and extracting reports.

3.4.8 NHS Western Isles has recently been widening the scope of Datix and its internal document management system to support document control and compliance with timescales. The NHS board intends to increase the percentage of adverse incidents started, conducted and concluded on the system.

3.4.9 On reviewing the evidence provided, we noted there was no document or version control for the majority of the paperwork submitted. This makes it difficult to track progress and to identify what stage each review is at. Some of the evidence submitted had missing information, or dates that did not match those listed in related documents. A lack of comprehensive documentation made it difficult to demonstrate whether the process outlined in the policy had been followed.
3.4.10 NHS Western Isles reported examples of improvements and training activity in response to thematic learning. This included:

- training and implementation of an integrated care pathway for chest pain
- a standardised integrated admission documentation for all admissions, and
- various interventions to reduce incidence of *Staphylococcus aureus* bacteraemias.

3.4.11 However, based on the evidence provided, we consider that thematic learning could be strengthened and reported to the clinical governance committee more effectively, with clear links to organisational learning.

**Recommendations**

To support its information management processes, NHS Western Isles should:

11 ensure that staff make full use of the Datix system and consistently capture all documentation for each stage of the adverse event management process, including how a decision is made to carry out a particular level of investigation and who made the decision

12 ensure that staff include version number, date and author on all relevant documents to allow the NHS board to track progress of adverse events, and

13 introduce a system for capturing and sharing thematic learning from adverse events across the organisation.

### 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.**

3.5.1 NHS Western Isles reported that every ward and department has a risk register of actual and potential risks to help reduce the occurrence of adverse events. The risk registers are developed in consultation with staff. These risks are identified proactively and both actual and potential risks are managed in order to reduce adverse events. If an adverse incident happens, the risk management process will be followed and the incident will be escalated up through the organisation as required. Managers are expected to discuss their department risk registers with the chief executive every 3 months. NHS Western Isles also has a corporate risk register which is discussed at the meetings of the risk monitoring and audit committee, the clinical governance committee, corporate management team and the Board.

3.5.2 The NHS board reported that the risk registers for acute clinical services and infection control were mostly compiled following adverse events. However, we did not see any evidence demonstrating how outcomes and learning from significant adverse events are used to inform risk registers across the organisation.
3.5.3 The policy states that:

“When an adverse incident has been reported, the person in charge of the ward, department or team is required to grade the incident in terms of the severity of the incident’s actual or potential consequences using the ‘Risk Matrix’, which is widely used and has been agreed for use in NHS Western Isles. The matrix uses an assessment of the consequence and likelihood of an incident to assess the overall risk to the person or organisation. The actions taken to manage the adverse incident will be based on this risk assessment.”

3.5.4 On the visit, staff reported that the incident handler completing the initial record of the incident uses their judgement to determine the level of risk. There is guidance within the policy about grading a risk, and support and guidance is available from the risk manager. However, we noted potential for inconsistencies and subjectivity in the way risk is determined. There is no prompt on Datix to help the handler determine what the risk grading should be.

3.5.5 NHS Western Isles reported that the risk manager reviews all incidents on the system. The risk manager consults with the handler or investigator if further discussion on the risk rating is required. The NHS board reported that it is reviewing this approach and will introduce a key performance indicator to monitor the accuracy and appropriateness of risk grading.

3.5.6 Staff reported that the chief executive may be alerted about some serious untoward incidents before they are recorded on Datix. Depending on the nature of the incident, the chief executive would discuss the required level of investigation with the medical or nurse director and senior managers. If the incident being reviewed is particularly complex, NHS Western Isles reported that it would arrange for an external independent reviewer.

3.5.7 The NHS board reported that it does not have a set procedure whereby only high or very high graded adverse events are reviewed. The severity of the incident and likelihood of it happening again are used to determine the level of investigation. The NHSScotland Risk Matrix is used to determine the severity and likelihood.

3.5.8 One of the cases reviewed was initially graded as a medium risk, based on the handler’s non-clinical perspective. We did not see evidence of how a decision was made to undertake an investigation of this particular incident. Similarly, in the other three cases, there was no evidence to show how NHS Western Isles had arrived at a decision to undertake a particular level of investigation.

3.5.9 The NHS board also reported plans to introduce a new approach whereby a senior manager or director will decide if a review is urgent. Otherwise, the risk action team will look at the list of adverse events every month to decide the level of review.

3.5.10 NHS Western Isles agreed that a more systematic approach to grading risk is required, to determine the level of investigation and any requirement for early escalation to senior managers. Datix can be used to alert senior managers to adverse events recorded as high or very high. The NHS board should include an assurance mechanism to ensure that staff grade risks appropriately.

3.5.11 NHS Western Isles is considering a new escalation procedure similar to Freedom of Information requests. The chief executive will be informed when incident responses
exceed timescales. The chief executive will then communicate directly with the responsible manager to agree a completion date.

3.5.12 The NHS board reported that complaints are handled by an administrative assistant who reports directly to the chief executive. Complaints are sent to the relevant senior manager for a decision about any required level of investigation. Any root cause analysis or action plan is tracked through the complaints system. Complaints are reviewed by the clinical governance committee.

3.5.13 The clinical governance committee ultimately reviews adverse events and complaints. However, we did not see any evidence that complaints and adverse events are linked by a shared assurance framework throughout the entire process.

3.5.14 For the one case which arose from a complaint, staff suggested that the outcome of the complaint might have been more positive had the complaint been identified as an adverse incident early in the process.

3.5.15 NHS Western Isles reported plans to develop stronger links between incident reporting and the risk management process, including complaints and claims. For example, the NHS board has started uploading letters of complaint onto Datix when they relate to an existing incident on Datix.

3.5.16 In August 2011, Scott Moncrieff, independent chartered accountants, carried out a review of risk management within NHS Western Isles as part of the NHS board’s internal audit plan. The scope of the audit was:

“We examined NHS Western Isles’ risk management policies and processes and the approach taken to risk identification, risk analysis and risk mitigation at strategic and operational levels. We also assessed the arrangements in place for risk reporting throughout the organisation, including the escalation of risks to the Risk Monitoring & Audit Committee and links to the Clinical Governance Committee.”

3.5.17 The main findings of the audit were that:

“Risk management systems at NHS Western Isles require further development. Although we found clear evidence that there has been a great deal of work undertaken to embed risk management throughout the organisation, further work is required to ensure the consistent application of policies and procedures so that the Board, senior management and staff can demonstrate they are effectively managing risk. In particular, consideration should be given to simplifying aspects of the overall risk management process such as the risk register structure to create a clear delineation between strategic and operational risk and to increase the likelihood of compliance with procedures such as the completion of risk assessments and the implementation of action plans.”

3.5.18 In October 2012, the risk management team produced a discussion document in response to the publication of the NHS Ayrshire & Arran report. The document was compiled from a risk management perspective and highlights how NHS Western Isles could learn from the published report and what could be done locally to introduce improvements. The document was discussed and agreed at the risk action team and single operating division meetings on 9 October 2012. Managers agreed to discuss the
document at their own operational management team meetings.

3.5.19 The discussion document is based on the recommendations specific to NHS Ayrshire & Arran. NHS Western Isles should revise the document to focus on the generic NHS board recommendations as identified in the report.

**Recommendations**

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

14 introduce a more systematic approach to risk grading supported by staff training and a quality mechanism to ensure risks are graded and responded to consistently, and

15 develop an integrated approach that includes linking the complaints, adverse event and risk management processes. This should include a shared assurance framework throughout the entire process.

**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 includes timeframes for responses to adverse incidents as follows:

- risks rated as ‘low’ are recorded, verified investigated and closed in Datix within 10 days of incident occurring
- risks rated as ‘medium’ are recorded, verified investigated and closed in Datix within 15 days of incident occurring
- incidents rated as ‘high’ are recorded, verified investigated and closed in Datix within 27 days of incident occurring, and
- ‘very high’ risk adverse incident outcomes will be completed within 30 working days, unless otherwise justified on a case by case basis.

3.6.2 The policy states that:

“When managers pass incidents into the awaiting final approval bay in Datix they are taking responsibility and accountability that incidents have been investigated and closed and that all supporting evidence is attached to the incident in Datix. Response to a request for information or investigation following an adverse Incident must be treated as a priority, as there must be no unnecessary delay in conducting a fully enquiry/investigation to establish facts. Root cause(s) must be understood before lessons are learned and processes and systems are made safer.”

3.6.3 NHS Western Isles reported that the culture for reporting, and the effectiveness of systems for processing adverse events, has been improving over time. Staff are recording more adverse events.
3.6.4 We looked at papers provided to the clinical governance committee. The Datix report on incident management dated January-March 2012 revealed a number of incidents beyond their review deadline.

3.6.5 None of the four incident cases reviewed met the timeframes outlined within the policy. Three cases had significant delays across the incident management process. The fourth case arose through a complaint from a family in January 2011 and was subject to the NHS board’s complaints procedure.

3.6.6 All of the four cases still have outstanding actions to be progressed. NHS Western Isles recently changed how it ‘closes’ adverse events graded as high or very high on Datix. The risk management team now keep these incidents open until all arising actions and outcomes have been completed. This way the incident actions can be continually monitored.

3.6.7 To improve incident response timescales, NHS Western Isle is implementing an escalation process that informs the chief executive when incident management key performance indicator timescales are exceeded. The chief executive will then communicate directly with the responsible manager to agree a completion date. This process would follow a similar process already in place for complaints and Freedom of Information requests.

3.6.8 The NHS board reported it intends to make regular use of a system prompt on Datix to alert staff to outstanding items on the system. This will be supported by the 3-monthly key performance indicator reports for risk management which monitor grading and the progression of actions in line with deadlines.

**Action planning**

3.6.9 The policy states that:

“Reports relating to adverse incidents will include:

- the details of the incident, the initial investigation and the causes identified
- learning from incidents
- a plan of action.
- a record of which actions are completed and which remain outstanding.”

3.6.10 NHS Western Isles has produced a Uist & Barra Action Plan to collate some of the themes and action points identified through the adverse event management process.

3.6.11 We saw evidence of an action plan for three of the four cases reviewed. The action plans included details of action points, who was responsible for taking them forward, the deadline date and the current status. However, we found it challenging to assess the status of the action plans and action plan updates as the documents did not include version control dates. The lack of version dates on the documents will also limit the NHS board’s ability to track progress and understand at what stage each review is at.

3.6.12 As the four cases we reviewed are still open, the challenge remains for NHS Western Isles to complete all action points.
3.6.13 From the evidence provided, we were unable to confirm which of the case action plans had been discussed at the risk action team meeting or clinical governance meetings.

**Sharing of learning**

3.6.14 NHS Western Isles includes an aim within the policy to “promote a culture of openness and learning from adverse incidents.”

3.6.15 We did not see evidence of how NHS Western Isle’s compiles data on learning from adverse events. On the visit, staff involved in the cases said that the Datix field for capturing lessons learned is often left blank.

3.6.16 The January-March 2012 Datix report highlighted:

> “There remain issues in collating Lessons Learned from Datix as information is not consistently being entered on what actions are being put in place in relation to prevention of incidents, whether these actions are being carried out and if any lessons have been learned.”

3.6.17 NHS Western Isles has recently introduced a mandatory box to capture learning from adverse events.

3.6.18 The Datix report includes examples of generic lessons learned. However, there was little evidence of the outcomes from discussions of lessons learned from the risk action team or clinical governance committee meetings. There was also no evidence of how learning from adverse events is shared with staff across the organisation.

3.6.19 The policy states that:

> “Feedback is a vital part of ensuring the transparency of the incident reporting process. This will be achieved in several ways:

- individual feedback will always be offered to the person reporting the incident by the person leading the investigation
- learning events; for example an annual incident learning conference
- newsletters and news items, and
- assessment and the effectiveness of the system every two years.

Line managers with the responsibility for the management of risk are responsible for ensuring that all members of their team have received appropriate feedback following an adverse incident.”

3.6.20 NHS Western Isles reported that feedback is currently provided through the departmental communication plans and the 3-monthly Datix information reports.

3.6.21 On the visit, staff reported that only general feedback is given to those involved in the adverse event and would usually focus on staff working within the clinical area. Ward staff reported that they were not always aware of learning from adverse events. If an incident happened on another ward, they may hear about it informally. Some, but not all, staff read the clinical governance newsletter which includes examples of lessons learned.
3.6.22  NHS Western Isles has scheduled a reflective practice day with a practice education facilitator at the end of November 2012 for staff. One of the four cases used as part of this review will be used as an example for discussion.

3.6.23  The chief executive is also considering training for managers to allow them to provide feedback and coaching to staff in response to adverse events.

3.6.24  We noted that the NHS board’s plans for improvement appear to rely heavily on policy review and refining Datix. We recommend a broader review to identify how learning can be better captured, shared and translated into action and improvement. This will allow NHS Western Isles to develop a story showing the process from recording and investigating incidents to sharing learning and introducing improvements. The challenge is to identify suitable and effective communication channels to allow all staff to learn from adverse events. Communication channels should be regularly evaluated to ensure that they are effective.

**Recommendations**

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

16 ensure that the timescales for various stages of the adverse event management process are met in line with the policy. This should include support for staff to allow them to complete actions in a timely manner, and

17 embed a culture of capturing and sharing lessons learned across the organisation, supported by evidence of discussions at meetings and through feedback to staff.
Appendix 1 – Details of review team

The review of NHS Western Isles was conducted on Thursday 8 November 2012.

Review team members

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**Robin Creelman**
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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.